

Complex decongestant therapy with use of alternative material to reduce and control lymphedema in patients with endemic area of filariasis: a clinical trial

Terapia complexa descongestiva com uso de material alternativo na redução e controle do linfedema em pacientes de área endêmica de filariose: um ensaio clínico

Terapia compleja descongestiva con el empleo de material alternativo reduce y controla el linfedema en pacientes de zonas endémicas de filariasis: estudio clínico

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ABSTRACT | Lymphatic filariasis puts billions of people around the world at risk. Despite this, little is known about the impact of chronic disease morbidity, such as lymphedema. The complex decongestant therapy is a gold standard for treating lymphedemas, but there are no viable protocols for implementation in developing countries. The objective of this clinical trial was to evaluate the efficacy of this technique with the use of alternative material and compare its effects on quality of life, functionality and body weight. The intervention and control groups were evaluated using perimetry and limb volume calculation, the Whoqol-bref quality of life questionnaire, the Functional and Mobility test of the lower limbs Timed Up and Go, and body weight assessment. The intervention group received the complex decongestant therapy twice a week for ten weeks, using an alternative material for the bandaging, made with cambric tissue, which presents low cost in relation to the imported bands. The control group received a lecture with information about the disease and care and hygiene guidelines of the members. The sample consisted of thirty patients with a mean age of 50.8 ± 10 years, 52.9% of whom were women. In the statistical analysis, Student's t test, Multivariate analysis of variance, Wilcoxon test and Kolmogorov-Smirnov test were used. The significance was 5% (p<0.05). There was a significant reduction in lymphedema volume and

perimetry in the intervention group, and increased in the control group. The functionality did not show significant improvement in the evaluation by the Timed Up and Go test. The quality of life had significant improvement in the physical and environmental domains in the intervention group. The effect of treatment on body weight was also significant, presenting reduction in the control group and intergroups. Complex decongestant therapy was effective in reducing and controlling lymphedema and positively impacted, increasing the numerical values of the physical and environmental aspects of the quality of life of the intervention group.

Keywords | Filariasis; Lymphatic Filariasis; Lymphedema; Quality of Life; Morbidity; Physiotherapy.

RESUMO | A filariose linfática põe em risco bilhões de pessoas em todo o mundo. Apesar disso, pouco se sabe sobre o impacto da morbidade crônica da doença, como o linfedema. A terapia complexa descongestiva apresenta-se como padrão ouro para tratar linfedemas, mas ainda não existem protocolos viáveis para implementação em países em desenvolvimento. O objetivo deste ensaio clínico foi avaliar a eficácia dessa técnica, com o uso de material alternativo, e comparar seus efeitos na qualidade de vida, funcionalidade e peso corporal. Os grupos intervenção e controle foram avaliados por meio de perimetria e cálculo

Study developed at the National Reference Service in Filarioses of Centro de Pesquisas Aggeu Magalhães of Fundação Oswaldo Cruz – Recife (PE), Brazil.

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do volume dos membros, do questionário de qualidade de vida Whoqol-bref, do teste de funcionalidade e mobilidade de membros inferiores Timed Up and Go e avaliação do peso corporal. O grupo intervenção recebeu a terapia complexa descongestiva duas vezes por semana, durante dez semanas, utilizando-se um material alternativo para o enfaixamento, confeccionado com tecido de cambraia, o que apresenta baixo custo em relação às faixas importadas. O grupo controle recebeu palestra com informações sobre a doença e orientações de cuidados e higiene dos membros. A amostra foi composta por trinta pacientes com idade média de 50,8±10 anos, sendo 52,9% mulheres. Na análise estatística foram utilizados os testes t de Student, Multivariate analysis of variance, teste de Wilcoxon e Kolmogorov-Smirnov. A significância adotada foi de 5% ($p < 0,05$). Houve redução significativa do volume e perímetria do linfedema no grupo intervenção, e aumentou no grupo controle. A funcionalidade não apresentou melhora significativa na avaliação pelo teste Timed Up and Go. A qualidade de vida teve melhora significativa nos domínios físico e meio ambiente no grupo intervenção. O efeito do tratamento no peso corporal também foi significativo, apresentando redução no grupo controle e intergrupos. A terapia complexa descongestiva mostrou-se eficaz na redução e no controle do linfedema e impactou de maneira positiva, aumentando os valores numéricos dos aspectos físico e meio ambiente da qualidade de vida do grupo intervenção.

Palavras-chave | Filariose; Filariose Linfática; Linfedema; Qualidade de Vida; Morbilidade; Fisioterapia.

RESUMEN | La filiarisis linfática presenta riesgo para muchas personas en el mundo. Pero poco se sabe acerca del impacto de la morbilidad crónica de esta enfermedad, como es el linfedema. Y surge la terapia compleja descongestiva como la forma de tratarlo, pero todavía no hay protocolos que le posibilite su

implementación en países en desarrollo. Este estudio clínico tiene el propósito de valorar la eficacia de esta técnica, con el empleo de material alternativo, y de comparar sus efectos en la calidad de vida, funcionalidad y peso corporal. Se evaluaron a los grupos intervención y control a través de medición y cálculo del volumen de los miembros, de cuestionario de calidad de vida Whoqol-Bref, de la prueba de funcionalidad y movilidad de los miembros inferiores Timed Up and Go y la evaluación del peso corporal. El grupo intervención hizo la terapia compleja descongestiva dos veces a la semana, durante diez semanas, y utilizó un material alternativo, el linón, para el vendaje, lo que mostró ser de bajo costo en comparación a otras vendas importadas. El grupo control vio una charla que exponía información sobre la enfermedad y sobre los cuidados e higienización de los miembros. Treinta pacientes con promedio de edad de 50,8±10 años formaron la muestra, con un 52,9% de participantes mujeres. En el análisis estadístico se emplearon las pruebas t de Student, Multivariate analysis of variance, la prueba de Wilcoxon y Kolmogorov-Smirnov. El nivel de significación ha sido de 5% ($p < 0,05$). Se observó una significativa reducción en el volumen y en la medición del linfedema en el grupo intervención, pero había aumentado en el grupo control. La funcionalidad no ha presentado mejora en la evaluación por la prueba Timed Up and Go. La calidad de vida ha presentado mejora en los dominios físico y medioambiente en el grupo intervención. El efecto del tratamiento en el peso corporal también ha sido significativo por presentar reducción en el grupo control e intergrupar. La terapia compleja descongestiva puede ser eficaz en la reducción y en el control del linfedema, además de aumentar positivamente los valores en los dominios físico y medioambiente de la calidad de vida del grupo intervención.

Palabras clave | Filiarisis; Filariose Linfática; Linfedema; Calidad de Vida; Morbilidad; Fisioterapia.

INTRODUCTION

Lymphatic filariasis affects about 120 million people in 73 endemic countries, which are spread across Africa, India, the eastern Mediterranean, Southeast Asia and Central and South America, including Brazil¹. The disease, commonly known as elephantiasis, is one of the most stigmatizing, debilitating and disfiguring parasitic diseases, with important social and economic impact, with chronic lymphedema being considered the second world cause of incapacity for work. The clinical signs and symptoms of chronic manifestations of filariasis affect

25 million men, which develop with hydrocele, and 15 million individuals with lymphedema, representing about 30% of those infected with the disease^{2,3}.

The adult worms of *Wuchereria bancrofti* are transmitted by the mosquito vector *Culex quinquefasciatus* and live in the lymph nodes and human vessels, causing damage to the lymphatic system^{2,4}.

The Global Program for Elimination of Lymphatic Filariasis (GPELF), launched by the World Health Organization in 2000, calculates the elimination of the disease by 2020. The plan is based on two pillars, the first aims to stop the transmission of the parasite,

by means of mass treatment. The second pillar aims to alleviate the suffering of patients with chronic sequelae, such as lymphedema. GPELF is seeking sustainable and reproducible means that provide a better quality of life for this population^{1,5,6}. Although the plan has made great strides with the drastic reduction of transmission rates, the second pillar, the management of morbidity (lymphedema), has been a low priority and has evolved timidly in view of the irreversibility of most cases, which need the multidisciplinary team to accompany them indefinitely, demanding continuous programs and financial resources available for their viability^{5,7}.

Lymphedema is a chronic condition that, although not curable, can be treated and followed up, with actions that can prevent its complications. Once installed and untreated, this can progress and interfere in a negative way in the quality of life of the affected people, causing, in addition to physical sequels, psychological and social changes, especially when affecting the lower limbs, which are directly related to mobility and activities of daily living^{5,8-13}.

Treating lymphedema goes beyond aesthetic reasons, since, according to the International Society of Lymphology, although it is not possible to achieve the cure, reducing limb volume minimizes joint overload and reduces the presence of pain, facilitating the activities of daily living⁹. Lack of control of lymphedema can lead to repeated infections (cellulitis, lymphangitis), progression of enlargement of the limb, trophic changes in the skin, disability and, on rare occasions, the development of a highly lethal angiosarcoma (Stewart-Treves Syndrome)^{9,14-16}.

The technique that shows higher efficacy in the treatment of lymphedema – gold standard – is the complex decongestant therapy (CDT), which consists of an association of manual lymphatic drainage, kinesiotherapy, bandaging and care and hygiene guidelines of the limbs. However, few studies have evaluated the effects of CDT on the quality of life of patients with lymphedema¹⁷.

CDT has shown positive results in reducing the volume of limbs with lymphedema⁹. Despite this, there are limiting factors for the application of this technique, such as the high cost of the material (bandages and bands), which is often imported and difficult to access; The lack of professionals specialized in health services to perform the treatment; Clinical trials with little methodological rigor, without the use of a comparison group; And the lack of analysis of other variables in the

studies, as well as the impact on quality of life and limb functionality, given the reduction of its size.

In this context, the objective of this study was to evaluate the efficacy of CDT with the use of low cost alternative material and to verify its effects on the quality of life, body weight and functionality of patients with lymphedema residing in an endemic area of filariasis.

METHODOLOGY

This is a randomized, controlled clinical trial which sample, based on a pilot study (adopting a 95% confidence level and 80% study power) and randomized by the *Midi Randomizer* program, was composed of 30 patients, of both sexes, registered at the National Reference Service in Filariasis (NRSF) of the Centro de Pesquisas Aggeu Magalhães (CPqAM) of Fundação Oswaldo Cruz from Pernambuco (Fiocruz – PE). The participants' ages ranged from 35 to 74 years, and the diagnosis of lymphedema was performed by physicians of this service according to the clinical evaluation and classification of Dreyer, Addiss, Roberts and Norões¹⁵.

Patients who underwent another type of treatment to reduce lymphedema three months before inclusion in the study were excluded; patients who present active and untreated infectious processes, thrombophlebitis or contraindications for manual lymphatic drainage; patients who had contraindications for compressive bandaging, and also those that presented pathologies that could compromise the sensitivity and also the functioning of the muscular system. The study included patients of both sexes and those older than 18 years who presented lymphedema in lower limbs (below the knee) uni or bilaterally, classified from stage II, according to Dreyer, Addiss, Roberts and Norões¹⁵.

Intervention protocol

Participants were divided randomly, by the same randomization program mentioned above, into two groups: intervention (IG) and control (CG). The protocol lasted ten weeks. The groups were evaluated at the beginning and at the end of the protocol, by another researcher, who did not have access to the patients' treatment.

IG received CDT¹⁸⁻²¹ twice weekly in 50-minute sessions consisting of manual lymphatic drainage, kinesiotherapy, leg bandaging with lymphedema (up

to knee height), and limb care and hygiene guidelines. Manual lymphatic drainage was applied by the same physiotherapist in all sessions, using the Foldi technique¹⁸. The maneuvers were applied in the patients: stimulation of the cistern of the kilo or maneuver of the five points; Grouping of supraclavicular, axillary and inguinal lymph nodes; "S" maneuvers in the limb with lymphedema and simple and compound waves, always with elevation of the treated limb.

Kinesiotherapy aimed to mobilize lymph through the use of isotonic exercises countered by orange elastic band (strong), in three sets of ten repetitions for the movements of flexion and ankle extension and interval of 30 seconds between the series.

The knee was banded under the knee height in six layers. Firstly, the skin of the leg to be bandaged was hydrated, using a body moisturizer, in order to minimize the temperature increase of the skin during the bandaging, maintaining hydration. If the patient had folds in the skin due to lymphedema, a rash prevention cream was applied in that region. And if it presented interdigital lesions, characteristic of mycoses, antifungal ointment was applied in the areas for treatment, prescribed by the doctor of the clinic.

After hydration of the leg, the tubular mesh was placed to protect the skin from direct contact with the bands, to minimize possible allergic reactions. The leg was then wrapped with the first layer, using foam with 5 mm thickness by 10 cm wide and 2 meters long each, in order to protect the skin, bony prominences and articular regions.

Thereafter, the second layer was placed using low elasticity bandage. This bandage had the function of configuring the bandage format, not being considered compressive. The third, fourth and fifth layers were composed of 100% cotton (cambric type) white fabric color, without reliefs (smooth), 10 cm wide by 3 m long.

Each stripe was interleaved between counterclockwise to distribute the bandaging pressure. Thus, when one band was wrapped around the leg, starting in a clockwise direction, the next band started in the opposite direction. Greater distal pressure was achieved (in the foot region) and, as the band approached the proximal (knee) region, the stretching pressure of the bands was decreased, aiming to create a pressure column in the proximal direction (centripetal – Laplace Law), displacing the fluid (lymph) to regions of greater absorption (drainage). The overlap between each layer of the bands was 75%, on the circumference of the leg.

The sixth layer was applied with the same material as the second layer to finish the bandaging. Finally, a tubular mesh was applied over the bandage to protect the bands from direct contact with the external environment.

The patient remained with the bandaging for three days and was instructed to remove the material on the same day of the next care in the morning. When removing the bands, he was instructed to wash the limb with clean water and neutral soap and to dry it with soft cloth (cotton flannel). Later that afternoon, the limb was bandaged again by the physiotherapist after manual lymphatic drainage and kinesiotherapy, and the cycle was repeated until the ten weeks of treatment were completed.

Patient care guidelines were given to avoid injuries, such as cutting straight nails (taking care not to remove cuticles), using abrasive materials in limb hygiene, preventing falls and keeping the limb clean and hydrated and dry interdigital regions. Care was given to patients through a booklet and accompanied by a checklist.

Meanwhile, the GC received an informative lecture, addressing filariasis, lymphedema and self-care topics, and, on the same day, was evaluated. After ten weeks, the reevaluation was performed.

Allocation confidentiality was retained for randomization for the principal investigator. It was not possible to blind the study to both the principal investigator and the patients due to the type of intervention that impaired the placebo therapy. To minimize possible bias, the evaluator's blinding was performed.

Evaluation

The patients were evaluated, treated and followed up in the period from December 2013 to December 2014, in the Ambulatory of the NRSF - CPqAM / Fiocruz Pernambuco. Participants were previously informed about the research objectives and procedures and signed the informed consent form. This study was approved by the Ethics Committee in Research of Fiocruz (PE), under opinion N° 547.572 / 2014. The clinical trial is registered with Rebec under No. U1111-1152-3063.

The limb volume change with lymphedema was measured indirectly through perimetry of the limb and directly through the volumetry, using the truncated cone formula. A tape measure was used to measure the circumference of the limb affected by lymphedema in the unit of centimeters. Six points of the limb were

measured, taking as a reference the apex of the patella (knee), which was the zero point, being performed every 7 cm, four measures below the bone accident and another measurement of circumference in the foot, 7 cm below the medial malleolus, as shown in Figure 1.

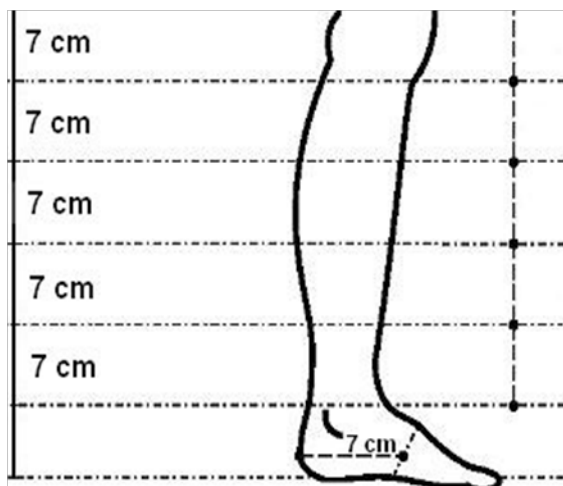


Figure 1. Schematization of the points measured in the assessment of the circumference of the lower limb through perimetry

Quality of life was assessed using the Whoqol bref questionnaire, developed by the World Health Organization and validated in Brazil by Fleck et al.²². This multidimensional questionnaire, which evaluates the quality of life, independent of health conditions, is composed of 26 questions, which are translated into facets, covering the domains: physical, psychological, social relations and the environment. According to the Whoqol Group, each domain is calculated by the sum of facet questions and the value found is divided by the number of questions. The total score of each domain ranges from 0 to 5, being interpreted as follows: results from 1 to 2.9 mean poor quality of life (needs improvement); Between 3 and 3.9 (regular); 4 to 4.9 (good); And 5 (very good).

Functionality and mobility of the lower limbs were assessed using the Sit-Up and Go (TUG-Test) test developed by Podsiadlo and Richardson²³. The orientation of the test is that the individual stands up from a chair (height of the seat 43 cm, height of the backrest 43 cm, depth 42 cm, width 40 cm) and, after the verbal command “go”, walks 3 m, turns around, walks back to the chair, and sits down. The timer is triggered at the first trunk forward movement and ceases when the patient rests his back in the chair. Patients are instructed to walk barefoot at a fast pace, comfortable and safe, and receive no physical assistance. The test result is measured

in seconds and the time to perform is compared before and after the intervention of this study.

Body weight was assessed using an anthropometric scale in kilograms, at the initial and final moments of the study.

Statistical analysis

Initially a comparison was made between the control and intervention groups, related to the characteristics of the subjects in order to observe a possible selection bias. For that were applied Student's t-tests, means comparison, and Fischer's exact test to compare the frequencies. In the analysis of the measurements of the circumference of the affected limb in the different points as well as the quality of life scores, the paired Student's t-test was applied in the intragroup comparison at the initial and final moments and between groups applying a Manova (Multivariate analysis of variance) for Repeated measures to test the effect of the intervention group. In the comparison of the total volume of the limb the measurement used for the analysis was the median, because the variable did not have a normal distribution. In this case the test applied was the Wilcoxon test. The normal distribution of variables was assessed by the Komogorov-Smirnov test. The significance used in the analysis was 5% ($p < 0.05$) and the software used for data analysis was STATA version 12.0.

RESULTS

Table 1 shows the comparison of groups according to biological characteristics, presence of comorbidities and degree of lymphedema. There was a predominance of lymphedema in the left limb in both the intervention and control groups. As for the degree of lymphedema, in the intervention group the degree III was predominant and in the control group, the degrees IV or V.

In Table 2, the measurements showed a significant difference in all measurement points between the moments before and after the treatment.

Table 3 shows the data with the results of the quality of life questionnaire, the Timed Up and Go test and body weight test. It was observed that the participants' quality of life was already poor in both groups. Comparing quality of life scores at the beginning and at the end of follow-up, there is a significant increase in the physical domain in the intervention group ($p < 0.039$). In the domains of control there was reduction.

Table 1. Comparison between control and intervention groups according to the biological and clinical characteristics of patients with lymphedema treated at the NRSF (Recife, 2013-2014)

Characteristics	Treatment groups		p-value
	Intervention (n=15)	Control (n=12)	
	Biologics		
Age (average±dp) ^a	52,8±11,0	50,5±9,4	0,571
	Sex^b		
Male	8 (53,3%)	3 (25,0%)	0,238
Female	7 (46,7%)	9 (75,0%)	
	Comorbidities^b		
Hypertension	7 (46,7%)	8 (66,7%)	0,299
Diabetes	4 (26,7%)	3 (25,0%)	0,922
Obesity	7 (46,7%)	9 (75,0%)	0,239
	Related to lymphedema^b		
<i>Side of edema</i>			
Right	4 (26,7%)	5 (41,7%)	0,447
Left	3,3%)	7 (58,3%)	
	Degree of lymphedema		
II	5 (33,3%)	5 (41,7%)	0,490
III	7 (46,7%)	3 (25,0%)	
IV or V	3 (20,0%)	4 (33,3%)	

^a Statistically significant difference (p<0.05); ^b Student's t-test; ^c Fisher's exact test

Table 2. Comparison of measures of circumference of the limb affected by lymphedema at different points above and below the knee, and in the foot, before and after intervention, of patients with lymphedema treated at the NRSF (Recife, 2013-2014)

Measuring points of limb circumference	Treatment groups						p-value ^a
	Intervention			Control			
	Initial	Final	p-value ^c	Initial	Final	p-value ^c	
Volume ^d	12018 (11.276;16075)	11151 (9496; 13911)	0.125	11551 (10577; 14694)	12347 (11745; 17693)	0.232	0.016 [†]
Ground zero (knee)	42.33±5.47	41.61±3.55	0.482	47.85±11.8	48.83±12.3	0.010 [†]	0.060
Leg - below the knee (bandaged area)							
28 cm	39.12±13.1	33.22±7.27	0.003 [†]	40.54±11.8	40.81±12.4	0.651	<0.001 [†]
21 cm	44.44±13.3	38.84±8.06	0.003 [†]	47.32±13.3	47.90±13.4	0.231	<0.001 [†]
14 cm	48.84±12.7	42.94±6.06	0.011 [†]	51.57±11.9	52.09±11.9	0.138	<0.001 [†]
7 cm	44.87±5.23	41.82±5.41	<0.001 [†]	50.29±12.5	51.08±12.1	0.305	<0.001 [†]
Foot (7 cm of the medial malleolus)	29.60±3.71	28.09±3.22	0.005 [†]	30.10±3.95	30.40±4.06	0.327	0.008 [†]

^a Manova - treatment groups factor; ^b Mean ±dp; ^c Paired Student t test; [†] Statistically significant difference (p<0.05); ^d Volume measured in milliliters (ml)

Table 3. Comparison of quality of life scores, functionality - TUG and body weight at the initial and final moments of treatment

Variables	Treatment groups				p-value ^a
	Intervention		Control		
	Initial	Final	Initial	Final	
Quality of life					
Physical	3.29±0.55	3.65±0.53	2.98±0.70	3.01±0.79	0.039[†]
p-value ^b		0.009[†]		0.791	
Psychological	3.46±0.72	3.66±0.59	3.40±0.79	3.21±0.76	0.233
p-value ^b		0.462		0.050	
Social relationships	3.51±1.00	3.68±0.87	3.51±0.86	3.38±0.59	0.510
p-value ^b		0.545		0.407	
Environment	2.91±0.70	3.29±0.51	2.93±0.49	3.03±0.56	0.339
p-value ^b		0.046[†]		0.429	
Functionality	7.91±1.34	7.51±2.16	9.02±2.24	9.19±2.32	0.210
p-value ^b		0.378		0.601	
Body weight	84.3±18.3	81.9±16.3	95.2±24.5	97.2±24.7	0.034[†]
p-value ^b		0.202		0.044[†]	

^a Manova - treatment groups factor; ^b Paired Student t test; [†] Statistically significant difference (p<0.05)

DISCUSSION

The results indicate that CDT with alternative material use was effective in reducing the volume of lower limb lymphedema and in the body weight of patients residing in areas endemic to filariasis. The application of the technique also presented significant results in the quality of life and in the physical and environmental domains. Patients who did not receive treatment continued with lymphedema evolution (IG reduced on average 7.21%, while CG had a mean increase in volume of 6.89%).

Similar results were found by Tacani et al.²⁰, who observed reduction of lymphedema at all points measured in the treated lower limb. The authors treated two groups: one with four patients, who received manual lymphatic drainage and elastic restraint once a week; another group with three patients, who received CDT twice a week.

The use of CDT to reduce lymphedema was used in an endemic area, as shown in the study conducted in Haiti by Addiss et al.²⁴. The researchers chose one of the components of the technique, the compression bandaging, which was performed by the patients themselves. In this period of self-treatment the members were measured and evaluated by health professionals. However, the authors report that patients who self-bandaged had a higher incidence of adenolymphatic seizures.

It should be noted that CDT has shown favorable results, when applied by trained professionals and monitored periodically^{25,26}, as it is a specific technique that requires skill and continuous monitoring of hygiene care in its application. It is noteworthy that during the treatment, in this study, one IG patient presented erysipelas, whereas in the CG, 50% presented seizures during the study.

One of the major concerns with the chronic patient is with their health conditions, especially in developing countries. It was observed in this study that lymphedema is strongly associated with the presence of comorbidities. Nearly 60% of the patients in both groups were hypertensive and / or obese. Similar results were found by Gethin, Byrne, Tierney, Strapp and Cowman²⁵, in which 55% of the sample of 418 participants from a cross-sectional study was hypertensive.

It was also observed that 63% of the sample in this study was composed of patients with more advanced lymphedema (above III). Many questions are asked

regarding the evolution of lymphedema and the appearance of comorbidities. Lymphedema is a chronic condition and chronic diseases, when undiagnosed and treated early, can lead to serious complications, or even death, because they are long-term, limiting diseases with a high risk of complications. On the contrary, it must be taken into account that the injuries can be reduced if the patient receives adequate guidance regarding his illness and the possible complications²⁶. Knowledge of the disease minimizes the effects of its complications.

Frequently the literature has reported the difficulties in relating results of statistical tests with what would in fact be clinically significant^{7,27-31}. Although is not clear in the literature that volume change metrics are minimally important for patients, CDT appears as an alternative to reduce the suffering of patients with peripheral lymphedema, since there is a reduction in varied percentages, even if they are not statistically significant signifiers.

The publications on lymphedema treatment received much criticism regarding methodological rigor, lack of standardized protocols and uncontrolled studies^{9,30,31}. Most clinical trials focus on results and discussion on reducing lymphedema volume, without more detailed analysis, and assess few variables in addition to limb volume. Therefore, information on the real impact of treatments on the lives of patients with lymphedema remains largely unknown.

The improvement of the quality of life is an important point in the treatment of chronic diseases, since it is limiting and unfeasible the possibility of cure. The simple fact of controlling the chronic illness can contribute positively to the quality of life of the patients.

The chronic condition of filariasis and lymphedema may limit the quality of life of those affected. In this study it was observed that the patients, since the first evaluation, already presented a poor quality of life, varying the scores between bad and regular. Adhikari, et al.⁶ found even more relevant results in relation to poor quality of life in a study in Nepal with 410 patients with filarial morbidity (lymphedema and hydrocele). They also used the Whoqol bref and found that patients' quality of life was poor in all domains.

It is noticed that there is still no consensus as to the best instrument to evaluate the patient with lymphedema³²⁻³⁴. Whoqol bref was used in this study, advocated by WHO because it is an instrument already validated for the Brazilian population, but it is a generic instrument. It is suggested in future studies

the validation of instruments in Brazil to assess specific quality of life for lymphedema. The same occurred with the evaluation of the functionality, by the TUG test, which despite being validated in Brazil, is not specific for patients with lymphedema. The results for this variable did not show significant improvement after the intervention.

The costs of treating complications from lymphedema are a major concern. Lack of care with lymphedema can lead to repeated infections (cellulitis, lymphangitis), progression of enlargement of the limb, trophic changes in the skin and sometimes disability^{9,14-16}. Patients with uncontrolled lymphedema often present with multiple attacks of erysipelas per year. A study conducted by Okajima et al.³⁵ demonstrated that the mean time of hospitalization of patients with erysipelas is 9.9 days, with an average cost of US\$ 249.51 for a single treatment. Patients in India reduce their workload by 11 to 33% annually with the complications of lymphedema^{36,37}. Another study conducted at the same site reveals that men with lymphedema had a 27% decrease in productivity when compared to controls³⁸.

One of the limitations of the implementation of the CDT is that this technique is not accessible to developing countries, since it requires the participation of specialized professionals and the use of high-cost and imported materials. Thus, this study proposed the use of low cost materials, such as 100% cotton cambric type fabric, which can be replaced by expensive and imported bandages. In this study, the total cost of treatment for each patient over the ten-week period was \$ 244.03. Thus, the study demonstrated efficiency, since the cost of the full treatment represents 97% of the treatment of a single crisis of erysipelas.

As limitations of the study, the difficulty of inclusion of evaluated patients such as those with comorbidities, mainly uncontrolled arterial hypertension, are highlighted. Another limiting factor is dealing with a chronic non-curable disease. It is a challenge to keep patient adherence to ongoing treatment and to make them aware of the importance of their participation in treatment with self-care. The chronic patient needs care and follow-up throughout his life, and his motivation for adherence to treatment and self-care are determinant factors for health maintenance.

There was no time to follow up patients after lymphedema treatment. In future studies, it is suggested, in addition to the use of larger samples, follow up, in order to evaluate the effect of CDT in the long term

and also to verify for how long these treatment gains are maintained.

Treating lymphedema is a challenge, especially in developing countries, where treatment and control programs are not yet viable and affordable. This research shows that physiotherapy is a great ally in the implementation of these programs, and may establish partnerships with the WHO in the approach to morbidities in neglected diseases (such as filariasis), in order to improve the quality of life of the affected population.

CONCLUSION

Complex decongestive therapy has been shown to be effective in reducing and controlling lymphedema, preventing its evolution. The technique improved the quality of life in the physical and environmental aspects.

The results of this study are considered to contribute to the Global Plan for the Elimination of Lymphatic Filariasis, considering it proposes the application of a viable and low-cost protocol for developing countries, inserting and strengthening the action of physiotherapy in the treatment of diseases neglected.

ACKNOWLEDGEMENTS

We thank the Project PPR-002-Fio-12 Laboratory Networks Management, for the financing of part of the project. A special acknowledgment to Estácio Faculty of Recife for funding the scholarships of the project, and to the entire staff of Fundação Oswaldo Cruz in Pernambuco – especially the Department of Parasitology, in the person of dr. Zulma Medeiros. We also thank the Master's Degree in Physiotherapy from the Federal University of Pernambuco for the support of this research; The patients assisted by the service and who have contributed so much to the development of this project; And to the physiotherapy academics involved in the project since its implementation.

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