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CRYOLIPOLYSIS WITH PLATE FOR TREATMENT OF LOCALIZED ADIPOSITY

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Abstract

BACKGROUND: Cryolipolysis is a non-invasive method capable of reducing the thickness of the fat layer. **OBJECTIVE:** To evaluate the effects of cryolipolysis with the use of plate applicators in the treatment of abdominal fat in women. **MATERIALS AND METHODS:** The sample was composed of 15 participants, who were evaluated before and at the end of the intervention. Three applications of cryolipolysis were performed in the infraumbilical portion of the abdominal region. The volunteers were divided into three groups G-1 (temperature of -2°C), G-2 (temperature of -3°C) and G3 (temperature of -4°C). **RESULTS:** There was a reduction in plicometry measurements in groups G2 and G3, in the comparison between the initial and final moments ($p < 0.05$), and a reduction in perimetry and ultrasound ($p < 0.05$) in all groups. It was found that the G3 group was subject to higher risk of first degree burns and redness when compared to the other groups. **CONCLUSION:** It is suggested that plate cryolipolysis is a possibly effective resource for reducing adiposity, as shown in the evaluation of perimetry, plicometry, and ultrasound results, and in the photographic analysis.

Keywords: cryolipolysis; localized adiposity; physiotherapy.

INTRODUCTION

Cryolipolysis uses cooling to eliminate localized adiposity and its mechanism of action has been widely discussed in the literature (1, 2). It is suggested that cooling promotes destruction of adipose cell membranes with subsequent apoptosis that results in reduced measurements (3, 4), in addition to hormonal and biochemical adaptations that favour the metabolism of fat reserves (5, 6).

The application of cryolipolysis with a plate system consists of a modality of the cooling technique that uses equipment without the suction system, which does not use negative pressure and only the contact of the applicators. Initially, this equipment was indicated for application on body regions of difficult coupling (4, 5). Subsequently, the use of this equipment began to be indicated in the treatment of regions such as: abdominal, chest, and painful regions. It aims to provide greater safety regarding application methods, since among its objectives, it proposes to reduce the risk of burns and of skin problems on the application area (7, 8).

Different studies have already demonstrated the adiposity reduction response when using this system, as verified through anthropometric measurements, ultrasound, and photographs (9, 10). In a sample of 40 patients, it was verified that an application time of 1 hour and 20 min, with a temperature of -5°C, promoted a reduction of adiposity in the outer thighs saddlebags region as determined through

ultrasound and photographs (11). Friedmann et al (7), used flat applicators in the infraumbilical region and verified the reduction of adiposity by observations using ultrasound, as well as through satisfaction questionnaires. These results were more significant after two applications, with a response similar to the analysis of this study. Cooling, therefore, activates the fat cell destruction mechanism, favouring the reduction of measurements (12). Based on these fundamentals, this study sought to investigate the effects of plate cryolipolysis in the treatment of localized adiposity.

MATERIALS AND METHODS

This is an experimental, controlled, and randomized study. The study sample was a non-probabilistic convenience sample composed of 15 women with localized abdominal adiposity. The study was carried out at the Kinephy-Argentina Clinic, located in the autonomous city of Marcos Juárez, Argentina. The study was approved by the Research Ethics Committee of Universidade Potiguar, UnP, following resolution 466/12, under opinion Nº. 3,548,979, in compliance with the standards established by the Declaration of Helsinki. All women who chose to participate in the research signed the Free and Informed Consent Form (ICF).

The inclusion criteria used for the study were: women aged 20 to 50 years old, weighing between 50 kg and 85 kg, who had localized abdominal adiposity, be it multiparous or nulliparous, who maintained the capacity for understanding and preserved local sensitivity, whether or not they use contraceptives, or were sedentary. The exclusion criteria were: women who were pregnant or in the postpartum period, with diabetes or metabolic changes, scars or wounds in the region to be treated, patients with previous allergy to cold, peripheral circulatory diseases and Raynaud's syndrome. Participants who did not agree with the procedures, presented sensitivity disorder during therapy, or who did not adapt to the times and procedures were removed from the research.

The instruments used for data collection in this research were an evaluation form, which addressed the following topics: identification, anamnesis, smoking, physical examination, measurements, and tests such as weight, height, BMI, skin folds, and circumference measures.

For measurements and evaluation, we used: a Fiber™ measuring tape, Sanny™ plicometer, Glicomed™ scale, NikonD500™ camera, Techline™ infrared thermometer, high frequency ultrasonography (12 MHz) model XG, Samsung™ brand, and a fat tissue analysis and measurement device. Treatment was performed using the Meditea™ cryolipolysis equipment.

After being selected, all the participants were submitted to evaluation, during which general evaluation data and anthropometric data were collected. The perimetry was performed using a tape measure, measuring the circumference 5 cm below the umbilical scar. Plicometry was performed with a plicometer that has a measurement range from 0 to 65 mm. The skin fold was taken three times in the left infraumbilical region, and the result was based on the average of the values obtained in the three measurements. Weight was also monitored in the evaluation, and subsequently in the reevaluations using a scale.

The photos were recorded in orthostatism in the anterior and lateral view (right and left). The camera used was the same in all the photos, being positioned on a support tripod at a height of 66 cm from the floor and placed at a distance of 55 cm from the participant. This enabled better viewing and standardization of the photos. Subsequently, the participants underwent an ultrasound examination, which was performed by a specialized doctor. The examination was performed in the infraumbilical region, in an area of 10 cm^2, delimited by a mold made of rubber, positioned 2 cm below the umbilical scar.

The application of cryolipolysis was performed in the supine position, with the aid of elastic bands to maintain the contact of the plates with the skin, using the Fryss™ device (Meditea, Argentina). An application time of approximately 40 min was chosen. The selected participants were divided into three groups, each with five participants. In group G1, the temperature parameter used was -2°C, compared with -3°C in group G2 and -4°C in group G3. The applicators were positioned in the same place where the ultrasound was performed, and temperature stability was verified with an infrared thermometer. All groups received three treatment sessions with an interval of 30 d between them. For analysis of the results, a reassessment was performed 28 d after the third session with the repetition of all the aforementioned examinations and photos.

The analyses of the statistical data of this research were done using the Package for the Social Sciences (SPSS) software version 22.0 for Windows. The Kolmogorov-Smirnov (K-S) test was performed to verify the normality of the data. In inferential statistics, the ANOVA test, with Tukey's post hoc, was used to analyze the differences between before and after, and

Table 1. Comparison of the measurements of the variables analyzed before treatment.

Initial	G1 (-2°C)	G2 (-3°C)	G3 (-4°C)	P value
BMI	26.11±3.12	24.12±1.46	25.05±2.53	0.65
Left plicometry (cm)	4.41±1.12	3.50±2.8	5.35±0.61	0.12
Right plicometry (cm)	4.56±1.11	4.42±1.12	4.00±1.8	0.87
Perimetry (cm)	95.60±7.45	92.50±9.1	97.90±11.1	0.16
Ultrasound (cm)	2.98±0.90	2.41±0.44	2.88±0.63	0.18

between groups. Throughout the statistical analysis, a significance level of 5% and a 95% confidence interval (CI) were assigned.

RESULTS

According to the study protocol, after the intervention and evaluation period and the exclusion criteria were applied, five volunteers in G1 group, two in G2 group, and three in G3 group remained in the study.

Table 1 shows the results of the groups and variables in the initial moment, before the interventions. No significant difference was observed between the groups, indicating a similarity of the volunteers before the intervention.

Table 2 shows the results of the comparison after the interventions. We observe that there was a significant difference in the variables.

Figure 1 shows the graphs of the comparison between the groups and the moments (initial, final) of the study.

In the plicometry analysis, we observed that the groups on both sides behaved in a similar way when comparing the initial and final moments. Groups G2 and G3 showed a reduction in the measure on the right side ($p = 0.02$ and 0.01, respectively) and on the left side (respectively, $p = 0.03$ and $p = 0.01$). In the ultrasound analysis, we observed that all groups showed a significant reduction, ($p = 0.02$, 0.001 and 0.01 for G1, G2 and G3, respectively). And in the perimetry analysis, all groups showed a reduction ($p = 0.01$, 0.02 and 0.01 in G1, G2 and G3 respectively).

DISCUSSION

In the analysis of anthropometric measurements, there was no variation in BMI among the groups studied, in any comparison, showing that weight distribution was maintained.

The reduction in measurements appeared in the analyses of plicometry, perimetry, and ultrasound. There was a reduction in measurements in plicometry in groups G2 and G3. In the analysis of the perimetry, a reduction was observed in all groups, with a response similar to what was found in the analysis performed through ultrasound. The results observed can be explained by the effect of cooling adipose tissue, which induces the mechanism of cellular apoptosis. This induction promotes the reorganization of the adipose tissue through cryolipolysis, facilitated by local freezing when the cooling plate was applied to the region selected for treatment (6, 13).

It was observed that, despite the different temperatures used in the groups studied, there was no significant difference between the responses of the groups. Therefore, all three

Table 2. Comparison of the measurements of the variables analyzed after treatment.

Final	G1 (-2°C)	G2 (-3°C)	G3 (-4°C)	P value
Left plicometry (cm)	4.34±0.99	3.50±2.8	4.50±0.61	0.03*
Right plicometry (cm)	4.34±1.11	3.00±1.8	4.00±1.8	0.04*
Perimetry (cm)	75.60±7.45	86.50±8.1	93.90±11.1	0.04*
Ultrasound (cm)	2.35±0.40	1.90±0.14	2.53±0.42	0.01*

*Significant statistical difference ($p < 0.05$)

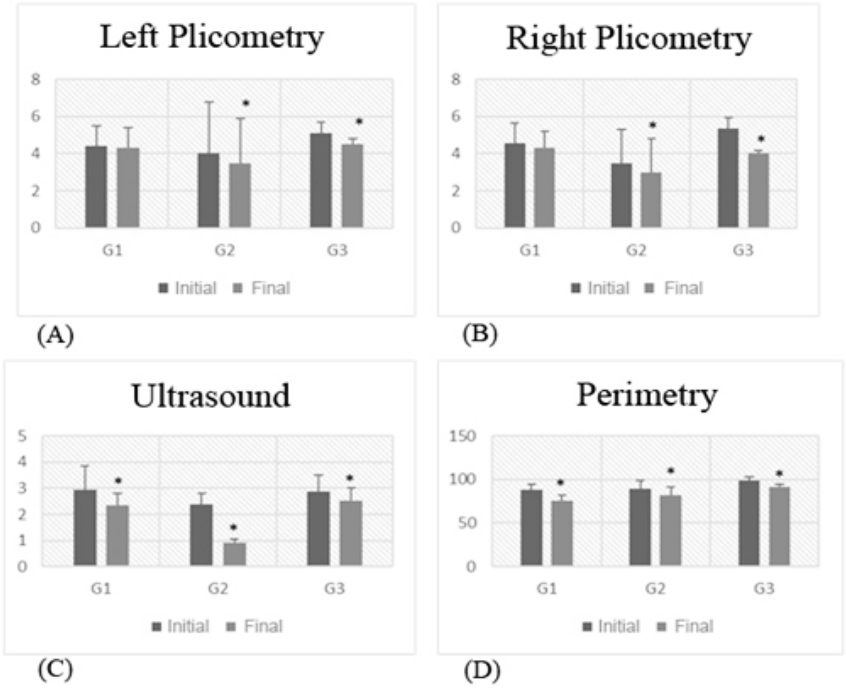

Figure 1. Comparative analysis of plicometry, perimetry and ultrasound variables (cm). *Significant statistical difference ($p < 0.05$).

temperatures (-2°C, -3°C double stacking or -4°C) induce a similar response (14) with the groups showing reduced measurements.

However, temperature change led to the appearance of an inflammatory response in adipose tissue. This may have resulted from the triggering of a mechanism in adipose cells of progressive and continuous disruption of cell membranes, stimulating adipocyte apoptosis, and resulting in reduced measurements (15, 16).

This answer corroborates the findings of Kennedy, et al (2015) (17), who in a systematic review analyzed more than 27 studies on the methods used in the treatment of localized adiposity. Six of these studies used cryolipolysis on a total of about 700 patients. Greater effectiveness was observed in the flank region, after 60 days of intervention. Friedmann et al, (2019) (7), in his study, used flat applicators in the infraumbilical region, where he could see a reduction in adiposity observed through ultrasound. Such results were more significant after two applications, similar to our findings.

In conventional cryolipolysis equipment, the average temperature reduction can reach -15°C. In addition to cooling, the application of the technique is characterized by a suction mechanism in the equipment's applicator. Through a negative pressure, this pulls the subcutaneous tissue into the applicator, intensifying the cooling. According to the literature, despite the suction, no significant damage is observed in the region of the dermis and epidermis, only confirming an increased response in the subcutaneous tissue with this technique (9, 18, 19). However, the application of cryolipolysis with the use of equipment in the form of plates, without the suction system, can minimize complications caused by the presence of the vacuum system, and also facilitates the application in regions of the body that are difficult for equipment-patient coupling (9, 18, 19).

The use of plate cryolipolysis has been applied in clinical practice in the treatment of non- “nailable” areas, such as outer thighs saddlebags, and upper abdomen, with a concentration of fibrotic tissue. However, a reported drawback is exactly the need for longer application times when compared to traditional applicators (9, 13, 17). In a sample of 40 patients, it was verified that an application time of 1 h and 20 min, with a temperature of -5°C, could reduce the adiposity in the outer thighs saddlebags

region, as verified through ultrasound and photographs (7).

In our study, we observed the presence of excessive redness, petechiae in G3 (i.e., cooling was-4°C). As this may increase the risk of burns, it is suggested that only temperatures up to -3°C are used.

Plate cryolipolysis enables the treatment to be applied to localized adiposity. The reduced measurements post-treatment determined here are similar to those seen in other studies that also used plicometry, perimetry and ultrasound. Importantly, the plate cryolipolysis method promotes the reduction of localized adiposity at a temperature that can be used safely and does not promote burns (19, 20).

This study had limitations, such as sample size and sample loss, which makes it difficult to project results. Moreover, future studies should be supported by histological and immunological analysis of the adipose tissue.

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REFERENCES

1. Meyer PF, Silva JDCE, Vasconcellos LS De, Carreiro EDM & Silva RMV Da (2018) *Clin Cosmet Investig Dermatol* **11**, 499–503.
2. Derrick CD, Shridharani SM & Broyles JM (2015) *Aesthetic Surg J* **35(7),** 830–836.
3. Alizadeh Z, Halabchi F, Mazaheri R, Abolhasani M & Tabesh M (2016) *Int J Endocrinol Metab* **14(4)**, e36727.
4. Meyer PF, Furtado ACG, Morais SFT, De Araujo Neto LG, Da Silva RMV, Medeiros ML & de Queiroz CAM (2017) *CryoLetters* **38(5),** 379–86.
5. Lipner SR (2018) *J Cosmet Dermatol* **17(2)**, 145–151.
6. Savacini MB, Bueno DT, Molina ACS, Lopes ACA, Silva CN, Moreira RG, Almeida S, Guidi RM, Sant'Ana E & Liebano RE (2018) *Dermatol Res Pract* 5276528.
7. Friedmann DP (2019) *Dermatol Surg* **45(9)**, 1185–1190.
8. Peterson J & Bruce S (2016) in *Dermatological Cryosurgery and Cryotherapy*, (eds) Abramovits W, Graham G, Har-Shai Y & Strumia R, Springer, London, pp. 193–199.
9. Kilmer SL (2017) *Lasers Surg Med* **49(1)**, 63–68.
10. Ingargiola MJ, Motakef S, Chung MT, Vasconez HC & Sasaki GH (2015) *Plastic Reconstr Surg* **135(6),** 1581–1590.
11. Stevens WG & Bachelor EP (2015) *Aesthet Surg J* **35(1),** 66-71.
12. Putra IB, Jusuf NK & Dewi NK (2019) *Open Access Maced J Med Sci* **7(9)**, 1548-1554.
13. Stevens WG (2016) *Plastic Reconstr Surg* **138(1)**, 153–155.
14. Suh DH, Park JH, Kim BY, Lee SJ, Moon JH & Ryu HJ (2019) *J Cosmet Laser Ther* **21(4)** 238–242.
15. Zelickson B, Egbert BM, Preciado J, Allison J, Springer K, Rhoades RW & Manstein D (2009) *Dermatologic Surg* **35(10)**, 1462–1470.
16. Manstein D, Laubach H, Watanabe K, Farinelli W, Zurakowski D & Anderson RR (2008) *Lasers Surg Med* **40(9)**, 595–604.
17. Kennedy J, Verne S, Griffith R, Falto Aizpurua L & Nouri K (2015) *J Eur Acad Dermatology Venereo* **29(9)**, 1679–1688.
18. Bernstein EF, Bloom JD, Basilavecchio LD, Plugis JM (2014) *Lasers Surg Med* **46(10)**, 731–735.
19. Bertolini SMG, Coelho KC, Fries LMV, Sorti GS & Zorzi YR (2015) *Rev Científica JOPEF* **19(1),** 104-113.
20. Meyer PF, Valentim da Silva RM, Souza FR, Farias SLQ, Vasconcelos LS, Carreiro EM & Borges FS (2020) *CryoLetters* **41 (4)**, 223-229.