

TREATMENT OF BODY LOCALIZED ADIPOSITY BY USING CRYOLIPOLYSIS AND CARBOXYTHERAPY ASSOCIATED WITH A KETOGENIC DIET REGIMEN

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Abstract

Localized obesity is the accumulation of adipose tissue, even in small quantities, in a specific area of the body. The use of non-invasive techniques represents a new way to eliminate fat by activating lipolysis and for the remodelling of the body. The current study aimed to evaluate effect of Ketogenic Diet (KD), cryolipolysis and carboxytherapy (CDT) for localized adiposities. Ketogenic diet had a significant effect on body weight.

Keywords: *Localized obesity, Ketogenic Diet, Cryolipolysis, Carboxytherapy.*

Introduction

The ketogenic diet is a nutritional regimen characterized by a reduction in carbohydrates and a relative increase in protein and fat. Carbohydrates are the primary source of energy production, when the availability is low, the body enters a catabolic state with different metabolic processes as gluconeogenesis and ketogenesis as energy source to brain cells, having effects on seizure control (1). A role in blocking the onset of seizures is however due to medium-chain fatty acids (ketogenic diet of medium-chain triglycerides) as they directly inhibit the AMPA glutamate receptors, inducing a change in cells energy. KD is a nutritional therapy used successfully and scientifically validated both to combat generalized and localized adiposity (2,3), and to prevent and treat inflammatory and chronic-degenerative diseases. The biochemical mechanisms of the ketogenic diet play an important role in the prevention of neurodegeneration in Alzheimer's disease, cancer proliferation, obesity, cardiovascular disease and insulin resistance in type 2 diabetes (4-7).

Keeping fit and improving the aesthetic appearance is a combination that is today sought after not only by women but also by young and old men. Today well-being and beauty represent something new to which everyone is striving. However, many patients are reluctant to undergo surgery and prefer conservative treatment options. The ketogenic diet helps aesthetic medicine, increasing the result obtained with treatments alone, helping to achieve physical as well as emotional improvements. The ketogenic diet represents a therapeutic potential to strengthen routine aesthetic interventions, decreasing their invasiveness. Cryolipolysis is a new technology that uses cold exposure, or energy extraction, to result in localized panniculitis and modulation of fat and is a noninvasive treatment option that may be of benefit in the treatment of excess adipose tissue (8-10). Carbon dioxide therapy, better known as carboxytherapy, relates to percutaneous infusion of medical carbon dioxide with therapeutic approaches, and its use in the treatment of localized fat has demonstrated good results (11-13). The ketogenic diet and medical-aesthetic

treatments, can cooperate, improving results and integrating perfectly (14).

Cryolipolysis

Local adipose tissue (AT) cooling is used to manage obesity and overweight and cryolipolysis is a valid option. Cryolipolysis is a noninvasive technique that involves the application of cooling for localized fat reduction. In recent years, cryolipolysis has been increasingly favored for its limited side effects compared to more invasive methods. The acute local cooling of AT induces adipocyte cell disruption and inflammation that lead to adipocyte cell death, with loss of subcutaneous fat being recorded over a prolonged period of months (8).

Carboxytherapy

Carboxytherapy (CDT, carbon dioxide therapy) was born in the 1930s, in France, as therapeutic approach to skin and vascular disorders. In recent years, the success of carboxytherapy has increased, the technique has improved becoming more effective, safer and less annoying. It is a medical treatment related to carbon dioxide injection in a gas form, into the dermis or subcutaneous tissue for therapeutic purposes. Used as treatment in dermatology, aesthetic medicine (skin aging as an adjuvant antiaging treatment, regenerative and reconstructive), vascular medicine, venous and lymphatic insufficiency, any disorder of microcirculation, ulcers, psoriasis, localized cellulite and adiposity, stretch marks, scars, alopecia, Raynaud's phenomenon, with histologic evidence (15).

Methods

The study started in February and ended in April 2019. We have established the following criteria for patients' determination:

Inclusion criteria: Age between 20 and 75 years. Normal weight with subcutaneous localized fat. Overweight. No diseases associated.

Exclusion criteria: Age not between 20 and 75 years. Patient who undergo to other treatments

(medical and/or surgical) during the study. Surgery of any type within 12 months from the start of the study. No compliance in following the treatment protocol used in the study.

Patients. Ten patients were enrolled in the study. The average age was 42 years, in a range between 21 and 72 years. This study began with a sample of ten candidates and finished with ten.

All subjects signed informed consent forms for the study and one for every single treatment performed. The treatment was performed in the Studio Medico Dr. Tedesco. Patients were excluded if they have had some kind of treatment in the area we were going to treat, if they were pregnant or have had a recent pregnancy (<12 months); if they have had cardiovascular problems, metabolic disorders, respiratory disorders, immunosuppression, kidney and liver failure, and skin lesions at the treatment site; or if they had diabetes mellitus. A classical mechanical scale and a stadiometer (Seca 700 mechanical column scale) were used. The BMI was evaluated by applying the formula $BMI = \text{weight in kilograms} / \text{the square of the height in meters (kg/m}^2\text{)}$. Body subcutaneous fat percentage of each volunteer was measured with Mechanical Plicometer (Model Gima 27320). Abdominal circumferences were recorded at the levels of the upper abdomen (5 cm above the umbilicus), the mid abdomen (at the umbilicus), and the lower abdomen (5 cm below the umbilicus), (Wurst Abdomen Circumference Measurement). All patients received directions about the treatment steps and procedures to be performed. The treatment protocol consisted of eight carboxytherapy treatment sessions with an interval of seven days between sessions (total 8 weeks), cryotherapy in a single session, ketogenic diet and amino acid supplementation for 8 weeks. Throughout the treatment, patients completed a maximum of 8 visits (every 7 days); during the first visit they received dietary instructions, two visits involved a complete physical and anthropometric assessment, while the remaining visits involved control of adherence to the program and evaluation of potential side effects. In all patients a high compliance was registered.

Dietary Intervention and Assessment

The recommendations for daily nutrient intake were met during the entire study time. The participants met a study dietician every week to verify food intake and adherence to administered dietary intervention. During group meetings, the diet regimen was given to subjects with encouragement and instructions for the use of dietary supplements. Treatment efficacy was assessed at baseline (T₀) and after 8 weeks (T₁)

Diet recommendations for psoriasis patients included the consumption of a very-low-calorie (<500 kcal/day) protein-based diet providing 10–20 g of carbohydrates (from vegetables, 400–500 g/day), 20–30 g of lipids, and 1.4 g per kg of ideal body weight (calculated using Lorentz's equation) of protein per day. Half of this protein dosage is sufficient to supply 12 g of 90% whey protein, with the addition of L-arginine, α -ketoglutarate, L-ornithine, L-carnitine, L-glutamine, taurine, L-citrulline, L-cysteine, and vitamin B6. Other dietary supplements were alkalizing substances (calcium carbonate, magnesium citrate, potassium bicarbonate, potassium citrate, and sodium bicarbonate) and herbal remedies (with diuretic, anti-inflammatory, hepatoprotective, and antioxidant activities), such as garcinia (*Garcinia cambogia*), hawthorn (*Crataegus oxyacantha*), java tea (*Orthosiphon stamineus*), dandelion (*Taraxacum officinale*), thistle fruit extract (*Silybum marianum*), a multivitamin (C, D, K, and A)/multimineral supplement, and 10 g of hydrolyzed collagen powder (16-18). All treatments with hypoglycemic agents and diuretics were interrupted.

Cryolipolysis session

Cryolipolysis was performed in a single session, for 50 minutes, with vacuum at 50 mmHg and high-frequency micro currents. During the cryolipolysis procedure the sophisticated applicators are located in the areas to be treated, adapting to tissue texture and body contour, and thanks to the simultaneous action of the active and continuous vacuum suction (45-50 cmHg) they are able to reach -10°C. After analysis of the area and consultation, four points were

selected for cryo applicators (Figure 1). The procedure is under continuous temperature monitoring. A temperature sensor in contact with the applicator's plate allows to monitor the safety and the efficacy of the procedure. The temperature sensor dynamically controls plate's cooling keeping the temperature stable at -10°C .

The applicator utilizes constant flow of vacuum to hold in place, (Vacupulse) between two plates and the targeted area of fat. The constant tissue mobilization eliminates the risk of frostbites which frequently occur when performing similar procedures.

The ergonomic applicator ensures optimum coupling with the skin and a high level of thermal insulation, so it is possible to selectively hit only the fat cells of this area. After treatment the fat cells go into apoptosis. At this stage, the body reacts with an inflammatory response which causes the elimination of damaged fat cells through macrophages. In the same handpieces are inserted cycles of excitomotor currents (Coolfrequency 20%-50%), a sequence of electrical frequencies generate tissue micro-contraction tightening the skin, generating tissue microcontractions in the absence of heat, preserving skin vascularization (TissueActive).

The procedure allows a significant improvement in the texture of the treated area. The intensity of the biostimulant impulses is regulated by the physician in accordance with the patient tolerance, and gradually increased to guarantee maximum efficacy and comfort (19-22).

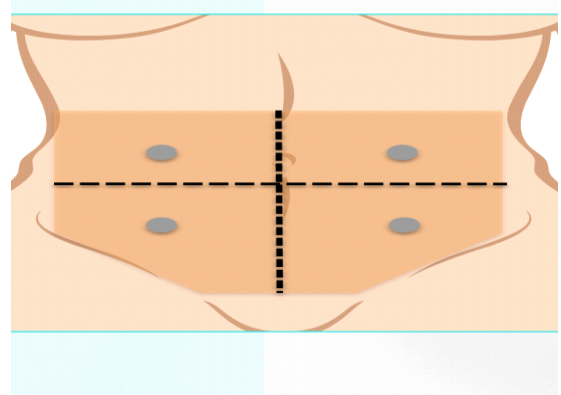
Figure 1



Carboxytherapy

After analysis of the area, four points were selected for the infusion of CO_2 (in the abdomen area) as shown in Figure 2.

Figure 2.



The treated area was inspected and constantly monitored during all session. The antisepsis was performed with alcoholic chlorhexidine at 0.5%. Carbon dioxide was infused into affected areas using the Carbomed Carboxytherapy apparatus and 30gauge, 13 mm microlance needles at a 90° angle, using lipolytic effects, with a controlled flow rate of 100 mL/min. So the depth of infusion was 13 mm and the total of CO_2 infused was 1000 ml for the abdomen over a 10 min period of time. In the same session we practiced injections of carbon dioxide (CO_2) with a 45° angle injection, flow of 15-20 cc/min, with temperature of $38-42$ centigrade degrees, for 5-15 cc-per-area in order to improve the quality of the skin. (Figure 3), (23-27).

Figure 3

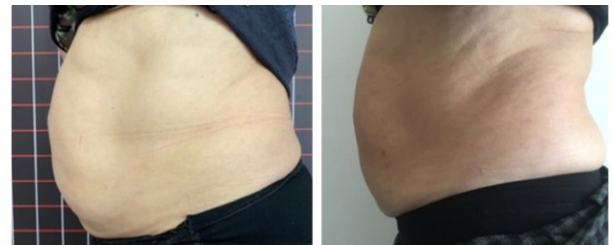
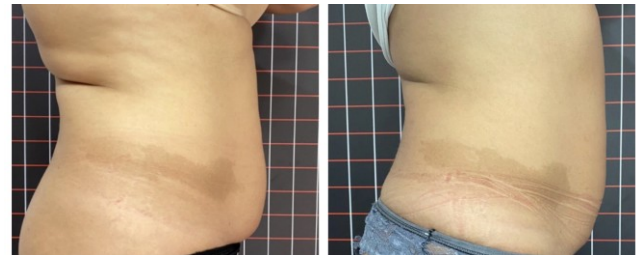
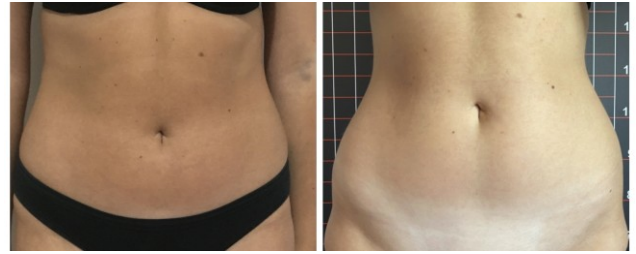
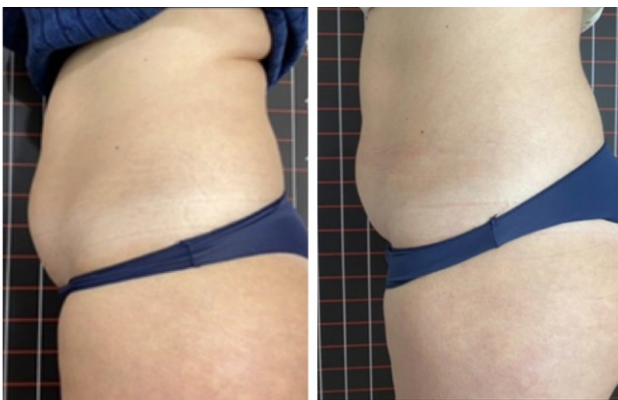


Analysis: We have performed a comparative analysis of the body weight data and the abdominal circumference data in the two different times of the study, T₀- T₁ (Time 0 at the beginning, Time 1 after 60 days treatment).

Results

In the analysis of the images, reduction of adipose tissue and morphological improvement of skin quality was verified. Comparative photographic register of the aspect of abdomen (Figures 4-8).

Figures 4-8



There were significant changes in anthropometric measures and weight, at baseline and after the treatment (Table 1).

Discussion

The evaluations were performed before the first treatment, at baseline, and 60 days after the cryo treatment session. The total time between the baseline and the post treatment evaluation was ~2 months. Weight, abdominal circumference measurements and standardized digital photographs were compared. All patients were photographed in standing positions in three views: rear view, right side, and left side. In assessing weight and height, the patients wore only underwear without shoes.

No Side Effects and Complications were reported. During carboxytherapy session, pain at the injection site as well as crepitus and minor aches, which did not last more than 30 min, and some needle-entry bruises were referred. (Figure 9).

Figure 9



Cryolipolysis side effects, are mild and temporary, such as erythema, hematoma, sensibility alteration, and pain. The elimination of the “ice block,” (Figure 10), effect in the treated tissue area resolved within one week, after the procedure, restoring skin’s elasticity and tissue trophism. Erythema is caused by vacuum pressure and skin exposure to cold temperature, but there was no significant threat for patients. Immediate return to normal daily activities, with no discomfort.

Figure 10



The results obtained after a 8 weeks lasting treatment, certainly show a synergy between the various treatments carried out. Ketogenic diet, carboxytherapy and cryolipolysis are an effective association of treatment of local fat of healthy patients.

The highest percentage of the performance on body weight is actually attributed to ketogenic diet.

This protocol is a procedure free of side effects or important complications and can be used, in selected cases, as a substitute for liposuction and in aid of not perfectly successful liposuction. The synergy of techniques is currently one of the best non-invasive treatments of localized fat and the high tolerability and almost no side effects encourages us to experiment with new combined protocols to optimize results.

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Table 1. Comparative register of the aspect of patients at baseline (To) and 60 days after cryolipolysis session and ketogenic diet.

SEX	AGE	WEIGHT AT BASELINE	HEIGHT	DAILY PROTEIN	(To)	T60	TARGET WEIGHT
F	42	122 kg	160 cm	120 g	135-140-155	118-124-138	99 kg
F	72	63 kg	155 cm	68 g	103-100-105	92-88-96	54 kg
F	32	99 kg	170 cm	108 g	104-105-109	86-95-98	82 kg
F	44	59 kg	166 cm	65 g	84-93-99	77-83-85	51 kg
F	21	66 kg	168 cm	71 g	84-95-103	71-77-93	56 kg
M	42	95 kg	180 cm	123 g	110-112-107	96-100-94	80 kg
M	43	101	185 cm	138 g	92-97-104	79-84-92	91 kg
M	40	117 kg	180 cm	150 g	128-117-110	113-104-96	103 kg
M	33	89 kg	183 cm	120 g	89-98-106	79-90-97	78 kg
M	52	93 kg	180 cm	128 g	111-119-104	101-108-94	84 kg