CryoLetters **33** (3), 176-180 (2012)
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A STUDY TO EVALUATE THE ACTION OF LIPOCRYOLYSIS

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Abstract

Since ancient times human beings have been conceiving methods that could help reduce the accumulation of undesired fat tissue in their own bodies. Lipocryolysis has already been recognized as an therapy for localized fat reduction by means of a combination of regulated and controlled vacuum and heat extraction therapy. This study was designed to quantify the claimed reduction of local adiposities. For this purpose, 16 treatments were analysed. The data suggested that lipocryolysis is effective for localized reduction of adiposities and that the reduction obtained are measurable.

Keywords: Lipocryolysis, localized adiposities, heat extraction, triglycerides.

INTRODUCTION

Since ancient times human beings have fought to conceive methods that would allow them reduce the accumulation of adipose tissue in undesired places of their own bodies. During the past decades, obesity treatment has experienced great advances, especially in the surgical field. We have witnessed the blossom and development of bariatric surgery, intragastric balloons and gastric banding. All these treatments are invasive methods that require anaesthesia, hospital admission and considerable recovering time. Their effects are, moreover, systemic. On the other hand, advances in techniques directed to localized reduction of adipose tissue accumulation are limited (even less for those with a non-invasive nature).

Recently, the treatment for localized adiposities by means of lipocryolysis has been established (1, 2). The term "lipocryolysis" was used in this therapy, but it can be found indistinctly in literature as cryolipolysis, cryolisis, selective cryolisis. This novel therapy combines vacuum application and heat extraction for localized adiposities reduction (2, 3, 4, 5), being its effectiveness maximum when we treat moderate adiposities (1). It is a technique that does not require anaesthesia and can be performed in an outpatient department.

Available clinical data are few, and these available are the results after application of a treatment session. Our aim in the present study is to analyze short-term results following 1 or 2 consecutive lipocryolysis sessions in localized adiposities, and to establish methodological bases in order to generate future therapeutic protocols. Our hypothesis is that the reduction of localized corporal adiposities is possible by means of a combined, regulated and controlled vacuum together with heat extraction, in a single therapy known as lipocryolysis.

MATERIALS AND METHODS

Before heat extraction in a lipocryolysis procedure, the machine generates vacuum. The vacuum assures the correct placement of the fat tissue inside the treatment unit (2), and a local blood flow reduction with the obvious loss of its heat providing effect (2). The vacuum is required to reduce adipose tissue temperature down to the lipocryolysis therapeutic range (2). Without the vacuum, there is not enough heat extraction.

Once the tissue reaches its treatment position (inside treatment unit), skin gets in contact with two Peltier devices placed one in front the other. Connected to 220V power supply, Lipocryo® is capable of developing 140 mW/cm^2 heat extraction. Lipocryo® machine reduces epidermal temperature at 3.1ºC in less than 4 minutes. When the skin temperature drops and gets close to 3.1ºC, the machine reduces the heat extraction energy. If the temperature drops to 3.0ºC, the energy is interrupted. Once the own skin re-heats up to 3.2ºC the machine re-starts its automatic heat extraction routine by augmenting the energy. Through this on/off control mechanism, Lipocryo® machine manages to keep the epidermis temperature at 3.1ºC throughout the whole therapeutic session (Fig 1 and Fig 2).

Superficial temperature correlates perfectly well with the temperature achieved inside the adipocytes (real therapeutic goal). With the 3.1ºC generated on epidermis during the 25 to 35 minutes that will last any session, an intra-adipocytary temperature below 10.4ºC will always be achieved. At these temperatures adipocyte damage occurs (6). Not only saturated fatty acids inside adipocytes suffer physical changes (crystallization), but also unsaturated fatty acids whose crystallization temperatures are lower. Intra-adipocitary 10.4ºC is the trigger of a not yet fully understood biological message that will unleash an apoptotic stimuli that will finally destroy adipose cells in the incoming days or weeks (1, 2). Other tissues are preserved from this cellular autolytic response (7).

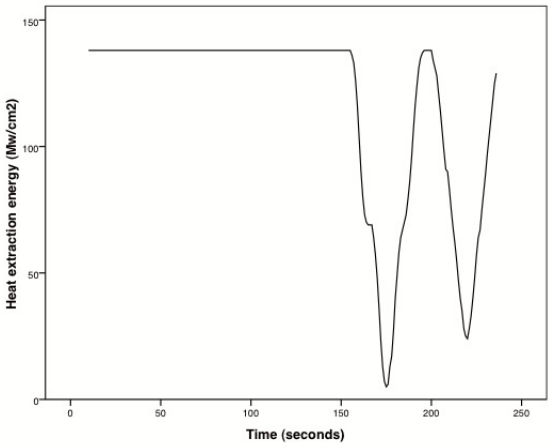

Figure 1. Heat extraction during the first 4 minutes of the session.

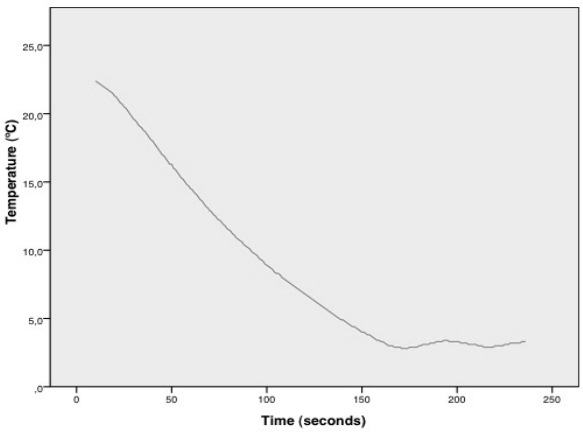

Figure 2. Peltier device-epidermis interface temperature during the first 4 minutes.

Our experimental study is performed on women at the age from 18 to 65 years old, with a body mass index (BMI) between 25 and 30 kg/m^2, with no associated systemic pathologies, not receiving any pre-treatment, non-pregnant or breastfeeding and did not present any of the contraindications for lipocryolysis application (Raynaud's phenomenon, cryoglobulinemia, no cutaneous lesions on the application area, dermatitis, cold urticarial or severe varicose veins). Approval for the study was obtained from all patients by Informed Consent and conforms to the standards set by the Declaration of Helsinki. In the period between 30 days prior and 45 days after the completion of the lipocryolysis session, patients did not follow any other treatment either for localized fat reduction or for reducing body weight.

The assignment of participants in two study groups was performed by randomization (8). Subjects in Group 1 (G1) received a single dose of lipocryolysis, whereas those in Group 2 (G2) had two consecutive sessions of lipocryolysis, with a 45-day interval between them. The application of lipocryolysis was conducted by the Lipocryo® team (Clinipro S.L., Sant Cugat del Vallés, Spain). Each session was divided by application area into two areas: right and left pertrochanteric areas.

To quantify the effect of lipocryolysis, the thickness of skinfolds was measured using a commercial plicometer (Harpenden Skinfold Caliper®). The baseline measurement (M1) was performed 10 days before first therapeutic session. At 40 days of first treatment a new measurement (M2) was performed. Patients in group 2 had a third measurement (M3), at 40 days of second treatment. Analysed variables were: age, weight, height and pertrochanteric adipose skinfold measurement (right and left) both before and after receiving the treatment.

To test the hypothesis of differences in skinfold measurement after application of 1 or 2 sessions of Lipocryolysis, we compared the means of both groups by Student-Fisher t test after verification of the normality assumption of the variable using the Shapiro-Wilks and the Levene test. We performed the Mann-Whitney *U*-test, a non-parametric statistical hypothesis test when these application conditions did not meet. All statistical analyses were carried out by SPSS program for Windows® (Ver 17, SPSS Inc., Chicago, Illinois, USA).

RESULTS

A total of 16 women were evaluated, 8 in G1 and 8 in G2. Mean basal skinfold was 36.0 ± 3.5 mm (mean ± SD) in G1 groups and 36.4 ± 3.0 mm for those women in G2 group, with no significant statistical difference between two groups (p=0.916) (Fig 3). We have registered a decrease in skinfold thickness in the areas where we had applied the lipocryolysis (Fig 4). G1 patients had a final skinfold of 28.2 ± 2.5 mm, whereas the final thickness in G2 patients decreased to 25.9 ± 2.7 mm, a statistically significant difference (p=0.04) (Fig 5). At the end of the treatment, a 19.7 ± 5.9% decrease was observed in G1 and 28.5 ± 7.3% in G2. This was a statistically significant difference (p=0.046) (Fig 6).

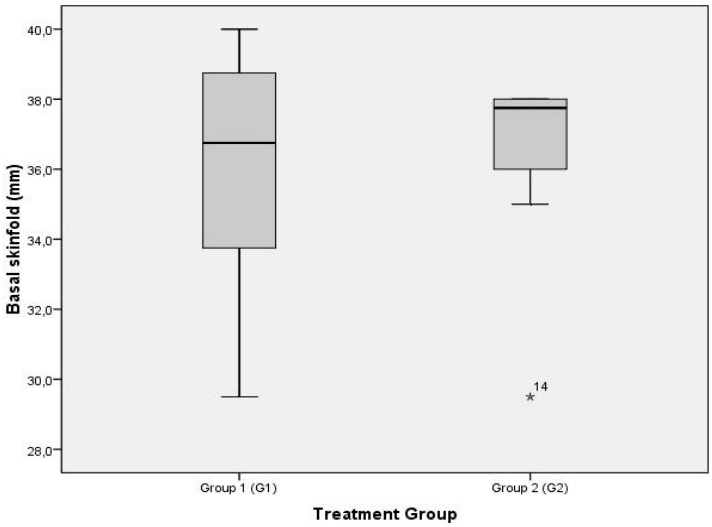

Figure 3. Basal skinfold (mm) of G1 group and G2 group.

If we take under consideration G2 results, mean skinfold was 30.3 ± 2.4 mm after first session and 25.9 ± 2.7 mm after the second session of Lipocryolysis. This implies a 16.5 ± 5.1% reduction after the first session, and 14.5 ± 3.8% after the second session, taking into

consideration skinfold thickness at the beginning of each session. There are no statistically significant differences between these results (p=0.0529).

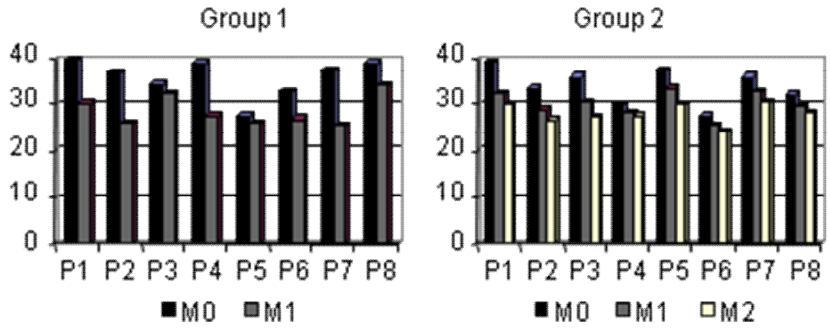

Figure 4. Progress of skinfold (mm) of patients in two patient groups.

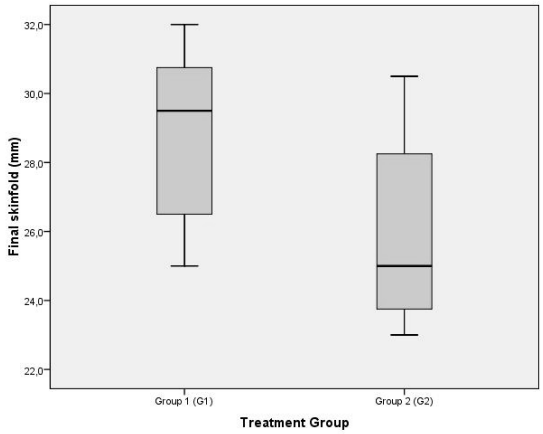

Figure 5. Final skinfold (mm) G1 and G2 groups.

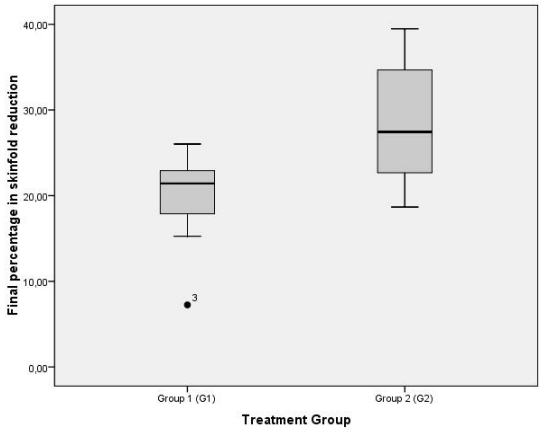

Figure 6. Final percentage of skinfold decrease.

DISCUSSION

Lipocryolysis is a treatment that combines heat extraction with vacuum, and is effective for reducing localised fat. But beyond this, little is known. First unanswered question is how far lipocryolysis can reach (i.e., it's potential). This is a hard question to answer or to be precise, because although we have shown that a second session also produced significant results, it is clear that if we increased the number of sessions systematically, eventually we would get non-significant results from a statistical point of view. Nowadays, very few commercial platforms are able to offer this technology in an efficient way. Moreover, several market attempts at new developments have not reached to offer the minimum technical characteristics to produce the desired therapeutic effect. For all these, therapeutic results (when obtained) vary from one machine to another and are limited mainly by: a) maximum amount of energy for heat extraction available in the market (140 mW/cm^2); b) technological efficiency in the exhaustive control of epidermal temperature, which will allow the optimization of intra-adiposity temperature drop without compromising security; c) capacity of extracting heat from adipose tissue without cooling in excess the overlying skin layers; d) vacuum interruption of blood heat input. In future, probably new technological developments will broaden new horizons within lipocryolysis applicability.

In conclusion, Lipocryolysis is a non-invasive technique effective in localized adiposities treatment. The implantation of a protocol that includes two separate therapeutic sessions of 45 days achieves a greater reduction in skinfolds than a single session treatment. We recorded the same result as a percentage of decrease skinfold after the first and second session of Lipocryolysis, which means that the technique remains effective if done again.

Acknowledgements: We would like to acknowledge Andrea Sallent for her contribution to reviewing the manuscript.

Conflict of interests: Hernán Pinto is an external medical advisor of Clinipro, S.L.

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Accepted for publication 13/2/2012