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Bioimpedance assessment of edema in patients with mastectomy-related lymphedema treated by mechanical lymph drainage using the RAGodoy® device

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Abstract

Few apparatuses have been developed for the treatment of arm lymphedema. The objective of this study was to use bioimpedance to evaluate the efficiency of the RAGodoy® mechanical drainage device in reducing swelling in the treatment of mastectomy-related arm lymphedema. Twenty-one patients with arm lymphedema after mastectomy were enrolled in a prospective study (clinical trial) to quantitatively evaluate reductions in limb size using a passive electromechanical device to perform mechanical lymph drainage. The study was conducted in the Vascular Laser Center in Sao Jose do Rio Preto. The InBody S10® body composition analyzer was used to evaluate edema. The paired t-test was used for statistical analysis with significance being set for an alpha error = 5% (p-value < 0.05). The results showed that a significant reduction in edema was observed after mechanical lymph drainage using the RAGodoy® device (p-value < 0.012). In conclusion, lymph drainage performed with the electromechanical RAGodoy® device is effective in reducing volume of arm lymphedema as assessed by bioimpedance.

Key Words: lymphedema, breast cancer, treatment, bioimpedance

Introduction

Lymphedema is characterized by an abnormal accumulation of protein-rich fluid in the tissues resulting from dysfunction of the lymphatic system, that is, an imbalance between the formation of lymph and its absorption in the initial lymphatic system (1,2).

It is one of the diseases that most leads to disability from work in the world, however there are few specific clinical trials that correctly guide treatment.

It is well known that lymphedema is one of the main complications of the treatment of breast cancer and that this affects hundreds of women all over Brazil. The World Health Organization estimates that annually there are more than 1,050,000 new cases of breast cancer worldwide making it the most common cancer among women (3). For Brazil, the estimated number of new cases of breast cancer in 2010 was 49,240, with an estimated risk of 49 cases per 100 000 women; in the southeast of the country, breast cancer was even more common with an estimated risk of 65 new cases per 100 000 women (4). Publications reporting the development of mastectomy-related lymphedema show that the prevalence can increase to up to 50% with axillary lymph node dissection (5).

A combination of therapies is recommended for the treatment of lymphedema with the main approaches being mechanical and manual lymph drainage (6-11), bandages (12,13), hygienic care (14), exercising (15,16), myolymphokinetic activities (17,18) and drug therapy (19).However, there are few mechanical apparatuses to treat arm lymphedema. The RAGodoy® apparatus is an electromechanical device that performs passive movements of the elbow. The physiological principle used

is stimulation of the veno-lymphatic return caused by passive muscle contractions (11,16).

The objective of this study was to evaluate, by bioimpedance, the efficiency of the RAGodoy® device in reducing swelling in the treatment of arm lymphedema after mastectomy.

Methods

This study was designed as a randomized, blind, clinical trial that used bioelectrical impedance to quantitatively evaluate the reduction in swelling after mechanical lymph drainage.

Twenty-one female patients with mastectomy-related arm lymphedema with lymph node dissection treated in the Vascular Laser Center in Sao Jose do Rio Preto were enrolled in this study. Lymphedema was diagnosed when there was a difference of more than 100 mL compared to the healthy contralateral arm. Patients with active infectious and limitations in joint mobility were excluded from the study.

An electromechanical device that passively performs flexion and extension movements of the elbow was used to reduce the lymphedema. Standardization consisted of 20 cycles of flexion-extension movements per minute for 30 minutes.

Evaluation of the lymphedema using a body composition analyzer (InBody S10 ®) was performed before and after the mechanical lymph drainage session. The paired t-test was used for statistical analysis with significance being set for an alpha error = 5% (p-value < 0.05).This study was approved by the Research Ethics Committee of the Medicine School in São José do Rio Preto n0 295/2011.

Results

The mean age of the participants was 61.23 years old and the median was 58 years.

The bioelectrical impedance readings, obtained before and after mechanical lymph drainage using the RAGodoy device, are listed in Table 1.

The paired t test identified a statistically significant difference (p-value < 0.0127) between the bioelectrical impedance measurements before and after mechanical lymph drainage.

Discussion

Using bioelectrical impedance analysis, this study demonstrated the efficiency of mechanical lymph drainage using the RAGodoy device to reduce lymphedema in patients who had been submitted to mastectomy. Published studies, using water displacement plethysmography, have demonstrated the effectiveness of this equipment to perform mechanical lymph drainage by measuring changes in the volume of the arm (11).

Body composition analysis (Bioimpedance) is a test that has been used both in the diagnosis and follow up to treatment of lymphedema (20); this method is more practical and reliability than water-displacement volumetry.

RAGodoy is a new mechanical lymph drainage device that uses therapeutically-based passive movements to stimulate lymphovenous drainage. It performs the flexion and extension of the elbow thereby employing the major muscle groups. Another mechanism described in the literature is pressure therapy, which uses external, segment and sequential compression of the limb (21). Thus, these devices produce different mechanisms of action.

The RAGodoy device was developed after studying the physiology of venous and lymphatic return and uses muscle contractions to generate a differential pressure in the vessel. The passive movements require less force than active muscle movements and, consequently, require a lower blood supply to the limb. In this study, 18 of 22 patients had a reduction in the edema. Now it is important to identify why there was no reduction in four of the participants. With the use of active and passive exercises, some factors that affect the reduction have been identified such as the speed of movements, the positioning both of the limb and of the patient, the force employed and the duration of the exercising session. This device is passive, but the patient can, and sometimes does, exert force and try to control the movements of the device, thereby becoming active in the exercises which can lead to an increase in the volume of the limb.

This work reports on the first phase of a study to determine the effectiveness of a 30-minute session using the device to treat edema as assessed by bioelectrical impedance. Another study in the publication phase, evaluates the use of this device for different lengths of time (1, 2 and 3 hours) by volumetry and shows that a period of one hour of use is the most efficient and safe; the duration of the session affects the results and identifying the optimal length of sessions is very important. Further assessments that compare the reduction in edema using mechanical lymph drainage and resting for this period is suggested.

Conclusion

Lymph drainage performed with the electromechanical RAGodoy® device is effective in reducing volume of arm lymphedema as assessed by bioimpedance.

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