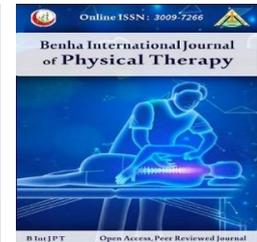


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Original research

Effect of cryolipolysis on localized adiposity in postnatal women: a randomized controlled trial.

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Abstract

Background: Clinical obesity is common worldwide. Women often have increased adiposity and weight postnatally. This increases the risk of obesity, which contributes to metabolic and cardiovascular diseases. Cryolipolysis can effectively reduce this adiposity in a noninvasive and safe way, but it needs more research. **Purpose:** To determine the effect of cryolipolysis on postnatal obesity. **Methods:** This randomized controlled trial included 60 primipara women with postnatal obesity. Their ages were between 25 and 35 years, while their BMI was between 30 and 35 kg/m². Participants were selected from a care clinic in Cairo, Egypt. Participants were randomly distributed into two equal groups: Group A (study) received cryolipolysis and a diet with low calories, while Group B (control) received only a diet with low calories. All women in both groups were assessed by in-body and tape measurements to assess BMI, percentile body fat, and waist height ratio. **Results:** The scores of waist height ratio, BMI, and percentile body fat decreased significantly only in group A. **Conclusion:** Cryolipolysis is an effective method for reducing local adipose tissue in postnatal women.

Keywords: Cryolipolysis, Localized adipose tissue, Obesity, Postnatal.

Introduction

World health organization (WHO) defined overweight and obesity as abnormal or excessive fat accumulation that presents a risk to health. A body mass index (BMI) over 25 is considered overweight, and over 30 is obese.¹

Obesity or overweight increases the risk of cardiovascular diseases as hypertension, musculoskeletal disorders as osteoarthritis, polycystic ovarian syndrome, diabetes mellitus, and some cancers.¹ These diseases lead to large clinical and economic burdens. Obesity reduction

can reduce the negative health effect of these diseases reducing morbidity and mortality.

Obesity (BMI \geq 30 kg/m²) affects about 40% of the population and affects female more than male (about 50% vs. 30%). Its economic burdens will surpass \$4 trillion by 2035 and more than 50% of the global population will be affected within 12 years if prevention, treatment and support do not improve.^{2,3}

Body weight increases postnatal. The higher the natal weight increase, the higher the weight retention postnatal.⁴ Higher weight retention

postnatal is associated with physical inactivity and high-calorie intake causing physiological and biological changes.⁵ This further complicated with the lack of time, energy, and motivation to lose the increased weight by women postnatal.⁶

Cryolipolysis is a conservative way for reducing localized adiposity. It is based upon that adipocytes are sensitive to cold more than others. Cold exposure causes panniculitis and subcutaneous fat damage. This in turn leads to decrease in the subcutaneous fats.^{7,8} As a result, a new non-surgical way for reducing fats with freezing by Manstein and colleagues in 2007 that is cryolipolysis.⁹

A “low caloric diet” is a structured eating plan that reduces caloric intake to 1200–1500 kcal daily (50–60% carbohydrates, 10–20% proteins and < 30% fats), to decrease body weight.^{10,11} Pattern of the meal should be divided into five-six servings throughout the day (three major and two–three minor meals).¹¹

Searching literature (Using Google scholar engine) with keywords (Cryolipolysis AND diet AND postnatal AND obesity) showed there is lack of research about the effect of combining cryolipolysis and diet with low calories in reducing obesity in postnatal women. In support of that, Kream et al.¹² recommended that further clinical trials focusing on the postpartum patient would further help create a standardized approach for postpartum abdominal fat. So, the objective of this trial was to determine the effects of cryolipolysis on localized adiposity in postnatal women.

Methods

This randomized control clinical trial enrolled of 60 females diagnosed with central obesity selected from Care Clinic, Cairo, Egypt. Participants were equally and randomly allocated into group A (study) and group B (control). The study group undertaken cryolipolysis and had diet low in calories and the control group had only diet low in calories.

Patients were included if they were primipara and had age from 25 to 35 years old, BMI from 30 to 35 kg/m², waist circumference >80 cm, and 6 months postnatal. Patients were excluded if they were breastfeeding and had BMI >35 kg/m², cardiac or vascular disease, pacemaker, liver and kidney diseases, or skin disease.

Interventions:

Cryolipolysis: group B received one session weekly of cryolipolysis by “vacuum applicator” for 30 minutes over the umbilical area for 2 months. Participants were positioned in a relaxing supine-lying position during cryolipolysis.

Low caloric diet: patients of both groups were instructed to limit their caloric intake to 1200–1500 kcal daily for 2 months. The composition of the diet (energy) was 50–60% carbohydrates, 10–20% proteins and < 30% fats.

Outcomes:

All participants in groups A and B were assessed by Inbody and tape-measurement to assess BMI, percentile body fat and waist height ratio. Body weight was divided by the square of the body height to calculate BMI. Percentile body fat (PBF) was calculated In Body (230, system h 6 FW_5.53/OS hook). Waist circumference (in cm) was divided by the height (in cm) to get the ratio of Waist to height (WHR).

Statistical analysis:

Assumptions of homogeneity of variance and normality were met as Levene's test and Shapiro-Wilk test respectively were insignificant ($P > 0.05$), so parametric tests were used. The statistical analysis was conducted by using statistical SPSS Package program version 25 for Windows (SPSS, Inc., Chicago, IL). Mixed design 2 (group A&B) x 2 (Pre & post) MANOVA-test was used. P -value was set at ≤ 0.05 .

Results

General patients’ demographic data showed that there were no significant differences between groups in the demographics ($P > 0.05$) (table 1).

Table 1: Demographic data of participants

Items	Groups		P-value
	Group A (n=30)	Group B (n=30)	
Age (year)	29.43 ±3.02	30.50 ±3.74	0.228
Weight (kg)	91.30 ±8.04	90.53 ±13.94	0.879
Height (cm)	161.87 ±4.47	164.00 ±10.05	0.290
BMI (kg/m ²)	34.84 ±1.87	33.66 ±1.87	0.735

Data were expressed as mean± standard deviation
P-value: probability value

Within group comparison:

All studied outcomes significantly improved (P<0.05) at post-treatment within both groups. (Table 2) (Figure 1-3).

Between group comparison:

Groups were comparable at baseline in the studied outcomes (P>0.05). At post-treatment, groups did not differ significantly (P>0.05) in terms of weight, BMI, and percentile body fat. However, group A improved significantly more

than group B in terms of waist circumference and “waist to height ratio” (P<0.05). Moreover, group A who received cryolipolysis with diet program improved higher in weight (8.07%), BMI (8.07%), waist circumference (9.99%), waist to height ratio (11.11%) and percentile body fat (4.51%) than group B who received diet only program (6.11, 6.12, 5.23, 6.25, and 2.74%, respectively) as shown in (Table 2) (Figure 1-3).

Table 2: Within and between group’s comparison for outcome variables

Variables	Items	Groups		Change	P-value
		Group A (n=30)	Group B (n=30)		
Weight (kg)	Pre-treatment	91.30 ±8.04	90.53 ±13.94	0.77	0.879
	Post-treatment	83.93 ±7.11	85.00 ±13.31	1.07	0.651
	Change (MD)	7.37	5.53		
	Improvement %	8.07%	6.11%		
	P-value	0.038*	0.045*		
BMI (kg/m ²)	Pre-treatment	34.84 ±1.87	33.66 ±1.87	1.81	0.735
	Post-treatment	32.03 ±1.75	31.60 ±1.85	0.43	0.906
	Change (MD)	2.81	2.06		
	Improvement %	8.07%	6.12%		
	P-value	0.0001*	0.0001*		
Waist circumference (cm)	Pre-treatment	102.47 ±8.37	105.17 ±10.73	2.70	0.243
	Post-treatment	92.23 ±6.50	99.67 ±9.44	7.44	0.002*
	Change (MD)	10.24	5.50		
	Improvement %	9.99%	5.23%		
	P-value	0.0001*	0.018*		
Waist to height ratio	Pre-treatment	0.63 ±0.05	0.64 ±0.05	0.01	0.477
	Post-treatment	0.56 ±0.03	0.60 ±0.04	0.04	0.002*
	Change (MD)	0.07	0.04		
	Improvement %	11.11%	6.25%		
	P-value	0.0001*	0.006*		
Percentile body fat (%)	Pre-treatment	47.94 ±1.73	47.08 ±2.88	0.86	0.140
	Post-treatment	45.78 ±1.35	45.79 ±2.67	0.01	0.995
	Change (MD)	2.16	1.29		
	Improvement %	4.51%	2.74%		
	P-value	0.0001*	0.027*		

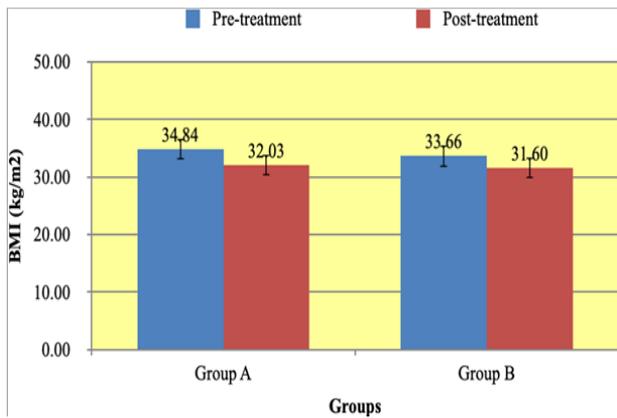


Figure 1: BMI pre and post treatment

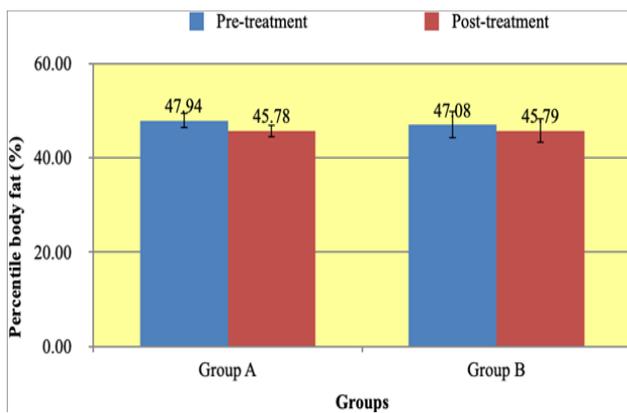


Figure 2: PBF pre and post treatment

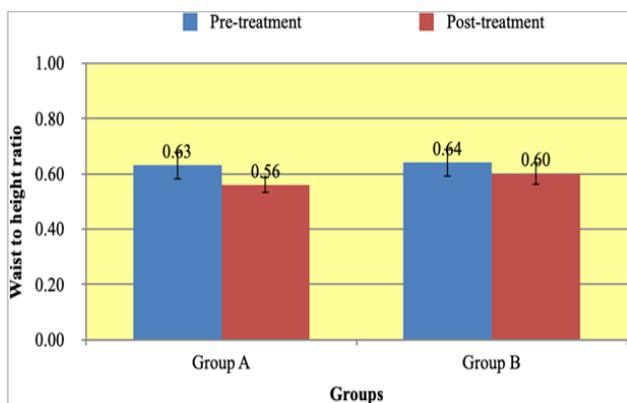


Figure 3: Wht ratio pre and post treatment

Discussion

This study aimed at investigating effects of adding “cryolipolysis” to a diet low in calories on localized adiposity in postnatal women. Results of this study showed that “cryolipolysis” in conjunction with low caloric diet has a positive effect on localized adiposity in postnatal women leads to significant reduction of waist height ratio, BMI, and percentile body fat post treatment.

Findings of the current study are agreed with Mostafa and Elshafey (2016)¹³ who carried out a

study on 45 obese subjects aged 13 to 16 years old divided into group A, B & C who received diet for 2 months. In addition, group A received 60-minute weekly session of cryolipolysis and group B received Laser lipolysis. The group who received cryolipolysis significantly improved in waist-hip ratio, suprailiac skin fold, and subcutaneous adipose tissue.

The present study supports the results of Meyer et al. (2016)¹⁴, who reported that a case of a 46-year-old female patient, with complaint of localized abdominal fat and in the preoperative period of abdominoplasty, was submitted to a single 60-minute application of cryolipolysis (temperature of -5°C, on the hypogastrum area, 5 cm below the umbilicus) led to significant reduction of abdominal adiposity (decreased adipocytes and fat layer).

Also, it agreed with Abdel-Aal et al. (2020)¹⁵, who studied the effects of three cryolipolysis sessions plus low-calorie dietary regimen on thirty central obese women and they concluded that waist circumference reduction is coincided with reduction of abdominal subcutaneous fat.

As well, the current work supports the work of Al-Agamy et al. (2021)¹⁶ who used abdominal cryolipolysis on a group of 30 women with abdominal obesity (30-45 minutes 1 session/3 weeks for 3 months) and cold laser on the other group (30-45 minutes 2 sessions/week) it resulted in decrease of abdominal fats and waist circumference.

Also, it agreed with El Sayed et al. (2023)¹⁷, who studied on forty overweight patients, they were split evenly into two groups; group A (control) were instructed to have a diet low in calories and engage in aerobic exercise, while participants in group B of the trial were given cryolipolysis sessions in combination to the control group's diet; they concluded that patients who underwent cryolipolysis and aerobic exercise with low caloric diet program exhibited considerable improvement in skin fold of abdominal subcutaneous fat and waist-hip ratio.

The results of this work contradicted with the work of Nabil et al. (2022)¹⁸, who studied on 60 subjects with central obesity were divided equally and randomly to 3 groups who received low caloric diet. In addition, group (A) received cavitation and radiofrequency and group (B) received cryolipolysis. They found that adding cryolipolysis (three sessions, one per month) to diet low in

calories has less effect than cavitation and radiofrequency plus diet regimen who had six sessions per 3 months on skinfold, waist circumference, and BMI.

Authors of this study recommend adding cryolipolysis to a low caloric diet to treat obesity in postnatal women. However, low caloric diet can be used alone as it improved all outcomes.

Conclusion

Adding cryolipolysis to low caloric diet effectively reduced BMI, percentile body fat and ratio of waist to height in postnatal women. This can improve the appearance and self-confidence in this population.

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This research did not receive any fund.

Conflict of interest

None

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