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RESEARCH ARTICLE

CRYOLIPOLYSIS VERSUS LIPOSUCTION IN ABDOMINAL ADIPOSITY IN FEMALES

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ABSTRACT

Purpose: The current study was conducted to compare between the effects of cryolipolysis and liposuction in abdominal adiposity in females. **Subjects and Methods:** Thirty females suffering from localized fat deposits at the abdominal area were involved in the study. Their Body Mass Index(BMI) between 30 kg\m2 -34.9 kg\m2.Participants age was ranged from 30-40 years. They were classified randomly and equally into two groups **Group I:** This group was composed of fifteen female suffering from localized fat deposits at the abdominal area. They were received cryolipolysis program for three months one session every two weeks plus aerobic exercise training three times/week for six month. **Group II**: This group was composed of fifteen female suffering from localized fat deposits at the abdominal area. They had liposuction for the treatment of abdominal adiposity The study was started from the 2nd week after the operation they were received aerobic exercise training three times/week for six months. Both groups were received the same dietary regime. **Results:** Group I, II showed significant reduction in body weight, BMI, skin fold, and waist circumferences but there was no significant differences between both groups. **Conclusion:** cryolipolysis plus aerobic exercise training showing the same effect of liposuction plus aerobic exercise training in the treatment of abdominal adiposity in females.

INTRODUCTION

Obesity is the most common metabolic disorder in humans. There are many etiological causes for obesity. Obesity is the Excess fat accumulation caused by imbalance between energy intake and expenditure (Sweeting, 2007). Obesity is an important risk factor for cardiometabolic diseases, including diabetes, hypertension, dyslipidemia, and coronary heart disease (CHD). Body fat distribution is also an important risk factor for obesity-related diseases. Excess abdominal fat (also known as central or upper-body fat) is associated with an increased risk of cardiometabolic disease (Samuel *et al.* 2012). Obesity is an increasingly significant health problem. Over 4 decades, the prevalence of obesity (BMI≥30 Kg/m2) has increased from 13% to 31% in adults, concurrent increases occurred in adolescents and children. Obesity is especially common in developed countries (Bray, 2004). Abdominal obesity is known as belly fat or clinically as central obesity, it is the accumulation of abdominal fat resulting in an increase in waist size. There is a strong correlation between central obesity and cardiovascular disease (McTigo *et al.* 2003). Central obesity, also known as abdominal obesity, refers to an excess fat deposit around and within the abdominal cavity. Central obesity has been linked to hypercholesterolemia, high blood pressure, type 2 diabetes, coronary artery disease, and other health concerns (Nigel *et al.* 2018).

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The most widely used index of obesity is the body mass index (BMI) which correlates well with both the direct measures of fatness, morbidity and mortality. Body mass index = weight in Kg/height in m^2 (Flegal *et al.* 2000). Liposuction, also known as lipoplasty ("fat modeling"), liposculpture, suction,lipectomy or simply liposuction ("suction –assisted fat removal") is a cosmetic surgery operation that removes fat from many different sites on the human body. The range of areas affected differs from the abdominal, thighs and buttocks, to the neck, backs of the arms and elsewhere (Mark *et al.* 2006). Moreover, side effects of liposuction are medically minor, although it can be uncomfortable, annoying and even painful such as bruising, swelling, scars, pain and numbness, sometimes persists for a few weeks post-operative, weight gain and limited mobility that will depend on the exact procedure. As with any surgery, there are certain risks beyond the temporary and minor side effect. The surgeon should mention them during a consultation. Careful patient selection minimizes their occurrence. This is somewhat increased when treated areas are very large or numerous and alarge amount of fat is removed (Sadick, 2009). Cryolipolysis is a unique non-invasive method for the selective reduction of fat cells 'with controlled, localized cooling. Cryolipolysis results in the death of adipocytes that are subsequently engulfed and digested by macrophages (Mathew, 2009). We describe and define' 'selective cryolysis'' as the intentional destruction of adipose tissue by cooling at temperatures that do not substantially affect adjacent tissues. Potentially, this may be developed into a clinical alternative

treatment for fat removal. Prolonged and controlled local skin cooling can induce selective damage and subsequent loss of subcutaneous fat without damaging the overlying skin. Selective cryolysis warrants further study as a local treatment for removing adipose tissue (Dieter *et al.* 2008).

MATERIALS AND METHODS

Thirty females suffering from localized fat deposits at the abdominalwere selected and recruited randomly from"Agouza Police Hospital "their body mass index was ranged between 30kg/m2 and 34.9kg/m2 and Their ages was ranged from 30 to 40 years old.

Criteria of patient selection: The patients had the following criteria:

(a) Inclusion criteria: Body mass index between 30kg/m2 and 34.9kg/m2 (moderate obesity).Their ages were ranged from 30 to 40 years.

(b)Exclusion criteria: The current study was excluded the following patients:

Patients with previous neurological disorders or previous gastrointestinal disorders which might affect the results. Athlete females Patient with previous abdominal surgery Lactating females Females who had labor in less than two years before beginning of the study Those who had abdominal disorders which might affect the study Patients who had missed two sessions.

The patients were randomly assigned into two equal groups.

Group I: This group was composed of fifteen females suffering from localized fat deposits at the abdominal area. They were received cryolipolysis program for the first 3 months 1 session every 2 weeks plus aerobic exercise training 3 times/week for 6 months.

Group II: This group was composed of fifteen females suffering from localized fat deposits at the abdominal area. They had liposuction for the treatment of abdominal adiposity and the study was started on the 2nd week after the operation plus aerobic exercise training 3 times/week for 6 months. Both groups were received the same dietary regime.Measurements were conducted before starting the treatment as a first record and at the end of 6 months of treatment as second record.

Instrumentations and Materials:

1. Plastic tape measurement to measure: -Abdominal circumferences.
2. Weight and Height scale was used to measure weight and height for detection of BMI (BMI = Weight (kg)/Height m^2)
3. Electronic fat caliper used to determine abdominal skin folds (measured before starting the treatment and at the end of six months of the treatment.).

Therapeutic equipment

I-Cryolipolysis: Cryolipolysis was performed as an outpatient Acoupling gel was applied to the skin surface before placement of the applicator on the treatment area to ensure consistent thermal contact. The applicator was positioned on the skin with the use of moderate vaccum. Treatment with the cold exposure, which includes a predetermined energy extraction rate expressed as a cooling intensity factor (CIF) and duration of up to 60 minutes, was initiated for each two areas. At the conclusion of the treatment time, the system automatically discontinues the cold exposure and the applicator is removed by release of the vaccum Gently massage Each patient was instructed to stay 15 minutes after sessions before leave. The procedure was repeated 1 session every 2 weeks for the first 3 months. Patients were received diet and aerobic exercises from the start of treatment and for 6 months. Patients typically resumed normal activities immediately post treatment.

II-Treadmill: Walking Exercise on the treadmill as the following stages: First stage (warming up): Consisted of 5 minutes warming up in the form of slow walking on the treadmill -Second stage (active stage): Consisted of: fast walking on the treadmill. Duration: 30 minutes *Third stage (cooling down):* Consisted of 5 minutes cooling down in the form of slow walking on the treadmill, At Frequency: 3 sessions per week for 6 month. For the second group (liposuction) the study was started after operation

-Low caloric diet protocol :(for both group): Low calorie, low fat diet, with intake of 1800 kcal of energy per day was described and given for both groups.

Statistical producers:

Descriptive statistics: In this study, the descriptive statistics (the mean and the standard deviation) was calculated for all subjects in all groups of the study to determine the homogeneity of the groups.

Analytical statistics: Student's t-test was used to compare the variables between all groups of the study. Paired t- test was used to compare before and after treatment in the same group. The statistical package for social science (SPSS) was utilized for data analysis and a value of $p \leq 0.05$ was considered statistically significant

RESULTS

Group I, II showed significant reduction in body weight, BMI, skin fold and waist circumferences but there was no significant differences between both groups

1-General Characteristics: The current study was conducted on 30 participants. They were assigned into two equal groups. Group (A) consisted of 15 participants with mean age and height values of 34.46±2.97 years and 159.26±4.06 cm respectively. Group (B) consisted of 15 participants with mean age and height values of 34.66±2.66 years and 159.06±3.84 cm respectively. As indicated by the independent t test, there were no significant differences ($p>0.05$) in the mean values of age and height between both tested groups (Table 1).

Table 1. Physical characteristics of participants in both groups (A&B)

Items	Group A	Group B	Comparison		S
	Mean ± SD	Mean ± SD	t-value	P-value	
Age (years)	34.46±2.97	34.66±2.66	-0.194	0.848	NS
Height (cm)	159.26±4.06	159.06±3.84	0.139	0.891	NS

*SD: standard deviation, P: probability, S: significance, NS: non-significant.

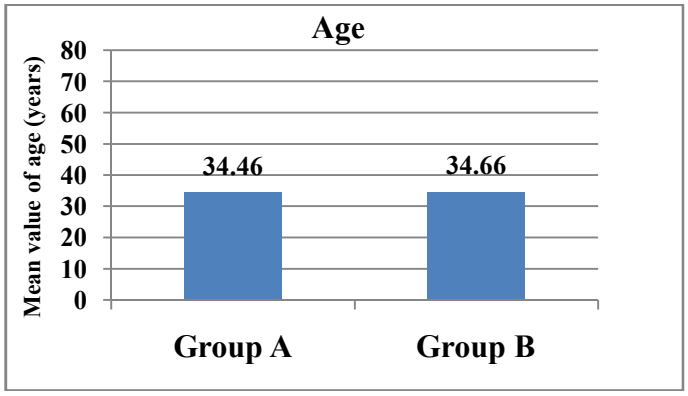

Fig. 1. Mean values of age between both groups.

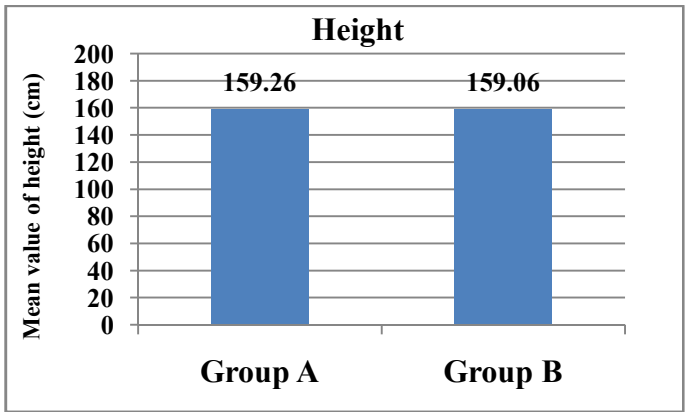

Fig. 2. Mean values of height between both groups.

1. 2× 2 mixed design MANOVA

A.**Overall effect:** Statistical analysis using 2x2 mixed design MANOVA indicated that there were no significant effects of the tested group (the first independent variable) on the all tested dependent variables; weight, BMI, waist circumference and skin fold (F=0.822, P=0.524). However, there were significant effects of the measuring periods (the second independent variable) on the tested dependent variables (F=392.828, P=0.0001*). However, the interaction between the two independent variables was not significant, which indicates that the effect of the tested group (first independent variable) on the dependant variables was not influenced by the measuring periods (second independent variable) (F=0.07, P=0.991) (Table 2).

Table 5. The 2x2 mixed design Multivariate Analysis of Variance (MANOVA) for all dependent variables at different measuring periods between both groups

Source of Variation	F-value	P-value
Groups	0.822	0.524
Measuring periods	392.828	0.0001*
Interaction	0.07	0.991

*Significant at alpha level <0.05.

1. Weight:

1-Within groups: As presented in Table (3) and illustrated in Figure (3), within group's comparison the mean ± SD values of Weight in the "pre" and "post" tests were 82.4±4.06 and 70.13±4.7 respectively in the group (A). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Weight at post treatment in compare to pre-treatment (P-value =0.0001*). While, the mean ± SD values of Weight in the "pre" and "post" tests were 80.86 ±3.24 and 68.73±4.36 respectively the group (B). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Weight at post treatment in compare to pre-treatment (P-value =0.0001*).

2- Between groups: Considering the effect of the tested group (first independent variable) on Weight, Multiple pairwise comparison tests (Post hoc tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with (P=0.264). As well as, multiple pairwise comparison tests (Post hoc tests) revealed that there was no significant difference of the mean values of the "post" test between both groups with (p=0.405).

Table 3. Mean ±SD and p values of Weight pre and post-test at both groups

Weight (Kg)	Pre test	Post test	MD	% of change	p- value
	Mean± SD	Mean± SD			
Group A	82.4±4.06	70.13±4.7	12.27	14.89	0.0001*
Group B	80.86 ±3.24	68.73±4.36	12.13	15	0.0001*
MD	1.54	1.4			
p- value	0.264	0.405			

*Significant level is set at alpha level <0.05; SD: standard deviation; MD: Mean difference; p-value: probability value

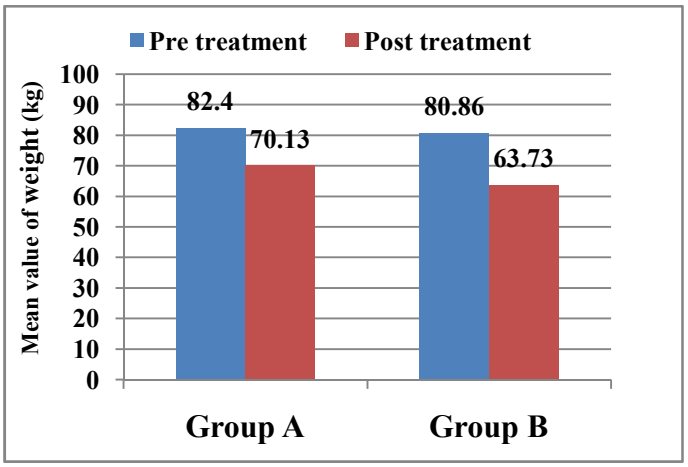

Fig. 3 Mean values of weight pre and post tests in both groups

2. BMI:

1-Within groups: As presented in Table (4) and illustrated in Figure (4), within group's comparison the mean ± SD values of BMI in the "pre" and "post" tests were 32.49±1.29 and 27.63 ±1.37 respectively in the group (A). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of BMI at post treatment in compare to pre-treatment (P-value =0.0001*). While, the mean ± SD values of BMI in the "pre" and "post" tests were 31.96 ±0.83 and 27.17±1.76 respectively the group (B). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of BMI at post treatment in compare to pre-treatment (P-value =0.0001*).

2- Between groups: Considering the effect of the tested group (first independent variable) on BMI, Multiple pairwise comparison tests (Post hoc tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with (P=0.129). As well as, multiple pairwise comparison tests (Post hoc tests) revealed that there was no significant difference of the mean values of the "post" test between both groups with (p=0.434).

Table 4. Mean ±SD and p values of BMI pre and post-test at both groups

BMI (Kg/m^2)	Pre test	Post test	MD	% of change	p- value
	Mean± SD	Mean± SD			
Group A	32.49±1.29	27.63 ±1.37	4.86	14.95	0.0001*
Group B	31.96 ±0.83	27.17±1.76	4.79	14.98	0.0001*
MD	0.53	0.46			
p- value	0.129	0.434			

*Significant level is set at alpha level <0.05; SD: standard deviation; MD: Mean difference; p-value: probability value

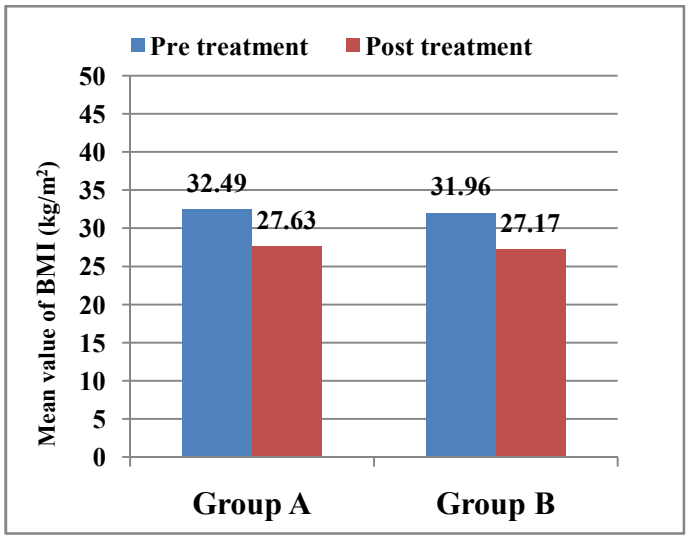

Fig. 4. Mean values of BMI pre and post tests in both groups

3. *Waist circumference*:

1-Within groups: As presented in Table (5) and illustrated in Figure (5), within group's comparison the mean ± SD values of Waist circumference in the "pre" and "post" tests were 101.86±7.36 and 83.4±3.26 respectively in the group (A). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Waist circumference at post treatment in compare to pre-treatment (P-value =0.0001*). While, the mean ± SD values of Waist circumference in the "pre" and "post" tests were 100.73 ±2.63 and 82.86±3.35 respectively the group (B). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Waist circumference at post treatment in compare to pre-treatment (P-value =0.0001*).

2- Between groups: Considering the effect of the tested group (first independent variable) on Waist circumference, Multiple pairwise comparison tests (Post hoc tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with (P=0.579). As well as, multiple pairwise comparison tests (Post hoc tests) revealed that there was no significant difference of the mean values of the "post" test between both groups with (p=0.663).

Table 5. Mean ±SD and p values of Waist circumference pre and post-test at both groups

Waist circumference (cm)	Pre test	Post test	MD	% of change	p- value
	Mean± SD	Mean± SD			
Group A	101.86±7.36	83.4±3.26	18.46	18.12	0.0001*
Group B	100.73 ±2.63	82.86±3.35	17.87	17.74	0.0001*
MD	1.13	0.54			
p- value	0.579	0.663			

*Significant level is set at alpha level <0.05; SD: standard deviation; MD: Mean difference; p-value: probability value

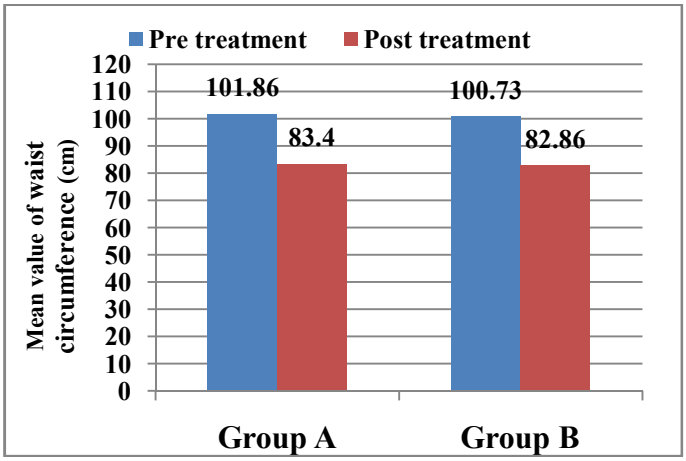

Fig. 5. Mean values of waist circumference pre and post tests in both groups

4. *Skin fold*:

1-Within groups: As presented in Table (6) and illustrated in Figure (6), within group's comparison the mean ± SD values of Skin fold in the "pre" and "post" tests were 51.4±2.64 and 36.33 ±3.52 respectively in the group (A). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Skin fold at post treatment in compare to pre-treatment (P-value =0.0001*). While, the mean ± SD values of Skin fold in the "pre" and "post" tests were 52.13 ±3.44 and 37±3.33 respectively the group (B). Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of Skin fold at post treatment in compare to pre-treatment (P-value =0.0001*).

2- Between groups: Considering the effect of the tested group (first independent variable) on Skin fold, Multiple pairwise comparison tests (Post hoc tests) revealed that the mean values of the "pre" test between both groups showed no significant differences with (P=0.518). As well as, multiple pairwise comparison tests (Post hoc tests) revealed that there was no significant difference of the mean values of the "post" test between both groups with (p=0.59).

Table 6. Mean ±SD and p values of Skin fold pre and post-test at both groups

Skin fold (mm)	Pre test	Post test	MD	% of change	p- value
	Mean± SD	Mean± SD			
Group A	51.4±2.64	36.33 ±3.52	15.07	29.31	0.0001*
Group B	52.13 ±3.44	37±3.33	15.13	29.02	0.0001*
MD	-0.73	-0.67			
p- value	0.518	0.59			

*Significant level is set at alpha level <0.05; SD: standard deviation; MD: Mean difference; p-value: probability value

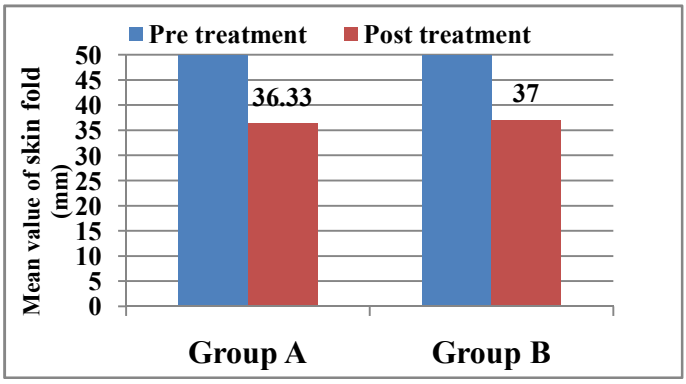

Fig. 6. Mean values of skin fold pre and post tests in both groups

DISCUSSION

The measurements in this study included: body weight, body mass index (BMI), waiste circumference and skin fold. A comparison was made between the two groups on these parameters.

So the results of this study showed clearly that:

- Treatment by cryolipolysis has a significant positive effects on the abdominal adiposity in females. Treatment by liposuction has appositive effects on the abdominal adiposity in females. There are no significant difference between cryolipolysis and liposuction effects in the treatment of abdominal adiposity in females.
- In agreement with the results of this study. Mathew *et al.* (2009) fond that Cryolipolysis has demonstrated efficacy in both human and animal studies. Histology findings also confirm the selective reduction of fat in both humans and animals, with evidence of a gradual thinning of the fat layer over a period of two to four months. Importantly, cryolipolysis has not produced any significant adverse side effects in studies to date and any noted effects have been minor and temporary.

The results of this study came in accordance with. Nelson *et al.* (2009) who found that significant reductions in the superficial fat layer thickness, ranging from 20% to 80%, following a single cryolipolysis treatment. The decrease in fat thickness occurs gradually over the first 3 months following treatment, and is most pronounced in patients with limited, discrete fat bulges. Erythema of the skin, bruising, and temporary numbness at the treatment site are commonly observed following treatment with the device, though these effects largely resolve in approximately 1 week. To date, there have been no reports of scarring, ulceration, or alterations in blood lipid or liver function profiles. The results of the study came in accordance with Lilit *et al.* (2014) who confirmed that Cryolipolysis is a novel method of selective removal of fat with cooling. This technique is based on the concept that fat cells are more sensitive to cold than the surrounding tissue. Prior studies and observations have demonstrated that cold exposure can induce selective damage to the subcutaneous fat via induction of panniculitis, resulting in reduction in the superficial fat layer of the skin. Cryolipolysis is a well-tolerated, safe, and effective non-invasive fat removal technique. There is on average about 40 cc of fat volume loss after a single treatment of the flank at 2 months post-treatment. Brian *et al.* (2009) confirmed that the treatments with cryolipolysis resulted in a significant reduction in the superficial fat layer without damage to the overlying skin. An inflammatory response triggered by cold-induced apoptosis of adipocytes preceded the reduction in the fat layer. Evaluation of lipids over a 3-month period following treatment demonstrated that cholesterol and triglyceride values remained normal. "Cryolipolysis" shown to significantly decrease subcutaneous fat and change body contour without causing damage to the overlying skin and surrounding structures or deleterious changes in blood lipids. Avram *et al.* (2012). found that the Cryolipolysis is a unique non-invasive method for the selective reduction of fat cells with controlled and localized cooling. The results of this study came in accordance with Jeffrey *et al.* (2014).who found that cryolipolysis utilizes targeted cold exposure to produce selective fat reduction without damaging overlying skin or surrounding tissue. as this treatment is completely noninvasive, there is no post procedure downtime and little risk for significant long term side effects or complication

Marzieh *et al.* (2016),reported that the non-invasive interventions appear to have better clinical efficacy, specifically in the body shape measurement, and less cost compared to invasive intervention (liposuction).

Wahrenberg *et al.* (1989) confirmed that In comparison to traditional surgical treatments for excess adipose tissue, cryolipolysis may be performed as an outpatient procedure in a clinic setting. There is no need for sterile conditions, anesthesia, or incisions and these factors both allow the procedure to be done at a comparatively lower cost and eliminate most of the potential risks associated with surgical procedures. therefore, patients who wish to minimize cost and avoid an invasive procedure requiring anesthesia, significant surgical risks, and post –treatment downtime are also ideal candidates. Patients who wish to undergo a noninvasive procedure with little associated discomfort or pain may also benefit from this treatment. A recent European study focusing on safety, tolerance, and patient satisfaction reported that 96%of 518 patients treated noted minimal to tolerable pain levels associated with the cryolipolysisprocedure.Pain that was reported as "severe "was only noted in 4% of patients and only occurred during the initial 5 minutes of treatment.

Michael *et al.* (2015), concluded that Cryolipolysis is a nonsurgical technique for localized fat reduction. With the increased risk of complications from more invasive methods such as liposuction, cryolipolysis presents a promising method for nonsurgical body contouring.Cryolipolysis is a promising procedure for nonsurgical fat reduction and body contouring and presents a compelling alternative to liposuction and other, more invasive methods. This procedure appears to be safe in the short term, with a limited side effect profile, and results in significant fat reduction when used for localized adiposities. Although liposuction is an effective therapeutic option for the removal of excess adipose tissue, it remains an invasive procedure and carries the inherent risks associated with surgery. In recent years, new modalities have been developed to address body contouring from a less-invasive perspective. These modalities primarily target the physical properties of fat that differentiate it from the overlying epidermis and dermis, thus resulting in selective destruction of fat.

In agreement with the results of the current study. Brian *et al.* (2009), who confirmed that Liposuction is one of the most frequently performed cosmetic procedures in the United States, but its cost and downtime has led to the development of noninvasive approaches for adipose tissue reduction.

Jeffrey *et al.* (2014), confirmed that cryolipolysis is completely non -invasive, there is no post procedure downtime and little risk for significant long term side effects or complications.

Ingargiola *et al.* (2015),concluded thatCryolipolysis is a promising procedure for nonsurgical fat reduction and body contouring and presents a compelling alternative to liposuction and other, more invasive methods. This procedure appears to be safe in the short term, with a limited side effect profile, and results in significant fat reduction when used for localized adiposities.

In contrast Mysore, (2017) reported that for decades, liposuction has been the only accepted procedures for body contouring. in recent times, howeverenon invasive modalities for fat reduction have been developed, and are being improved upon. their results are not immediate and are less dramatic, but they are useful in subset of patients who have fear of surgery.
Desiree *et al.* (2014) confirmed that although liposuction and surgical procedures remain the gold standard for patients seeking large volume fat removal, many patients prefere these novel non-invasive therapies as simple, no downtime alternatives to improve the appearance of limited fat and cellulite.

In contrast Jeffrey *et al.* (2014) concluded that cryolipolysis is not a replacement for the maximal fat reduction as liposuction or a surgical 'tummy tuck', and it is not for apatient looking for immediate improvement. Cryolipolysis has no utility in the treatment of visceral adipose tissue (which does not respond) or as a weight loss tool, and it has not been shown to impact insulin resistance. The common candidade for cryolipolysis is willing to expect a more modest gradual change in appearance than one would achieve with surgical treatments or liposuction, has a well –defined superficial layer of diet –and exercise –resistant adipose tissue at the abdominal, flanks,or back, and wishes to avoid the risks and recovery period associated with relatively more invasive fat reduction procedures.

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