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ORIGINAL ARTICLE

The Effect of Low Caloric Diet with Cryolipolysis on Anxiety and Depression in Overweight Population

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ABSTRACT

Background: Obesity has been managed using different treatments including cryolipolysis; while a relationship was reported between obesity and mental disorders too. This study aimed to assess the effect of low caloric diet plus cryolipolysis on depression and anxiety in comparison to low caloric diet alone in overweight subjects.

Methods: In a randomized controlled clinical trial, 50 healthy overweight females (25 kg/m^2≤ body mass index (BMI)<30 kg/m^2) aged 18 to 65 years were recruited in this study. Subjects were randomly allocated to two groups who received a calorie restricted diet with and without cryolipolysis. Anthropometrics and serum biochemistry tests were undertaken to measure the baseline and the end of the study (8th week). Depression and anxiety were assessed using the body shape questionnaire (BSQ), Beck's depression inventory (BDI) and Beck Anxiety Index (BAI) tests at the beginning and the end of study.

Results: All participants completed the study period. A significant difference was found in the BSQ at the baseline and the end of study between the intervention and control groups (9.96±18.61 vs. -19.24±26.55, respectively, p<0.001). A significant difference was found in BAI (-3.52±7.63 vs. 1.08±7.01, respectively, p=0.031) between the two groups. BDI changes between the two groups did not differ significantly (p>0.05).

Conclusion: Cryolipolysis was demonstrated to improve the anxiety in overweight subjects. The molecular mechanism is not clear yet and further studies with a large sample size are necessary to be investigated.

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Introduction

Obesity has become an important public health issue that is associated with physical problems and highly comorbid with depression and anxiety (1, 2). Obesity, especially abdominal obesity, that is independent of body mass index (BMI), is increasing in Asian population including in Iran (3, 4). Some studies have reported that obesity is related to the mental disorders (5). Although, it is not clear whether the obesity causes mood disorders or mood disorders causes obesity (6, 7). As well, it has been shown that there is a significant association between depression with decreased serum magnesium, calcium (8), and vitamin D (9), and increased gamma-glutamyl transferase (GGT), glucose and triglycerides levels (10).

Subjects with obesity who seek treatment have higher level of psychopathology, especially depression, compared to people who are not searching treatment (11). It is also unclear whether obesity is associated with gender and ethnicity or not (12). According to the American Dermatology Association (ASD) report in 2015, the most important reason for using the non-invasive methods is to look younger, which makes people more happy and increases their self-confidence. According to this report, the most common concern is related to overweight and waist circumference that 88% of the people have this concern (13). Over years, obesity was managed using different treatments, including diet, training, medications, body countering and surgical procedure (5, 14). Most of the drugs used to treat obesity have now been discontinued due to significant side effects. On the other hand, surgical method carried out to change the body shape resulted in many complications (15). So the tendency to use non-invasive methods along with diet, physical activity and lifestyle changes is more satisfactory (16, 17).

Currently, non-invasive methods such as radio waves, ultrasound cavitation, cryolipolysis and laser are used to deal with overweight and obesity (18, 19). Cryolipolysis is a preferred nonsurgical technique for localized fat reduction in body contouring. Cryolipolysis is a less complicated procedure compared with liposuction and gastric bypass that initially has received FDA approval for fat reduction (6, 20). It is programmed based on the sensitivity of the skin tissue to cold so that, when the energy is released through the skin by the applicator, it causes apoptosis in the fat cells while, the skin, muscles and nervous tissue are not affected (21). It has been shown that weight loss in subjects with overweight can improve depression (22, 23). As the best of our knowledge, there is still a room regarding the clinical effect of cryolipolysis on mood status in subjects with obesity. This study aimed to evaluate the effect of low caloric diet plus cryolipolysis on depression and anxiety comparing with low caloric diet alone in subjects with overweight.

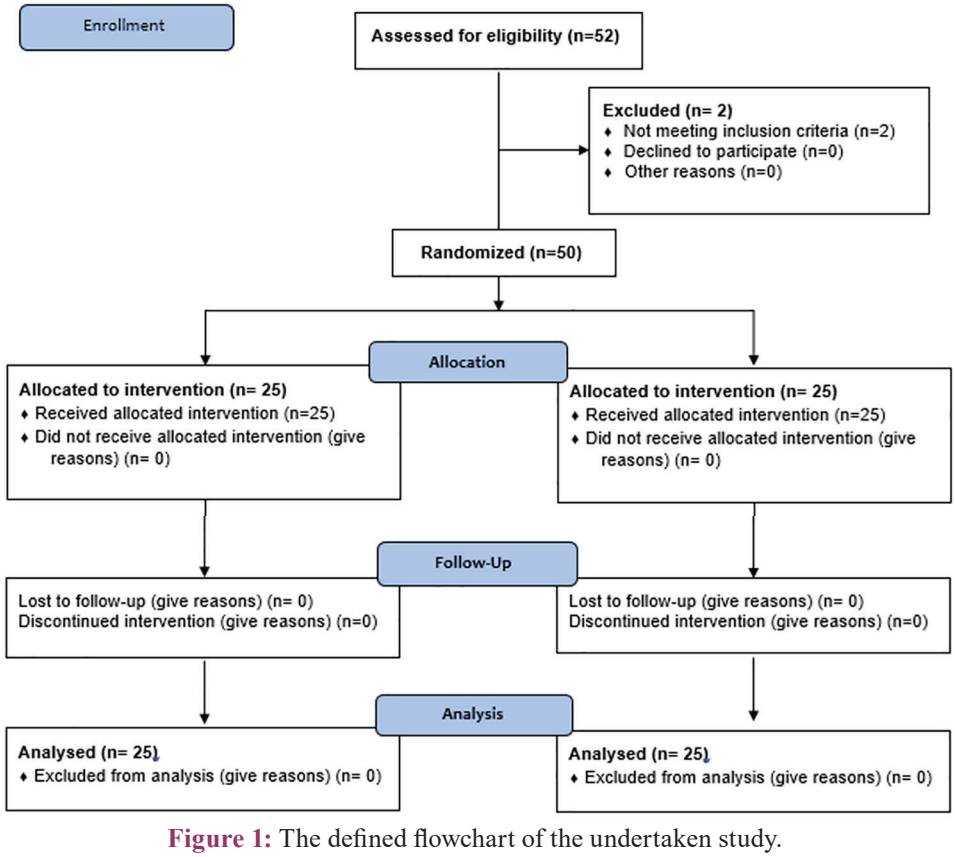

Figure 1: The defined flowchart of the undertaken study.

Materials and Methods

The current study was a randomized controlled clinical trial approved by Mashhad University of Medical Sciences Ethics Committee (Ethics reference Number: IR.MUMS.REC.1399.372; IRCT20200927048848N1, Registration Date: 2020.09.30), Mashhad, Iran. Apparently, overweight (25 kg/m^2≤body mass index (BMI)<30 kg/m^2) healthy females aged 18-65 years were recruited in this study. Subjects were randomly divided (Quadruple block randomization) into two groups including participants receiving a calorie restricted diet (n=25) and those treated with cryolipolysis (n=25). Figure 1 shows the study flowchart. Biochemical markers and mood status tests were measured at baseline, and at the end of the study (8th week) for all participants. The number of samples in each group was defined to show the changes in

Table 1: Effect of low caloric diet with and without cryolipolisis on anthropometric indices.

Variable	Status	Intervention			Control		
		Mean±SD	IQR	*P* value	Mean±SD	IQR	*P* value
Age (year)		37.88±9.37	38.00 (31.00_45.50)		40.16±11.6	39.00 (32.00_48.00)	0.438
BMI (Kg/m^2)	Before	28.06±2.25	28.80 (26.50_29.4)	<0.001	28.71±1.79	28.80 (27.00_30.10)	<0.001
	After	27.08±2.08	27.40 (25.70_28.85)		27.58±1.92	27.80 (25.85_29.25)	
	Changes	-0.98±0.78	-1.00 (-1.70_-0.35)		-1.12±0.53	-1.10 (-1.55_-0.75)	0.45
Waist to hip ratio	Before	0.92±0.05	0.93 (0.89_0.96)	0.003	0.93±0.05	0.93 (0.90_0.98)	0.287
	After	0.90±0.04	0.91 (0.89_0.93)		0.93±0.05	0.92 (0.89_0.96)	
	Changes	-0.01±0.02	-0.02 (-0.03_0.00)		0.00±0.02	-0.01 (-0.02_0.01)	0.19
Waist circumference (cm)	Before	93.23±7.03	93.70 (88.05_98.35)	0.001	95.34±6.40	95.90 (89.20_102.15)	0.001
	After	90.50±6.25	91.30 (87.25_94.50)		93.11±6.38	93.10 (87.55_98.25)	
	Changes	-2.72±3.60	-2.50 (-5.45_-0.55)		-2.23±2.78	-2.10 (-3.30_-0.50)	0.15
Hip circumference (cm)	Before	100.78±3.87	100.75 (98.07_102.95)	0.002	101.73±2.95	101.37 (98.92_103.83)	<0.001
	After	99.79±6.25	100.00 (96.95_102.55)		100.16±3.09	100.51 (97.30_101.94)	
	Changes	-0.98±1.73	-1.26 (-2.10_-0.14)		-1.57±1.00	-1.62 (-2.37_-0.76)	0.59
Systolic blood pressure (mmHg)	Before	121.76±10.09	122.50 (116.5_125.75)	0.291	121.00±13.74	123.00 (110.75_127.5)	0.221
	After	122.34±6.49	123.00 (122.00_126.25)		123.26±9.98	123.00 (113.00_132.25)	
	Changes	0.57±8.58	0.00 (-1.25_5.25)		2.26±11.70	1.50 (-4.50_9.25)	0.13
Diastolic blood pressure (mmHg)	Before	79.50±10.45	78.00 (74.75_86.75)	0.534	80.23±12.46	79.50 (71.75_90.25)	0.282
	After	78.68±11.80	75.50 (71.00_85.00)		78.11±9.39	79.00 (72.00_82.75)	
	Changes	-0.80±11.52	0.00 (-5.00_6.00)		-2.11±5.29	0.00 (-4.00_0.00)	0.13
Pulse rate (beats per minute)	Before	88.15±9.39	88.00 (80.75_92.50)	0.299	87.53±6.57	88.00 (80.75_6.57)	0.181
	After	89.57±9.66	89.50 (84.00_92.50)		90.30±7.14	91.00 (89.00_93.25)	
	Changes	1.42±8.98	0.50 (-2.50_4.00)		2.76±7.91	3.00 (-2.00_7.25)	0.5

Repeated measurement has been used. IQR: Interquartile range, SD: Standard deviation.

the intervention and control groups with a 95% confidence interval (95%CI) and the coefficient had a power of 0.961 and 0.598 for body shape questionnaire (BSQ), Beck's depression inventory (BDI) and Beck Anxiety Index (BAI), respectively.

A cryolipolysis device (Biotech, Fusiomed, Italy) was applied that was already explained in detail (24). Body composition and anthropometric measurements including waist circumference, hip and waist circumference were analyzed using a body analyzer (770 BIA, South Korea). The interview was done to gather information regarding socioeconomic, occupation, lifestyle, health behaviors, medication history, and anxiety/depression using BSQ (25), BDI and BAI (26). Anthropometric measurements were assessed at the beginning and at the end of the study (8th week) and biochemistry tests were done at the beginning and at the end of the study too (8th week).

Cryolipolysis was performed in 2 sessions, the first week and the fourth week, while each session included 60 minutes in each position. Diet and anthropometric indicators were assessed at the beginning and at the end of the study (8th week). Before and after the interventions, 10 mL overnight fasting blood samples were taken from each participant. Serum levels of biochemical factors including Gamma-glutamyl transferase (GGT), magnesium and calcium were determined using an autoanalyzer (BT3000, Pars Azmoon Co., Tehran, Iran). According to the thickness of the fat layer, the number of 50 subjects in the study was determined. The number of samples could create an effect of 56% with 95%CI and 80% power as an average (8, 9):

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left(\sigma_1^2 + \sigma_2^2\right)}{\left(\mu_1 - \mu_2\right)^2}$$

Data analysis was undertaken using SPSS software (version 18, Chicago, IL, USA). Data normality was checked based on the Smirnov-Kolmogorov test. Comparison of qualitative variables in 2 groups was done with a Chi-square test. The normal data was described as mean and standard deviation (SD), and in the case of abnormal data, it was presented as median and an interquartile range. Data analysis was conducted utilizing T-test and Mann-Whitney test and the correlation coefficient was evaluated by Pearson and Spearman test. Paired t test was applied to compare pre- and post-trials for normally distributed data. For non-parametric data, Wilcoxon signed rank test was employed to compare pre- and post-data. Finally, if needed, a linear regression test was used to adjust the effect of confounding variables. A p value <0.05 was considered to be statistically significant.

Results

All subjects completed the study and none of them were dropped out from the study, and there were

Table 2: Effect of low caloric diet with and without cryolipolisis on mood status.

Score/Status		Intervention			Control		
		Mean±SD	IQR	*P* value	Mean±SD	IQR	*P* value
BSQ	Before	151.48±29.93	155.00 (144.00_172.00)	0.05	136.76±36.16	144.00 (111.00_162.00)	0.03
	After	140.32±27.14	151.00 (122.00-159.00)		154.40±36.03	162.00 (125.00_187.00)	
	Changes	-11.16±18.27	-5.00 (-18.00_00.00)		17.64±26.27	10.00 (2.50_44.00)	<0.001
BDI	Before	11.56±8.42	8.00 (6.00-16.00)	0.14	8.92±5.09	8.50 (4.75-13.00)	0.14
	After	9.20±6.24	10.00 (3.50-12.00)		7.52±6.44	5.00 (2.00-12.50)	
	Changes	-2.36±6.24	-1.00 (-6.50_2.00)		-1.68±5.61	-1.00 (-6.00_2.50)	0.59
BAI	Before	13.88±8.04*	12.00 (10.00-19.00)	0.03	8.96±6.72*	8.00 (4.00-11.25)	0.65
	After	10.36±6.16	10.00 (6.00-14.00)		9.68±6.97	7.00 (5.00-15.00)	
	Changes	-3.52±7.63	-2.00 (-9.00_1.50)		1.08±7.01	1.00 (-2.50_6.00)	0.031

*There was a significant difference between the two groups at baseline. A: p value expressing comparison between groups was calculated using T test. B: p value expressing comparison within groups was calculated using Wilcoxon test. C: Data were presented as mean±SD or median IQR. Normality of data was measured by the Kolmogorov Smirnov explorer test. T-test and paired t-test were employed for variables. Abbreviations: BAI: Beck anxiety index, BDI: Beck depression inventory, BSQ: Body shape questionnaire, IQR: Interquartile range, SD: Standard deviation.

no complications for application of cryolipolysis during the study. There was no significant difference between the two groups regarding age, anthropometric parameters, systolic/diastolic blood pressure, pulse rate (Table 1), mood status (Table 2), and biochemical markers (Table 3) at the beginning of the study (p>0.05 for all variables). According to Table 1, there were no statistical differences in the BMI, waist circumference (WC), waist/hip ratio (WHR), systolic/diastolic blood pressure and pulse rate changes in the two study groups before and after the interventions (p>0.05). As summarized in Table 2, the BSQ showed a statistical difference before and after the study in both intervention and control groups (p<0.05). Likewise, there was a significant difference in the BSQ change between the two study groups (p<0.001); while, the changes for BDI between the two study groups did not differ (p>0.05). The changes of BSI demonstrated statistically significant difference between the two groups (p=0.031). As shown in Table 3, there were no significant differences for GGT, magnesium, and calcium changes between the two groups before and after the interventions (p>0.05). Moreover, there was no significant association between changes in weight and BSQ, BDI and BSI (Table 4) (p>0.05 for all variables).

Discussion

The pivotal role of diet ingredients has been emphasized before (27); among them calorie intake was shown to be a crucial factor in obese people (28). Cryolipolysis as a nonsurgical adiposity reduction treatment intervention has nowadays faced increasing in popularity globally and it can be associated with health outcomes, satisfaction and even adverse effects (29). Our findings revealed that anxiety decreased by -3.52±7.63 in the cryolipolysis group when compared with the control group (1.08±7.01) (p<0.031). To the best of our knowledge, there have been no available studies in literature on the effects of cryolipolysis on mood status. It was shown that there were more anxiety and depressive symptoms in subjects with obesity in comparison to subjects with normal-weight (30). Obese individuals had less body image satisfaction

Table 3: Effect of low caloric diet with and without cryolipolisis on biochemistry parameters.

Variable	Status	Intervention			Control		
		Mean±SD	IQR	*P* value	Mean±SD	IQR	*P* value
Gamma-glutamyl transferase (GGT) (mg/dL)	Before	25.92±9.58	24.50 (20.35_28.25)	0.641	28.61±8.73	26.50 (23.50_31.25)	0.45
	After	26.49±7.42	24.50 (22.00_29.25)		25.22±6.35	25.00 (21.75_28.25)	
	Changes	0.57±6.09	1.60 (-3.00_3.75)		-3.39±4.68	-3.00 (-5.50_0.00)	0.42
Magnesium (mg/dL)	Before	2.00±0.20	2.02 (1.85_2.09)	0.278	2.22±0.27	2.13 (2.02_2.44)	0.98
	After	2.37±1.60	2.00 (1.90_2.13)		2.21±0.73	2.09 (1.93_2.24)	
	Changes	0.37±1.48	0.02 (-0.07_0.14)		-0.003±0.68	-0.05 (-0.35_0.08)	0.33
Calcium (mg/dL)	Before	9.41±0.69	9.30 (8.90_10.10)	0.052	9.53±0.55	9.60 (9.00_10.00)	0.27
	After	9.13±0.55	9.20 (9.13_0.55)		9.38±0.40	9.30 (9.10_9.70)	
	Changes	-0.28±0.69	-0.20 (-0.90_0.30)		-0.14±0.64	-0.20 (-0.65_0.50)	0.46

*There was a significant difference between the two groups at baseline. IQR: Interquartile range, SD: Standard deviation.

Table 4: Association between changes in weight and BSQ, BDI and BAI.

Score change	Intervention r(P)	Control r(P)	Total r(P)
BSQ	0.28(0.16)	-0.25(0.51)	0.14(0.30)
BDI	-0.34(0.09)	-0.09(0.64)	-0.08(0.53)
BAI	-0.15(0.46)	-0.09(0.64)	-0.26(0.06)

r: Pearson correlation. P: p value. Pearson correlation was used for normal variables. BAI: Beck anxiety index, BDI: Beck depression inventory, BSQ: Body shape questionnaire, IQR: Interquartile range.

and self-esteem and also, there was more suicidal behavior in obese people (30). Kautzky *et al.* have evaluated the effect of caloric restriction with and without 7h clinical psychological intervention among women (n=43) over 2 weeks period. The psychological wellbeing was assessed using dimensional psychiatric symptom load (brief symptom inventory: BSI). They demonstrated that caloric restriction could improve the psychological wellbeing along with metabolic functions afterward a BMI reduction (31).

Our results were consistent with a previous study revealing that weight decreased by caloric restriction with and without cryolipolysis (24); as well cryolipolysis could improve the mood in subjects with overweight. Moreover, the depression score declined by cryolipolysis; but there was no significant difference between the two groups. This could be due to our small sample size. On the other hand, it is not clear whether multiple cryolipolysis treatments can enhance the efficacy of cryolipolysis or not. Also, more changes in BAI were observed in the intervention group who received both cryolipolysis and diet therapy in comparison to subjects who received only a diet therapy alone. Although there was weight loss in the two groups ($p<0.05$), there was no reduction in BAI among the control group. This result can be due to the cryolipolysis effect on BAI that was not independent of weight reduction. One of the study limitations was that the BDI and BAI tests were screen tests and not diagnostic tests. As well, the neurotransmitter and biomarkers were not measured for understanding the mechanism of these effects.

Conclusion

Cryolypolysis was demonstrated to improve the changes in anxiety score associated with weight reduction. The molecular mechanism is unknown and further studies with a large sample size are recommended to discover it.

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Authors' Contribution

All authors have read and approved the manuscript. Supervision: MGM, MSK and RAD; Conceptualization and Data curation: ME and MN; Project administration: HH, MMB and SVH; Methodology and Formal analysis: HE and SG; Writing – original draft: MV and HH; Writing – review and editing: GAF and MAN

Conflict of Interest

The authors confirm no conflicts of interest.

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