Effectiveness of manual lymphatic drainage associated with functional banding in the clinical improvement of gynoid lipodystrophy in pregnant women: a clinical, controlled and randomized trial

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Abstract

Μυνρο Γ

During pregnancy, women can trigger hormonal dysfunctions that induce the accumulation of edema and fibrotic nodules, favoring the formation of rifted skin causing a painful sensation. Therefore, this study aimed to compare the effectiveness of manual lymphatic drainage with or without the use of functional bandages in gynoid lipodystrophy (GLD) in pregnant women in the second and third trimester. This was a randomized clinical trial, composed of three groups: G1: Manual Lymphatic Drainage (MLD); G2: MLD + Functional Bandage (FB); G3: Control Group. Inclusion criteria: pregnant women in the second and third trimester, primiparous or multiparous and a single fetus pregnancy. MLD was performed in the gluteal region and lower limbs, and FB was applied from the inguinal region in the form of a web directed to the medial gluteal region, using a surface tension of 10%. An evaluation protocol for gynoid lipodystrophy (EPGLD) with anamnesis, a physical examination with an inspection, a grip test, tactile sensitivity test (Semmes-Weinstein monofilament test), assessing the patient's sensitivity, grade, pain, recommendation, and satisfaction was used. Photos were taken of the gluteus region before and after and were then evaluated by 10 specialists through photogrammetry. There was a significant clinical improvement in the drainage group and in the association with the bandage when compared to the control group by the 10 specialists. There was a significant improvement in the scores of specialists in groups G1 and G2, when compared to G3. Therefore, the present study demonstrated a clinical improvement in gynoid lipodystrophy of pregnant women who received MLD alone, and in association with FB, when compared to the control group.

Keywords: Manual Lymphatic Drainage. Massage. Compressive Bandages. Pregnant Women, Cellulite.

INTRODUCTION

During the gestational period, women can trigger aesthetic dysfunctions, resulting from hormonal and biomechanical changes imposed by pregnancy. These gestational aesthetic dysfunctions directly affect selfesteem, leading to a decrease in self body image. Among the aesthetic changes during pregnancy, there is gynoid lipodystrophy (GLD)¹, popularly known as "cellulite". It is an inflammatory process of connective tissue, resulting from circulatory changes that generate changes in the fundamental

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amorphous substance. During this process there is an accumulation of edema and fibrotic nodules, which favor the formation of skin rifts causing a painful sensation, especially in the gluteal region².

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The main hypotheses for the appearance of GLD in pregnancy are: hormonal changes, mainly due to estrogen; the decrease in venous return and peripheral vascular resistance; and the increase in abdominal (ventricle) content that compress the pelvic and iliac veins, triggering a decrease in circulation and the appearance of this pathology in the gluteal region³. It is divided into grade 1, with high amount of intracellular fat, causing voluminous cells of the adipose tissue; grade 2, with fat in the cells accompanied by fibrosis, with the formation of micro nodules: and grade 3 with the appearance of an "orange peel", can be visualized on the skin, as well as reports of heaviness and fatigue in the lower limbs and increased sagging and sensitivity^{1,4}.

Among the most used treatments during pregnancy, manual lymphatic drainage (MLD) and the use of kinesio taping (KT), known as functional bandaging, stand out, as they are techniques that do not have many contraindications during the gestational period⁵. MLD performs important functions throughout the body, such as improving blood

circulation, eliminating toxins, and decreasing liquid retention (swelling), in addition to activating cellular oxygenation, stimulating lactation, and desensitizing the breasts, preparing them for breastfeeding. Also, it helps prevent and fight varicose veins, the feeling of tired legs, fights cellulite and stretch marks, as well as provides nutrition to the tissue⁶. The purpose of DML is to create pressure differentials to promote the conduction of interstitial fluid and lymph, replacing it in the bloodstream, promoting the evacuation of waste from cellular metabolism^{6,7}.

In a study on the effects of KT in the treatment of GLD, Artioli and Bertolin⁸ evaluated non-pregnant women using the bandage alone and found an effect in reducing GLD. KT is a relatively new method, created in Japan by chiropractor Kenzo, in the 70s and became known as elastic bandaging, because in addition to exercising several functions, it has no contraindication in several treatments, and allows the patient to remain with a range of preserved movement⁹.

Thus, the objective of the study was to compare the effects of manual lymphatic drainage with or without the use of functional bandages on gynoid lipodystrophy in pregnant women in the second and third trimester of pregnancy.

METHODOLOGY

This was a controlled, randomized clinical trial, carried out from February to November 2019 and composed of three groups: G1: Manual Lymphatic Drainage (MLD); G2: MLD + Functional Bandage (FB); G3: Control Group. Randomization was performed using a computer with the Random Allocation Software version 1.0 program, which generated a table of random numbers.

Then, opaque envelopes numbered

from one to thirty were prepared by a researcher who was not involved in the study, thus ensuring confidentiality in the allocation of the study. This study was conducted in accordance with CONSORT recommendations for clinical trials.

The criteria used for inclusion were: age from 18 to 45 years, pregnant women from the fourteenth gestational week, nulliparous, primiparous or multiparous, with

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gestation of a single fetus. As for exclusion criteria: pregnant women with some clinical instability, diagnosed with uncontrolled gestational hypertension, kidney failure, and deep venous thrombosis (DVT).

This study was developed in accordance with the recommendations of Resolution No. 466/12, of the National Health Council of the Ministry of Health, which provide for research involving human beings, after approval by the Research Ethics Committee of the Hematology and Hemotherapy Foundation of the State of Pernambuco - HEMOPE, under CAAE number 86064118.2.0000.5195 and Opinion number: 2.650.349.

Before the beginning of the procedures, after the participants fit the eligibility criteria, the signatures of the Informed Consent Froms (ICF) were collected, and subsequently, they were submitted to an anamnesis to collect information from clinical, obstetric, and sociodemographic data.

Group 1 performed twice a week, totaling 10 sessions, lasting 60 minutes in the gluteal region and lower limbs. Initially, stimulation in the cervical region was performed with the physiotherapist's thumbs for 15 minutes, with the participant semi-seated and with a trunk elevation at 45 degrees, using an anatomical backrest (Figure 1). Then, she was positioned into a lateral decubitus and the massage was performed in the gluteal region and in the lower limbs, totaling 45 minutes (Figure 2).

The segments of the lower limbs were divided into three, and then the sliding maneuvers were started on the medial side of the thigh, on the anterior to medial side and from the lateral face towards the medial. With the lower limbs slightly flexed, drainage was performed on the posterior aspect of the thigh, with the lymph being drained into the entire medial surface of the lower limb.

Only the principles of the Godoy & Godoy, Vodder and Leduc method were used. The massage was in the form of sliding, using natural coconut oil, with a pressure of about 15-30 mmHg, in order to promote an adequate pressure gradient. The pressure exerted was strong enough to propel the interstitial fluid into the lymphatic capillaries, increasing their absorption by the capillaries. However, it remained below the value of the internal pressure of the lymphatic and blood capillaries, so as not to obstruct them. The rhythm was always uniform and slow, which is what cancels the strong and painful mechanical sensation, promoting a pleasant sensation in the maneuver. The massage was performed at the determined frequency and at the correct time and always obeying the direction of the return lymphatic circulation and centripetally; otherwise, the lower limbs that already had difficulties in maintaining the flow would be more burdened due to stasis.



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Figure 1 – Stimulation of the cervical region.

Group 2 performed MLD and used FB in the gluteal region (Figure 3). FB was applied to the gluteal region in the form of a web directed to the inguinal region, close to the ganglia, using a surface tension of 10%. Before placing the FB, the skin of the tape application area was cleaned with alcohol and cotton, so that it would be well fixed and last longer. The participant stayed as long as possible using the FB and, in the next session, the tapes were removed by the researchers. If the bandage was taken off at home, and or the volunteer felt some discomfort, they were instructed to do the removal correctly.

Both G1 and G2 carried out twice a week over a period of 5 consecutive weeks, totaling 10 sessions. MLD and FB application were performed by a team of physiotherapists with experience in the techniques. Vital signs and blood pressure were measured before and after the procedures.

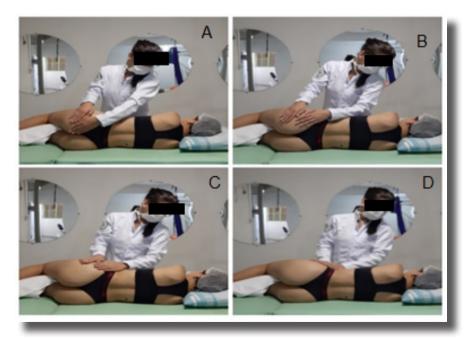


Figure 2 – Sequence of drainage in the gluteal region, starting at A and ending at D.





The control group participated in 10 meetings with pregnant women's group meeting promoted by the Academic League of Physiotherapy in Obstetrics of UNIFACOL, with themes focused on the preparation for childbirth and physical exercises, once a week lasting 60 minutes. The physical exercises consisted of: a warm-up phase (stretching and breathing exercises); a conditioning phase (active exercises for the upper and lower limbs using TheraBand and pelvic mobility); and a relaxation phase (massage therapy and guided imagination with music therapy).



Figure 3 – Application of the functional bandage in posterior (A) and lateral (B and C) views. Source: research collection.

The Evaluation Protocol for Gynoid Lipodystrophy (EPGLD) was applied in the first and last session. This evaluation form was developed and validated for the Brazilian population¹⁰. EPGLD evaluates anamnesis, physical examination with inspection, palpation of orange peel test, grip test, tissue adherence and GLD shape, classification, tactile sensitivity test (Semmes-Weinstein monofilament test), and complementary exams, with the main objective of assessing the patient's sensitivity, grade, pain, recommendation, and satisfaction.

The evaluation of clinical improvement was performed through photogrammetry analyzed by 10 specialist physiotherapists and with a minimum experience of 5 years in Dermatofunctional Physiotherapy or involved in teaching and research (academic) in Dermato-functional Physiotherapy, Women's Health or similar areas, and who accepted to be a member of the panel of evaluators. The photos were shown without identifying the participants, to assess the before and after, and to indicate whether there was a worsening, equal, or improvement in the visual aspect. The evaluation form produced was sent by e-mail, after confirmation of participation. A photo of the gluteus region was taken before and after, and there was the identification of each patient in both groups in which they had participated, and through this, it was possible to evaluate the clinical improvement of the GLD. Experts gave scores from 0 to 10 to assess the

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effectiveness of treatments.

Statistical analysis was performed with the software GraphPad Prism 4.0 (GraphPad Software Inc., USA) and SigmaPlot 12.0 (Systat Software, Inc., Germany). Continuous variables were expressed as mean and standard deviation, and the difference in mean and 95% confidence interval. Categorical variables were expressed in number of cases and frequency by the group studied. For data distribution analysis, the Shapiro-Wilk normality test was performed. Pearson's chisquared test or Fisher's exact test was used to compare categorical variables between groups. To compare continuous variables between groups, Student t-test or Mann-Whitney test for independent samples, and paired Student t-test or Wilcoxon tests were used for paired data to compare evaluations. The ANOVA Two Way test was performed with a post-test of multiple Holm-Sidak comparisons, in which they were used to compare interventions (control, lymphatic drainage, drainage + bandaging) and compare the effect of time within each intervention (Preand Post-intervention). Values of p<0.05 were considered significant. ANOVA One Way test or Kruskal-Wallis test was used to compare the three groups studied. Values of p<0.05 were considered significant.

RESULTS

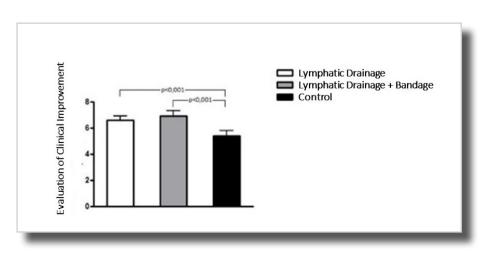
The characteristics of the research participants are described in table 1.

In figure 4 we could see that there was a significant clinical improvement, through the evaluation of ten specialists who participated in the analysis of photogrammetry in both groups (Drainage and Drainage + Bandage) when compared to the control group.

Regarding the orange peel test and the grip and monofilament test in the gluteal

region of pregnant women, there was no significant difference in both tests (Table 2).

When we look at the results in Table 3, we see that there was a significant difference both in the lymphatic drainage group (66.0 \pm 9.7), and in the lymphatic drainage and functional bandage group (65.0 \pm 15.8), when compared to the control group, which had a clear reduction in percentage (31.0 \pm 11.0).



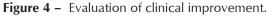




 Table 1 - Characteristics of the participants.

Characteristic	G1 (n=10)	G2 (n=10)	G3 (n=10)		
Age (years)					
Gestational Age (Weeks)	26.4 +3.53	25.9 +3.67	26.5 +2.29		
Number of deliveries	28+6.04	28+5.39	29+5.44		
Nulliparous	6 (60)	4 (40)	2 (20)		
Primiparous	1 (10)	4 (40)	6 (60)		
Multiparous	1 (10)	2 (20)	2 (20)		
Marital status					
Single	3 (30)	1 (10)	5 (50)		
Married	7 (70)	9 (90)	5 (50)		
Education					
8-11 years of study	3 (30)	2 (20)	5 (50)		
> 12 years of studies	7 (70)	8 (80)	5 (50)		
Origin					
Metropolitan region	1 (10)	2 (20)	1 (10)		
Interior of Pernambuco	9 (90)	8 (80)	9 (90)		
Occupation					
Housewife	3 (30)	4 (40)	8 (80)		
Others	7 (70)	6 (60)	2 (20)		
Presence of Varicose Veins					
Yes	2 (20)	1 (10)	3 (30)		
No	8 (80)	9 (90)	7 (70)		
Presence of Telangectasis					
Yes	3 (30)	2 (20)	1 (10)		
No	7 (70)	8 (80)	9 (90)		
Presence of Edema		. /			
Yes	7 (70)	8 (80)	6 (60)		
No	3 (30)	2 (20)	4 (40)		
Use of elastic stockings	. /	. /			
Yes	1 (10)	0 (0)	2 (20)		
No	9 (90)	10 (100)	0 (80)		

Data expressed as Average ± Standard Deviation or number of cases (percentage of the number of cases); n: sample; G1: MLD; G2: MLD + FB; G3: Control



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 Table 2 – Results of orange peel tests, grip test and monofilament test.

Variables	Lyr	nphatic draina	age	L	ymphatic dra + Bandago		Control		
-	Pre	Post	p-value	Pre Post		p-value	Pre	Post	p-value
Orange skin									
Positive	9 (90)	7 (70)	4.000	8 (80)	8 (80)		6 (60)	3 (30)	0.200
Negative	1 (10)	3 (30)	1.000	2 (20)	2 (20)	-	4 (40)	7 (70)	
Grip Test									
Positive	0 (0)	0 (0)		2 (20)	1 (10)	4000	1 (10)	1 (10)	
Negative	10 (100)	10 (100)		8 (80)	9 (90)	1000	9 (90)	9 (90)	
Monofilament	t								
Blue	4 (40)	2 (20)		1 (10)	1 (10)		4 (40)	4 (40)	
Green	5 (50)	7 (70)		8 (80)	9 (90)		4 (40)	4 (40)	
Purple	0 (0)	1 (10)		1 (10)	0 (0)		1 (10)	1 (10)	
Red	1 (10)	0 (0)		0 (0)	0 (0)		1 (10)	1 (10)	

Data expressed in number of cases (percentage of cases).

Table 3 – Data on the assessment and recommendation of treatments performed by physical therapists.	Table 3 –	Data on the assessment and	recommendation of treatments	performed by	physical therapists.
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Groups	1	2	3	4	5	6	7	8	9	10	Mean
Lymphatic drainage	70	60	80	60	60	60	70	70	50	80	66.0 ± 9.7
Lymphatic drainage + Bandage	60	50	80	80	30	70	60	70	70	80	65.0 ± 15.8
Control	50	30	30	40	20	40	30	30	10	30	31.0 ± 11.0

p-value¹ <0,001

Data expressed as a percentage of physiotherapists who reported clinical improvement through visual assessment for each volunteer in their respective group; and on average ± standard deviation.

¹Lymphatic drainage vs. Control (p <0.001); Lymphatic drainage + bandage vs Control (p <0.001).





DISCUSSION

Gynoid lipodystrophy is considered a condition that affects a large number of women already in post-puberty¹¹. In the present study, we investigated the comparison between MLD with or without the use of functional bandaging on GLD in pregnant women in the second and third trimesters in which clinical improvement was observed as well as a high level of recommendation by the evaluation of specialists in the groups that performed the lymphatic drainage with or without the application of functional bandages when compared to the control group.

The GLD treatments in the gluteal region aim to reduce the symptoms instead of curing it. With GLD being an aesthetic dysfunction resulting from hormonal changes that constantly increase during the gestational period, total healing is imperceptible, as we do not have any control in of hormonal and aesthetic changes during pregnancy, sometimes causing pain and functional alterations, in addition to influencing quality of life. Therefore, GLD should be treated a health problem and not simply for as aesthetic reasons¹⁰. In this context, we were able to observe a clinical improvement in the participants in our study, since the use electrothermal and phototherapeutic of resources at this moment are not indicated for treatment in pregnant women.

According to Sadick¹² understanding the etiology of cellulite is essential for the development of new approaches, and options are available to offer patients with GLD such as topical energy-based agents, subcision, injectable biological drugs, and electrotherapy, a concern that has already been reported in our work, which aims to offer new GLD treatment techniques to pregnant women.

According to Tunay *et al.*¹³, they carried out a study comparing the effectiveness of three different non-invasive treatment techniques on the fat mass and regional fat thickness of patients with cellulite in 60 subjects divided into 3 groups: one treated with mechanical

massage (MM), another treated with manual lymphatic drainage (MLD), and a third group treated with techniques of connective tissue manipulation (CTM). They reported that, all groups had an improvement in the thinning of the subcutaneous fat after the treatment. and that all the treatment techniques are effective in decreasing the regional values of fat of the patients with cellulite. When we think about the effects that pregnancy can cause on women at this moment, such as the accumulation of body fat, liquids, and vascular changes, our study has observed that MLD demonstrated a clinical improvement of GLD through analysis by photogrammetry. They also reported that there is no study in the literature on these techniques and the comparison of their effects on the formation of cellulite and fat mass. The mechanisms of action of such treatments are not yet clear.

In a study including 20 women aged 20 to 40 years, Schonvvetter, Bagatin and Soares¹⁴ performed fourteen sessions of manual lymphatic drainage once a week on lower limbs and gluteal regions of patients with GLD and found a significant improvement in quality of life (p = 0.018) of patients through analysis of ultrasound images. They also reported that manual lymphatic drainage was a safe method, although not as effective as an isolated approach for the treatment of cellulite. This fact is already corroborated by Khan et al.¹⁵. It is important to use these techniques due to clinical safety for the gestational period, as edema can overload the cardiovascular system leading to changes in peripheral vascular resistance and venous return, compromising blood pressure leading to symptoms such as dizziness, tingling, syncope, which were not observed with the techniques used in our study.

According to Delgado *et al.*¹⁶, manual lymphatic drainage is a physiotherapeutic treatment that is not indicated by many health professionals during the gestational period, as it does not have reliable studies through





evidence, and those that exist are mostly case studies where they present significant values of effectiveness according to their own interests.

In GLD, there are important clinical symptoms, such as changes in sensitivity and pain in the gluteal region, in addition to decreased self-esteem, self-image, and quality of life during pregnancy. In drainage, the technique is effective because it aims to mobilize accumulated fluids between interstitial spaces, particularly in the dermis, thus, contributing to the balance of tissue fluids through pressure differentials that will promote the displacement of the lymph and the interstitial fluid towards the bloodstream^{14,17}. This confirms our findings through the analysis performed by photogrammetry. Clinically, the participants reported improvement in the aspect of body image, a feeling of relief and lightness in the lower limbs and highlighted the reduction in swelling in both interventions.

In a clinical trial of randomized and blind treatment of GLD conducted by Silva et al.², 24 patients with GLD in the gluteal region (grades I, II, and III) were analyzed. The participants were randomly allocated to two subgroups of 12 individuals, where a control group (CG) and a treatment group using KT (GKT). Both the GC and the GKT were evaluated before and after the experiment, using the Evaluation Protocol for GLD (EPGLD) and photogrammetry. In GKT alone, four applications of bandaging were performed, once a week, in the gluteal region. It was concluded that treatment with KT was able to significantly decrease the degree of GLD and increase clinical improvement using photogrammetry. This result corroborates the findings of the present study, where a clinical improvement was observed in the patients, as well as in the grades attributed through the analysis of pregnant patients by specialists. This fact is pioneering, because, to this day, there is a fear due to the lack of clinical evidence in the indication of treatments given to pregnant women with GLD, which means

that many professionals do not recommend treatments during pregnancy.

Regarding the reduction in limb volume, Taradaj et al.¹⁸ demonstrated a progressive decrease with the passage of the MLD sessions associated with kinesio taping, however, it was much faster after the applications of kinesio taping. Tsai et al.¹⁹ studied the effects of treatment on water retention between standard decongestive lymphatic therapy combined with pneumatic compression and modified MLD, in which the use of a stretch bandage replaced by the use of kinesio taping tape in forty-one patients with unilateral lymphedema related to breast cancer for three months. They found that there was a better acceptance of kinesio taping and that the main benefits included longer use, less difficulty in use, and greater comfort and convenience to the patients.

This was also observed in studies by Tantawy et al.²⁰ where KT showed significant changes in limb circumference, handgrip strength, and overall quality of life in the treatment of individuals diagnosed with lymphedema after mastectomy. In a meta-analysis investigating the treatment of patients with cancer-related lymphedema, Gatt, Willis and Leuschner²¹ sought to determine the effectiveness and safety in the treatment of kinesio taping compared to compression bandages and concluded that kinesio taping should be used with caution, and that, more evidence is needed to be conclusive. The need for the association of techniques has been reported in the literature as a common and significant aspect in the process of treating gynoid lipodystrophy²².

In our study, there was a clinical improvement in pregnant women in the group that received drainages, and in the drainage group associated with bandaging, when compared to the control group. Similarly, no significant results were found for the handgrip test (pain) or for the orange peel test. For Santana and Uchôa³, the grip test causes a greater than normal uncomfortable, painful



sensation in the patient if there is already a change in sensitivity due to compression of the free nerve endings. This result can be interpreted with caution since we do not use analytical resources such as ultrasound. However, based on the results of analysis of questionnaires, personal observations, and measurements through photogrammetry, Karwacińska et al.23 concluded that, the application of the kinesio taping is effective for recovery from hypertrophic scars and keloids, as well as, its low cost, non-invasive approach, and it helps short period of time of the recovery process.

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Regarding the monofilament test (sensitivity), there were no significant changes in the results, sensory deficits are present, in most cases, in people with grade III GLD; however, they are not mandatory signs and symptoms². The results of photogrammetry performed by physical therapists through visual assessments of each patient, presented a significant result in the group of lymphatic drainage vs control (p < 0.001) and lymphatic drainage associated with bandage vs Control (p <0.001). This was evident in the groups that underwent the treatments, although there was no significant difference in the grip, orange peel, and monofilament tests between the groups. This aspect could probably have been demonstrated if we had assessed the patients' self-esteem and quality of life, since they reported a feeling of relief in the gluteal pressure, especially when they spent a lot of time sitting.

In our study, we found that the vast majority of patients in the drainage and functional banding group did not develop vascular problems, whereas in group 3, the appearance of (varicose veins, stretch marks, fibroids, edema, telangiectasis and lower limb edema) was observed associated with the gestational period. These results correlate with findings in the literature, where the demand for blood volume and pressure in the veins was associated, with vascular relaxation promoted by the effects of the hormone progesterone and the increase in body weight, increasing pressure in the veins of the lower limbs, and are responsible for the development of varicosities and edema in the gestational period²⁴.

According to Perez Atamoros et al.'s systematic review²⁵, they report that there are no randomized and controlled studies with an adequate sample size and methodology in this type of research. They also mentioned that it is necessary that professionals who treat this type of problem, should document and publish the results of treatments through clearly established procedures and methods, so that the diversity of treatments, as well as their lack of scientifically proven evidence, would minimize costs, time, and the expectations of patients.

In our study, we also found a lack of studies on the effects of lymph drainage or functional banding on pregnant women. There were no articles related to lymphatic drainage or functional banding associated with treatment with gynoid lipodystrophy in patients during pregnancy. The available evidence is insufficient and inconclusive as to the physiological repercussions and the clinical effects of lymphatic drainage on gynoid lipodystrophy.

Therefore, we found as a limitation the non-use of gold standard GLD assessment techniques such as ultrasound and digital thermography to precisely differentiate skin aspects, as well as an analysis for the effects of the techniques on fetal development in pregnancy. However, as it is a pioneering study, these techniques are sufficient to control the development of GLD in the gestational period, thus being techniques suitable for use by professionals in pregnant women, mainly minimizing the evolution of the pathology and, thus, promoting comfort in the peripheral vascular system of these patients.





CONCLUSION

It is concluded that the performance of manual lymphatic drainage, with or without functional bandage, promotes clinical improvement when compared to the control group. There were no changes in the aspects related to sensitivity, pain, and the grade of

gynoid lipodystrophy in pregnant women in the second and third trimester of pregnancy. We can also highly recommend that specialist professionals use lymphatic drainage associated or not with functional banding in pregnant women.

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