

## Effect of Cryolipolysis on Abdominal Anthropometrics in Patient with Cardiovascular Risk: A Randomized Control Trial

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**Abstract:** There was a high prevalence of Atherosclerotic cardiovascular diseases (ASCVD) and overweight among the elderly participants. This study was conducted to investigate the added effect of cryolipolysis on abdominal anthropometrics in patient with cardiovascular risk. Forty patients with cardiovascular risk had been participated in the study. Subjects were recruited from physical therapy department of Al Khanka Hospital. Patients were randomly divided into two equal groups using computerized random sequence generator method: Group (A) (Cryolipolysis plus Exercise) (Experimental group): It was composed of 20 patients who received cryolipolysis in addition to exercise therapy treatment. Group (B) (Exercise only) (Control group): It was composed of 20 patients who received exercise therapy treatment. Abdominal anthropometrics (waist circumference, skin fold thickness, visceral fat intensity) were measured before and after treatment. Results showed statistically significant improvement in both groups with more improvement with cryolipolysis in anthropometric measures with (p-value< 0.05) for waist circumference, skin fold thickness and visceral fat intensity. We can conclude that adding cryolipolysis to aerobic exercise will leads to improve abdominal anthropometrics.

**Key words:** Cryolipolysis • Waist hip ratio • Abdominal obesity • Cardiovascular risk

### INTRODUCTION

The prevalence of CVD and the CVD risk factors in the population might be underestimated in that study because the individuals were invited to attend the health examination and this may result in bias with healthier subjects joining the examination. Future follow-up study and studies in other regions will provide more information about the association of general or abdominal obesity and increased ASCVD events and risk and mortality and also whether better lifestyle can reduce the prevalence of overweight and obesity with educational advice in these elderly individuals [1].

Researchers first started to focus on abdominal obesity in the 1980s when they realized it had an important connection to cardiovascular disease, diabetes and dyslipidemia. Abdominal obesity was more closely

related with metabolic dysfunctions connected with cardiovascular disease than was general obesity. In the late 1980s and early 1990s insightful and powerful imaging techniques were discovered that would further help advance the understanding of the health risks associated with body fat accumulation. Techniques such as computed tomography and magnetic resonance imaging made it possible to categorize mass of adipose tissue located at the abdominal level into intra-abdominal fat and subcutaneous fat [2-5].

Precise application of cold temperatures triggers the death of adipocytes that are subsequently engulfed and digested by macrophages. No changes in subcutaneous fat are noticeable immediately after treatment. An inflammatory process stimulated by apoptosis of adipocytes, as reflected by an influx of inflammatory cells, can be seen within 3 days after treatment and peaks at

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approximately 14 days thereafter as the adipocytes become surrounded by histiocytes, neutrophils, lymphocytes and other mononuclear cells. At 14–30 days after treatment, macrophages and other phagocytes surround, envelope and digest the lipid cells as part of the body's natural response to injury. Four weeks after treatment, the inflammation lessens and the adipocyte volume is decreased. Two to 3 months after treatment, the interlobular septa are distinctly thickened and the inflammatory process further decreases. By this time, the fat volume in the treated area is apparently decreased and the septae account for the majority of the tissue volume [6, 7].

Cryolipolysis is established to be better from physiological point of view, So, the present study will be conducted to investigate the added effect of cryolipolysis on abdominal anthropometrics in patient with cardiovascular risk.

## **MATERIALS AND METHODS**

**Study Design:** Two group pre-test post-test randomized design was used. Patients were randomly be divided into two equal groups using computerized random sequence generator method: Group (A) (Cryolipolysis plus Exercise) (Experimental group): It was composed of 20 patients who received Cryolipolysis in addition to exercise therapy treatment. Group (B) (Exercise only) (Control group): It was composed of 20 patients who received exercise therapy.

**Participant:** Forty patients with cardiovascular risk had been participated in the study. Subjects were recruited from physical therapy department of Al Khanka Hospital. patients chosen with elevated lipid profile- Age will be ranged from 28 to 40 years - Body mass index between 25 and 35 Kg/m<sup>2</sup> - All patients are medically controlled - Waist hip ratio between 105 and 120 cm. weight and height assessed using ordinary scale also abdominal thickness was assessed using fat caliper in addition to using inbody to analyse body composition.

**Randomization:** Patients were randomly divided into two equal groups using computerized random sequence generator method.

**Outcome Measures:** Waist circumference, skin fold thickness and visceral fat intensity.

**Measurement Procedures:** All patients were given a full explanation of the protocol of the study and constant form was signed for each patient before participating in form was signed for each patient before participating in.

**Body Mass Index:** Weight and height scale was used to measure weight and height for each patient to ensure that he fulfill the criteria of being included in the study [8].

**Waist Circumference:** Tape measures are special types of rulers that can be made of metal, cloth, or plastic. They all include linear-measure markings, with many including both imperial and metric units. Imperial measurements are those commonly used in the United States, including feet, pounds and seconds.

**Skin Fold Thickness:** Fat calliper was used in the measurement of skinfold thickness and the estimation of total body fat.

**Visceral Fat Intensity:** The body composition analyser is an instrument used to estimate the amount of a person's body fat. The device delivers a mild, painless current through the body and measures the degree of electrical impedance in bodily tissues. This information can be used to estimate total body water, fat-free body mass and, in turn, body fat.

### **Treatment Procedures**

**Cryolipolysis:** Patients in the study group received Cryolipolysis which is consisted of a vacuum probe with a cable, connecting to the Cryolipolysis device and the patients were covered by anti-freezing membrane and the cryolipolysis was directed to the abdomen. The patients must be positioned in a relaxed position. The output power, working strength and suction setting was constant (output power is 600 W and working strength is adjustable, suction is 5 grades as tolerated by the patient) to be applied for 45-60 minutes at the selected point. Treatment period for Cryolipolysis is 3 sessions one time / month once daily for 3 months. The Patients have to be shaved skin to allow better suction.

**Aerobic Training:** Duration of the session is 40 minutes, the first 5 minutes are for warming up and stretching exercises then 30 minutes on the treadmill then the last 5 minutes for the cool down. Frequency: 3 sessions per week for 3 months, Mode: aerobic exercises in form of

walking on the treadmill. Intensity:65-75% of maximum heart rate HRmax is estimated using the age-predicted equation: MHR = 220 - age.

**Data Analysis Sample Size Calculation:** The walking shoes were well cushioned heel, good arch support, adequate to room and flexible slip-resistant soles. Wearing loose-fitting and layered clothing appropriate for the weather. Use of good posture, look forward (not at the ground) and the chin and head should be up. Walking along a straight line. Pushing off toes, concentrate on Landing on heel, rolling through the step and pushing off with toes. Use the natural spring of calf muscles to propel the body forward.

## RESULTS

Forty male patients with cardiovascular risk participated in this study were classified into two groups (A and B) of equal number.

Table 2: Waist circumference distribution among groups

|         | Pre         | Post        | MD    | % of improvement | P     |
|---------|-------------|-------------|-------|------------------|-------|
| Group A | 108.35±2.91 | 97±3.61     | 11.35 | 10.48%           | 0.000 |
| Group B | 108.95±4.12 | 103.95±3.89 | 5     | 4.59%            | 0.000 |
| MD      | 0.06        | 6.95        |       |                  |       |
| P       | 0.598       | 0.000       |       |                  |       |

Table 3: Skin Fold Thickness data between groups

|         | Pre        | Post       | MD    | % of improvement | P     |
|---------|------------|------------|-------|------------------|-------|
| Group A | 50.45±6.37 | 28.65±4.34 | 21.8  | 43.21%           | 0.000 |
| Group B | 51.95±6.15 | 39.3±7.57  | 12.65 | 24.35%           | 0.000 |
| MD      | 1.5        | 10.65      |       |                  |       |
| P       | 0.453      | 0.000      |       |                  |       |

Table 4: Visceral fat intensity distribution among groups

|         | Pre        | Post       | MD   | % of improvement | P     |
|---------|------------|------------|------|------------------|-------|
| Group A | 16.74±4.88 | 10.97±2.94 | 5.77 | 34.47%           | 0.000 |
| Group B | 17.1±5.22  | 13.91±4.25 | 3.19 | 18.65%           | 0.000 |
| MD      | 0.36       | 2.94       |      |                  |       |
| P       | 0.82       | 0.015      |      |                  |       |

## DISCUSSION

Weight loss in the obese seems to exert several beneficial effects on the CV system, as well as improving glucose metabolism abnormalities especially in the setting of increasing CRF. However, the confounding messages from numerous studies demonstrating the obesity paradox prevent clear guidance on the parameters of weight loss needed to combat an increasing obesity epidemic. Thus,

large randomized trials investigating the effects of intentional weight loss are imperative to determine the measures that are critical to improving clinical outcomes [9].

Obesity without T2DM and overt CV disease and after accounting for CV risk factors, is susceptible to pathophysiological adaptations that may predispose individuals to an increased risk of CV events [10]. The high prevalence and increasing incidence of obesity and associated cardiovascular risk emphasizes the need to focus on obesity reduction in this high risk population [11].

Cryolipolysis is becoming one of the most popular alternatives to liposuction for local reduction of adipose tissue. Due to its ease of use and limited adverse effects, this procedure is becoming the leading technology of noninvasive techniques as well. As cryolipolysis is a considerably novel procedure, treatment protocols still must be ameliorated to maximize results [12]. Cold-induced thermogenesis (“cryothermogenesis”) rather than adipocyte disruption underlies the reduction in AT volume, raising the prospect that more intensive cryotherapy may be a viable option for combating obesity and overweight [13] and this came in agreement with my study and this difference may be due to that they use only one single session of cryolipolysis.

Study was conducted to compare the effect of Cryolipolysis versus Laser lipolysis on adolescent's abdominal adiposity. There was a significant improvement for Cryolipolysis group in waist-hip ratio, Suprailiac skin fold and subcutaneous adipose tissue than other groups P-value (0.001). Cryolipolysis has a favorable effect than Laser lipolysis in the reduction of waist-hip ratio, skin folds at Suprailiac level and subcutaneous adipose tissue (SAT). [14] and these findings came totally in agreement with the findings of these study.

Another study that came in agreement with this study conducted to investigate the quantitative change of cross-sectional areas of abdominal SAT (subcutaneous adipose tissue) and VAT (visceral adipose tissue) following cryolipolysis. And find that single session cryolipolysis demonstrated to reduce visceral adipose tissue as well as waist circumferences tissue for 2 months [15].

The photogrammetry analysis showed that cryolipolysis positively affected subjects' results. A change in body contouring, especially in individuals with lower body mass, reinforces the idea that the parameters must be suitable for individual needs [16]. Both ultrasound cavitation and cryolipolysis are safe and

effective equally for the reduction of abdominal fat thickness and for abdominal contouring [17] and this came in agreement with this study. Cryolipolysis might be proposed as the first treatment choice for Asian patients who opted to do body contouring [18].

A single application of the utilized protocol of cryolipolysis does not produce any significant effect on fat thickness of the lower abdomen of healthy women [19]. And the difference between that study and ours may be due to single application and parameter difference. The effects of exercise training (ET) was investigated on miR-126 levels and skeletal muscle angiogenesis in obese Zucker rats and found that ET normalizes miR-126 levels and VEGF signaling and should be considered an important therapeutic strategy for vascular disorders [20] and that results came in agreement with the current study.

Weight loss might accelerate age-related loss of muscle and bone mass and resultant sarcopenia and osteopenia; weight loss plus combined aerobic and resistance exercise was the most effective in improving functional status of obese older adults [21] which supports the results of the current study. Substantial evidence has established the value of high levels of aerobic exercises, ET and overall CRF in the prevention and treatment of CVD, especially CHD and HF. Although there may be some risk of EEE, which was briefly reviewed, the major threat to health in the 21st century is clearly inadequate levels of PA. there is marked efficacy of ET for all patients and the routine referral of eligible patients with CVD, especially CHD and HF (particularly systolic HF but also HfpEF), to formal CRET programs [22].

Exercise training (ET) has been established as an important treatment for obesity suggesting that ET can prevent weight gain and pathological cardiac hypertrophy via increased of cardiac MED13 by the regulation of miRNA-208a. Therefore, miRNA-208a can be used as potential therapeutic target for metabolic and cardiac disorders [23].

More than 80% of patients with heart failure with preserved ejection fraction (HFPEF), the most common form of heart failure among older persons, are overweight or obese. A study was conducted to determine whether caloric restriction (diet) or aerobic exercise training (exercise) improves exercise capacity and QOL in obese older patients with HFPEF and found that Among obese older patients with clinically stable HFPEF, caloric restriction or aerobic exercise training increased peak  $\dot{V}O_2$  and the effects may be additive. Neither intervention had a significant effect on quality of life as

measured by the MLHF Questionnaire [24] and that trial came in disagreement with the current study and this difference may be due to patient criteria as that trial deal with patients with stable heart failure.

Study assessed the combination of aerobic exercise with other modalities to maximize its effect and find that combined resistance and aerobic exercise effectively attenuated metabolic syndrome, sarcopenic obesity and relevant biomarkers in an ethnically diverse sample of sedentary, overweight, or obese survivors of breast cancer suggesting a targeted exercise prescription for improving metabolic syndrome in survivors of breast cancer and support the incorporation of supervised clinical exercise programs into breast cancer treatment and survivorship care plans [25]. And this leads to the same conclusion the current study reach to as adding modalities to aerobic exercise will magnify its effect.

A study conducted to assess the combined effect of cryolipolysis with radiofrequency and ultrasound cavitation on anthropometric indices and found that applying cryolipolysis with RF/USC did not improve the anthropometric indices compared with RF/USC alone, apart from waist circumference [26]. Which came in disagreement with the current trial and this may be due to the difference to which cryolipolysis added

## CONCLUSION

The results obtained from the current study and the discussion that followed it was concluded that: adding cryolipolysis to treatment session will improve anthropometric measures.

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