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Effects of Ultracavitation Combined with Shockwave on Localized Adiposity

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ABSTRACT

The purpose of this trial was to verify the effects of shockwave therapy on localized adiposity through an experimental study that consisted of 4 weekly treatment sessions, comparing 50 participants of age between 19 and 35 years old, females, divided into two groups: the shockwave group (OC) and the group of ultra-cavitation combined with shockwave (OC+UC). In combined OC+UC, the results after intervention were greater if compared to OC the plicometry outcome (p=0.001), comparing both groups, was significant. Analyzing the groups alone, before and after treatment, significant difference of body weight was noticed in group OC and in group OC+UC (p=0.03, p=0.02, respectively), making it more challenging to draw any conclusion when it comes to the effectiveness of isolated shockwave orits application in association to ultracavitation, as both presented satisfactory results.

Keywords: Localized adiposity, Physiotherapy, Shockwave, Mechanical waves

INTRODUCTION AND AIM

The lipolysis process happens through the body's need for energy, which comes from protein lipase production increase, so that more combustion of accumulated and excess fats occurs. Even with the immense variety of resources that are being used aiming lipolysis and the consequent reduction of the localized adiposity excess, most are improperly used or do not present scientifically proven efficacy [1].

The shockwave treatment is one of the tools that aim adiposity reduction. The wave energy is transferred to the patient's skin through the ultrasound gel and it spreads in a radial fashion along the tissue. The energy is higher at the applicator's tip and it peripherally decreases by the distance quadrate. The biological mechanisms by which the extracorporeal radial shockwave therapy induces therapeutic effects in adipose tissue can make the healing process easier through damaged a vascular tissues rupture, growth factors release stimulation, stem cell recruitment and neovascularization [2].

Four reaction phases are postulated as occurring in the body. In the physical phase, extracellular cavitation, molecules ionization and membrane permeability increase occur. The physical-chemical phase consists of the interaction between the diffused radicals and the biomolecules released by the cells. As a consequence, the chemical phase occurs and it is characterized by intracellular reactions. The biological phase is established if the changes occurring in the chemical phase persists [3]. This phenomenon of the cavitation as a trigger for the lipolysis process was mentioned in the studies of

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Liang et al. [4] and Adatto et al. [5], but greater evidence and better enlightenment of this mechanism are required.

The therapeutic applications of high intensity ultrasound have gained new parameters, being used in the form of cavitational ultrasound – also called ultracavitation – for the treatment of localized adiposity. It is a system of selective action in the adipocytes, without damaging blood micro vessels. This method consists of the generation of vapor bubbles that implode in the interstitial zone of the connective tissue, causing mechanical waves to selectively affect the adipocytes membranes, releasing their stored fat [6].

Ultracavitation studies are still rare and its effects have not been fully elucidated. According to Silva et al. [7] in a descriptive study of 40 ultracavitation patients, the results showed a significant decrease in localized fat. Another study by Meyer et al. [8], using animal as subjects, exhibited prosperous effects on fat reduction after undergoing ultracavitation.

Similar to shock waves, the ultracavitation process and its implication need further investigation; therefore, this study aims to investigate shockwaves as an alternative process or agent for localized adiposity reduction, associated or not to ultracavitation. More effective conservative treatments for localized adiposity are constantly sought by researchers and professionals.

MATERIALS AND METHODS

The study was featured as a blinded and controlled clinical trial, which consists of the effectiveness testing of a treatment. The selection of subjects was made under non-probabilistic convenience and started after approval of the project by the Ethics Committee of the Potiguar University. The primary sample consisted of 50 active volunteers (19 to 35 years old, female), divided into two groups (n=25). The selection had to meet the following criteria: presence of infra-abdominal localized adiposity, comprehension/cognitive ability, preserved local sensitivity and no circulatory alterations. The exclusion criteria were applied to all individuals who did not provide timely execution, who lacked participation in the proposed procedures twice or more, those who did not agree with the proposed procedures, the ones who were not interested in participating in the project or in using anticoagulants. They were treated with four shockwave applications/sessions. The groups were named: shock waves+ultracavitation group (OC+UC) and shock waves group (OC). The choice of ultracavitation as a method to treat localized adiposity is due to the already proven efficiency identified in previous studies [1,7], in which the same equipment was used with the same parameters. After study/sessions conclusion and according to the exclusion criteria, the final sample consisted of 37 volunteers, whose results were compared and analyzed (18 in the OC group and 19 in the OC+UC group). The instruments to collect the data of this research were the Physiotherapeutic Evaluation Protocol of Localized Adiposity (PAFAL), validated by Meyer et al. [8], which addressed the following topics: identification, anamnesis, smoking habit, physical examination, measurements and indicators such as: body weight, height, BMI, skin folds and circumference measurements. A high frequency (7.5 MHz) SamsungTM ultrasonography device, model XG was used for evaluation, as well as a NIKONTM D5000 camera, the Liposonic ultracavitation device, model Meditea, Argentina and the D-actor 200, Storz Medical^{TM}, Switzerland, used for the shockwave treatment.

After selection, the volunteers were guided on the procedures, and signed a consent form (TCLE). Then, they were submitted to an evaluation under the PAFAL Validated Protocol, for the collection of general and anthropometric data. Perimetry was registered by measuring the abdominal circumference, 5 cm below the umbilical scar. The plicometry was performed with a Sanny^{TM} plicometer, which has a measurement range of 0 to 65 mm. The skin fold test was performed three times in the infra-abdominal region, 5 cm below the umbilical scar and the result was based on the mean values obtained in the three measurements.

Posteriorly, the volunteers underwent ultrasound examination in the outlined infra-abdominal region, an area of 10 cm², below the umbilical scar. The ultrasound transducer was used with no pressure to the skin, initially on the alba line and then moving left and right, obtaining two measurements: US1 and US2. The photographs were taken before and after treatment under the same parameters.

The application of the shock waves was made with the subject in dorsal decubitus with the applicator positioned in the same body area where the ultrasound was applied, that is, the infra-abdominal region below the umbilical line. The device settings were: intensity 3.4 bars, 4000 pulses and frequency of 16 Hz. The session time length was approximately 10 min. Ultracavitation was effected in the same area, after shockwave application, in the OC+UC group, using the following device settings: frequency of 3 MHz, intensity of 70%, 21 min application. The treatment consisted of one session per week, totalizing 4 sessions. The OC+UC group also received four ultracavitation applications performed on the same day.

The photos were recorded in orthostatism and frontal/lateral view (right) and the volunteer was asked to perform a 90° shoulder flexion. The used camera was the same in all photos and positioned on a 76 cm tripod placed 80 cm from the volunteer. The photos were forwarded to the evaluators in a text file format (docx). This photogrammetry, suggested by Mendonça et al. [9], has the purpose of analyzing any signs of clinical improvement with “before and after” photos to verify the effects of shockwaves on adipose tissue and to compare “before and after” treatment viewable changes.

Descriptive and inferential statistics were performed through SPSS 20.0 (Statistical Package for the Social Science version 20.0). Data normality was observed using the Kolmogorov-Smirnov (KS) test. For intragroup comparisons, whose data were parametric, the t-paired test was applied. In the analysis between the groups, the t-independent test was applied. The significance level was set at 5% ($p<0.05$). Qualitative data (descriptive analysis of ultrasound images) were based on medical reports [10].

RESULTS

Fifty volunteers were selected. At the end of the study, the results from 37 volunteers were analyzed according to the exclusion criteria, 18 in the OC group and 19 in the OC+UC group. Throughout the research, some volunteers withdrew. The withdrawal occurred in greater quantity when scheduling the last evaluation, compromising the result.

Initially, the **Table 1** refers to the comparison between moment before and final moments.

Table 1. Comparison between the initial and final moments.

	Group	Average ± SD Initial	Average ± SD End	P value
Weight	OC	68.16 ± 10.72	68.83 ± 10.24	0.95
	OC+UC	64.00 ± 8.64	63.24 ± 9.29	0.75
BMI	OC	21.3 ± 2.9	21.07 ± 2.80	0.99
	OC + UC	19.1 ± 1.91	19.92 ± 2.65	0.94
Perimetry	OC	92.80 ± 10.11	92.3± 9.26	0.35
	OC+UC	91.55 ±9.08	89.28 ± 8.46	0.04*
Plicometry	OC	24.05 ± 4.89	21.33 ± 3.25	0.02*
	OC+UC	2.69 ± 0.81	2.34 ± 0.81	0.02*
US1	OC	2.35 ± 0.69	1.93 ± 0.63	0.04*
	OC+UC	21.6 ± 2.30	16.00 ± 2.30	0.001*
US2	OC	2.00 ± 0.80	1.42 ± 0.55	0.03*
	OC+UC	2.40 ± -0.61	2.02 ± 0.74	0.04*

**There was a significant difference between the initial and final moments*

Initially, the comparison between before and end, perimetry OC (p=0.04) and OC+UC (p=0.02), plicometry (p=0.02) and OC+UC (p=0.001) and ultrasound exams US1 OC (p=0.04) and OC+UC (p=0.04). The US2 OC (p=0.03) and OC+UC (0.04).

The comparison between OC+UC and OC groups before intervention was statistically effected regarding weight (p=0.21), BMI (p=0.47), perimetry (p=0.64), plicometry (p=0.70) and ultrasound exams US1 (p=0.95) and US2 (p=0.49) and due to the non-significant results, the groups were found to be homogeneous concerning such parameters.

Table 2 refers to the evaluation comparison after the applications between the OC and OC+UC groups.

It was verified that in the OC group, the results after the intervention were greater in comparison to OC+UC results. The result of the plicometry (p=0.001) in the comparison between groups was substantial. The mean values of weight (p=0.91), BMI (p=0.47), perimetry (p=0.30) and ultrasound exams US1 (p=0.64) and US2 (p=0.35) did not present significant difference. In the OC group, the averages remained larger after the intervention in comparison to the OC+UC group.

However, when analyzing each group separately before and after the intervention, it was noticed that, in the OC group, mean weight increased from 68.16 kg to 68.83 kg and BMI from 20.88 to 21.07, besides reduction of the mean perimetry from 92.80 cm to 92.30 cm and plicometry from 22.94 mm to 21.33 mm, increase of thickness of US1 fat layer from 2.29 cm to 2.34 cm and reduction of US2 from 2.08 cm to 2.02 cm in comparison to before and after the intervention. Therefore, there was a statistically significant fluctuation in the weight variables (p=0.03), perimetry (p=0.03) and plicometry (p=0.05). Nevertheless, there was no statistically significant variation in BMI (p=0.22), US 1 (p=0.39) and US 2 (p=0.13).

The OC+UC group, when isolatedly analyzed before and after the intervention, presented a reduction of mean weight from 64.00 kg to 63.24 kg, BMI from 20.14 to 19.92, perimetry from 91 cm to 89.28 cm and plicometry of 21.05 mm to 16 mm. reducing the thickness of the US1 fat layer from 1.95 cm to 1.93 cm and an increase in US2 from 1.40 cm to 1.42 cm in comparison to before and after the intervention. It was verified that there was a statistically significant fluctuation in the variables of weight (p=0.02), perimetry (p=0.007) and plicometry (p=0.0001). However, there was a statistically significant variation in BMI (p=0.21), US1 (p=0.68) and US2 (p=0.81).

Regarding the photogrammetry analysis, each participant received scores varying from 0 to 10, according to the results presented in the photos, attributed by expert evaluators in the area.

Table 2 presents the results of the evaluators on the clinical improvement based on the photos analysis.

Table 2. Comparison between groups after intervention.

	Group	Average ± SD	P value
Weight	OC	68.83 ± 10.24	0.91
	OC+UC	63.24 ± 9.29	
BMI	OC	21.07 ± 2.80	0.47
	OC+UC	19.92 ± 2.65	
Perimetry	OC	92.30 ± 9.26	0.30
	OC+UC	89.28 ± 8.46	
Plicometry	OC	21.33 ± 3.25	0.001*
	OC+UC	16.00 ± 2.30	
US1	OC	2.34 ± 0.81	0.64
	OC+UC	1.93 ± 0.63	
US2	OC	2.02 ± 0.74	0.35
	OC+UC	1.42 ± 0.55	

**There was a significant difference between groups*

In both groups, there was a clinical improvement in localized adiposity after the interventions. Clinical improvement was observed by the evaluators in frontal and lateral views in the OC group, respectively (71.1% frontal and 62.8% lateral) and the OC+UC group (74.4% frontal and 77.8% lateral).

Table 3 presents the average of the evaluators' scores attributed to the observed results.

Table 3. Clinical improvement analysis after interventions in groups OC and OC+UC.

Clinical Improvement	**Front view**			
	Yes		**No**	
	Absolute Frequency	**Relative Frequency**	**Absolute Frequency**	**Relative Frequency**
OC	64	71.1%	26	28.9%
OC+UC	67	74.4%	23	25.6%
Clinical Improvement	**Lateral view**			
	Yes		**No**	
	Absolute Frequency	**Relative Frequency**	**Absolute Frequency**	**Relative Frequency**
OC	56	62.2%	34	37.8%
OC+UC	70	77.8%	20	22.2%

It was verified that both frontal (p=0.04) and lateral views (p=0.03) had the OC+UC group presenting higher mean scores than the group that underwent shock wave intervention only **(Table 4)**.

Table 4. Evaluator's grades attributed to the clinical improvement after the interventions.

	Frontal Grade	Lateral Grade
OC	6.73 ± 2.09	7.56 ± 2.26
OC+UC	7.89 ± 2.12	8.41 ± 2.26
P value	0.04*	0.03*

DISCUSSION

According to Adatto et al. [5], high-impact (focal) planar waves have several effects on the cells and their metabolism; among them it increases the permeability of the cell wall, increases the release of fat and triglycerides, respectively, as well as promotes regeneration of connective tissue. While the radial acoustic waves (low impact), used in this study, have the feature of promoting the increase of blood and lymphatic flow [11].

Nevertheless, other authors affirm that shock waves produce rupture of the adipose membrane through unstable cavitation, since it is a mechanical therapy [3]. According to Liang et al. [4], through the observation of adipose tissue laminae in animals, it was verified that adipose tissue is damaged by two types of mechanism: Compression and cavitation. It is then believed that the effect of the compression pressure causes shape modification with rupture of the adipose cells and that the cavitation effect causes an irregularity and consequently, lipolysis.

Analyzing the OC group, it was noticed that weight gain was significant after treatment, which may have had a negative influence on shockwave results alone. On the other hand, the shockwave group associated with ultracavitation (OC+UC) presented statistically significant reduction of weight, perimetry, plicometry and in the ultrasound examination, therefore, the results more satisfactory than in the OC group. Literature states that the ultracavitation foments the vibration of the adipocyte membrane, thus the microbubbles rupture and as they are close to the adipocytes, they also end up having their membranes fragmented and promoting fat spillage and flow, apart from preserving other tissue structures such as vessels, nerves and especially the lymphatic system, which is essential for triglycerides and diglycerides to be eliminated [1,3,6]. Yet, with the significant influence of the weight reduction presented by the group, it is difficult to consider that the results presented are only due to the association of shock waves with ultracavitation.

Regarding the photogrammetry analysis, the OC+UC group received higher scores and better clinical improvement evaluation compared to the OC group, but despite this significant result, the variable weight reduction may have contributed in this analysis.

Further studies, with greater control of the volunteers of both groups concerning the weight variable are suggested, so that there are no significant variations to interfere in the results, as they make it difficult to analyze the localized physical agent effect. Another suggestion is to increase the treatment period and, the number of applications/sessions, as there are studies with 6 and 8 applications of shockwaves which presented positive results. In the case of this study, the lending period of the shockwave machine was only one month, limited to 04 applications [12].

CONCLUSION

OC group, which performed the treatment using only shockwaves, compared to OC+UC group, which underwent associated treatment (ultracavitation and shockwaves), presented poorer results, showing that the conjunction of ultracavitation with shockwaves is more effective than shockwaves alone for lipolysis effect. Upon plicometry, this difference was statistically significant; in other words, the OC group values were higher after treatment compared to the ones obtained with the OC+UC group.

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