

Triple Therapy Versus Intra-Gastric Balloon in Treatment of Male Morbid Obesity

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ABSTRACT

*The purpose of this study was to investigate the effect of triple therapy (diet, exercises, and acupuncture) versus intra-gastric balloon on morbid obese men. **Subjects:** forty morbid obese male had body mass index (BMI) more than 35. They ranged in age from 30 to 50 years. They were classified randomly into two groups of equal number. Group 1: twenty patients underwent intra-gastric balloon. Group 2: twenty patients received triple therapy (diet, exercises, and acupuncture). **Procedures:** evaluation procedures in the form of initial evaluation and measurement of BMI and lipid profile pre treatment and after six months post treatment, and therapeutic procedures for group 2: (Program of aerobic training on bicycle, diet regimen, and auricular acupuncture). **Results:** showed a statistically significant decrease in BMI, total serum cholesterol and triglycerides in both groups, with the highest rate of reduction in triple therapy group. **Conclusion:** It concluded that triple therapy could be the first choice of treatment of morbid obesity, while intra-gastric balloon came in the second choice.*

Key words: Intra-gastric balloon, Triple therapy, Body mass index (BMI), Morbid obesity.

INTRODUCTION

There is a consensus between international organization and world experts that obesity is a disease state of epidemic proportions. A disease can be defined as human condition that impairs normal function and implies ill-health²².

Morbid obesity is also defined as an abnormal accumulation of body fat, usually greater than 20% or over an individual's ideal body weight¹².

It was reported that obesity can be classified as super-obese, morbidly-obese, and medically significant obese, other classification is obese and over weight¹³.

Surgery is considered the treatment of choice for well informed and well motivated severely obese (BMI 40 or 35 with comorbidities). Typically, people who seek

surgery have exhausted the more conservative weight less options without satisfactory results. Surgical treatment of obesity is based on two techniques gastric – restricting technique (gastric band, stapling, and ballon) and gastric restricting and malabsorptive technique (Gastric hypass)³⁴.

The liquid-filled intragastric balloon model decreases preprandial hunger, increases postprandial satiety, and promotes weight loss in the short term⁸. Additionally, the intragastric balloon is thought to help individuals to modify their eating habits by providing a self-education tool³⁴.

Dietary treatment is fundamental to the management of obesity but unless the obese person is willing and able to make long term changes in lifestyle (of which diet is the most important aspect) the treatment will fail²⁰.

Inserting acupuncture needles superficially into various parts of the body can facilitate weight loss by giving the person a feeling of well-being which can suppress the desire for excess food. Acupuncture also can stimulate metabolism and thereby enable the body to utilize food efficiently instead of storing it as fat³⁰.

Physical activity is recognized as an integral part of obesity treatment with other therapeutic means exercise is an activity requiring physical exertion done for the sake of health. Exercises use a variety of muscle groups continuously and rhyimically, increasing heart rate and breathing, specific aerobic activities include walking, jogging, bicycling, swimming, tennis and cross-country sking².

The aims of this study is to assess the effect of triple therapy (diet, exercises, and acupuncture) versus intra-gastric balloon on morbid obese men.

SUBJECTS, MATERIAL AND METHODS

Subjects

Forty male patients who had a body mass index (BMI) more than 35, selected from Educational Ahmed Maher Hospital, their ages ranged from 30 to 50 years participated in this study. The patients were randomly classified into 2 groups of equal number. Group (A) twenty obese men underwent intra-gastric balloon. While Group (B) twenty obese men received triple therapy in the form of (diet, aerobic exercise and auricular acupuncture).

Inclusion criteria: Patients were males only, their ages ranged from 30 to 50 years, had a body mass index (BMI) more than 35, were conscious and ambulant, and had the same surgical technique done by the same surgeon in intra-gastric balloon group.

Exclusion criteria: Smokers, alcohol drinkers or any substance abuse, osteoarthritic patients, cardiac patients, diabetic patients, those who had previous surgical procedures in lower limb (L.L) which may affect the study, those who missed two successive sessions, and athletic males.

Ethical consideration

The experimental protocol was explained in details for each patient before the initial assessment and informed written consent were obtained from all participants. The trial protocol was approved by the meeting of the department of surgery, faculty of physical therapy, Cairo University. There was no harm inflicted on the patients. On the contrary, all had benefited from the final results of the study.

Material and Methods:

1) Measurement procedures:

1 - Initial evaluation procedures:

- Each subject was examined medically in order to exclude any abnormal medical problems which previously mentioned.
- Each subject's history was taken in previously prepared questionnaire to collect information about:
 - a) The presence of any functional, social or economic problems.
 - b) Psychological status.

- The purpose of training program, diet, and acupuncture was explained for each subject in each group.

2- Measurement of height and weight:

Weight was determined, height was measured, then the body mass index was calculated where: Body mass index (BMI) = body weight (Kg)/ height (m²)¹⁸.

3- Estimation of lipid profile:

After fasting for at least 12 hours, 3mL venous blood was extracted from dorsal hand vein and allowed to clot at 37°C in the water bath, then serum was separated using a centrifuge for estimation of serum triglycerides and cholesterol level.

Measurements were taken as following:

- 1- Before starting any protocol (pre-treatment).
- 2- After six months (post-treatment).

2) Treatment procedures:

The procedures of this protocol were achieved under the following steps:

I- For intra-gastric balloon group

a- Bioenterics intra-gastric balloons were implanted during the study period. Placement was performed with patients under sedation or general anesthesia, immediately after upper gastrointestinal endoscopies if this revealed no contraindication (e.g., potentially bleeding lesion, large hiatal hernia).

b- The balloon was inflated with 500–650 ml saline mixed with 10 ml methylene blue. Patients were instructed:

- (i) To expect nausea, vomiting, and abdominal cramps during the following 72 hours.
- (ii) To take a liquid diet for 72 hours, including protein-rich drinks and starting at day 4, to progressively follow a personalized balanced-deficit diet of 1000 kcal per day less than their usual intake, with approximately 15% of energy derived from proteins, 30% or less from fats, and the remainder from carbohydrates¹⁷.

II-For triple therapy group: (dieting, aerobic exercises and auricular acupuncture):

a) Program of aerobic training:

Exercises were performed on the electronic bicycle ergometer as the following stages:

First stage (warming up):

Consisted of 5 minutes warming up in the form of pedaling at speed of 60 revolutions per min without load.

Second stage (active stage):

Consisted of:

- Duration: 30 minutes.
- Mode: pedaling at speed of 60 revolution per min with;
- Load: adjusted load to achieve 60% of the predictive age maximal heart rate which was calculated by the following equation:

Maximal heart rate = 220-age in years

Moderate work load = 60% of maximal heart rate

The heart rate will be measured through pulsometer attached to the patient's ear.

Third stage (cooling down):

Consisted of 5 minutes cooling down in the form of pedaling at speed of 60 revolutions per min without load.

Duration and frequency:

3 sessions per week for 6 months².

b) Recommended diet regimen:

Patients received low calorie diet, where patients received caloric intake below 1200 cal. / day.

This diet was used for 3 days at a time and followed by 4 days normal eating and repeat the 3 days after 4 days of normal eating²⁰.

Day 1:

Break fast: black coffee or tea, ½ grapefruit, 1 slice toast and 1 cup peanut butter.

Lunch: ½ cup tuna or 1 slice cheese, 1 slice toast and black coffee or tea.

Dinner: 2 slices any type meat, 1 cup string beans and 1 small apple.

Day 2:

Break fast: black coffee or tea, 1 egg, slice toast and ½ bananas.

Lunch: 1 cup cottage cheese or ½ cup tuna, 5 saltine crackers and black coffee or tea.

Dinner: 1 cup broccoli or cabbage, ½ cup carrots, ½ bananas and 1 cup vanilla ice cream.

Day 3:

Break fast: 5 saltine crackers, 1 slice cheddar cheese and 1 small apple.

Lunch: 1 boiled egg, 1 slice toast and black coffee or tea.

Dinner: 1 cup tuna, 1 cup carrots, 1 cup grains, 2 cup cantaloupe and ½ cup vanilla ice cream.

c) Auricular acupuncture therapy:

1- Patients were allowed to sit for at least 10 minutes to gain physical and mental relaxation.

2- Perfect sterilization of patients' ear using alcohol should be conducted and followed by drying of the ear using dry cotton.

3- Patients were informed about the procedure to gain their confidence and relaxation.

4- Then needles were embedded in the corresponding points of ears.

Hunger point (on the center of tragus),

Stomach (on the end of helix curz),

Shenmen (on triangular fossa, on the lateral 1/3 of triangular).

Endocrine (at the base of cavum-conchae in the in tertragic notch).

Five needles per each session were used and they were changed every 7 days for six months²³.

Statistical AnalysisData collection:

Data was collected two times as follows before starting any protocol (pre treatment) and after six months (post treatment).

Data analysis:

- In this study, the mean, standard deviation and standard error were calculated for all variables in both groups.
- Paired "t" test was used to compare before and after treatment in the same group of individuals.
- The F value of analysis of variance (ANOVA) was used to compare post values between both groups.
- A value of $P \leq 0.05$ was considered statistically significant.

RESULTS

Statistical analysis of data by using analysis of variance was used to find the significance level, mean and standard deviation for the effect of intra-gastric balloon, and triple therapy (diet, exercises and acupuncture) on BMI, serum cholesterol and triglycerides of these subjects.

The subjects were divided into 2 groups:

Group 1:

Twenty patients who underwent intra-gastric balloon.

Group 2:

Twenty patients who received triple therapy program (diet, exercises and acupuncture).

The results were presented as follow:

I- Results of group (1):

The mean value of body mass index before and after treatment was 53.28 ± 4.92 and 45.70 ± 4.78 respectively. The mean value of triglycerides level before and after treatment

was 167.80 ± 10.70 and 133.15 ± 5.75 respectively. The mean value of cholesterol level was 255.15 ± 20.21 and 227.00 ± 14.31 respectively. There was a significant decrease in body mass index, triglycerides, and cholesterol levels in comparison before and after treatment in the same group with $P \leq 0.05$ table (1) and figure (1).

Table (1): Comparison pre and post treatment for intra-gastric balloon group measurements.

	Body mass index(kg/m ²)		Triglycerides level(mg/dl)		Cholesterol level(mg/dl)	
	pre	post	pre	Post	pre	post
Mean	53.28	45.70	167.80	133.15	255.15	227.00
SD	± 4.92	± 4.78	± 10.70	± 5.75	± 20.21	± 14.31
t-value	21.41		22.60		12.74	
p-value	0.000		0.000		0.000	
Level of significance	significant		Significant		significant	

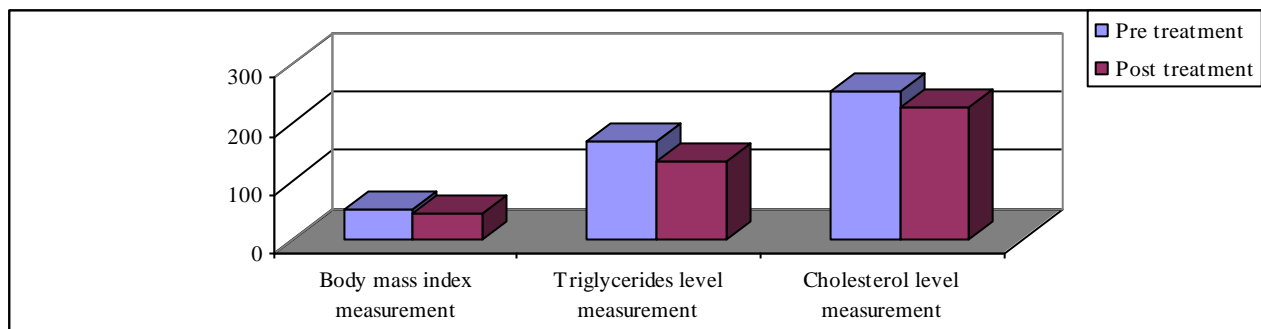


Fig. (1): Comparison pre and post measurement in intra-gastric balloon group.

II- Results of group (2).

The mean value of body mass index before and after treatment was 54.48 ± 5.04 and 33.03 ± 3.39 respectively. The mean value of triglycerides level before and after treatment was 166.85 ± 12.72 and 106.80 ± 15.29 respectively. The mean value of cholesterol

level was 251.35 ± 16.68 and 199.75 ± 15.97 respectively. There was a significant decrease in body mass index, triglycerides, and cholesterol levels in comparison before and after treatment in the same group with $P \leq 0.05$ table (2) and figure (2).

Table (2): Comparison pre and post treatment for triple therapy group measurements.

	Body mass index(kg/m ²)		Triglycerides level(mg/dl)		Cholesterol level(mg/dl)	
	pre	post	pre	Post	pre	Post
Mean	54.48	33.03	166.85	106.80	251.35	199.75
SD	± 5.04	± 3.39	± 12.72	± 15.29	± 16.68	± 15.97
t-value	49.61		28.19		16.35	
p-value	0.000		0.000		0.000	
Level of significance	significant		Significant		Significant	

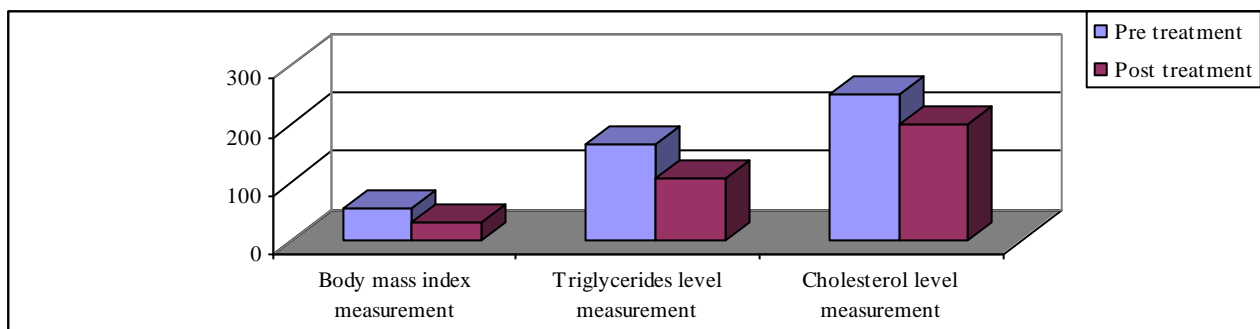


Fig. (2): Comparison pre and post measurement in triple therapy group.

III-Comparative analysis between groups (1) and (2) after end of treatment.

There was a significant decrease in all measurements between both groups with P-value ≤ 0.05 as follows:

The mean value of body mass index in intra-gastric balloon group 45.70 ± 4.78 , while in triple therapy group, it was 33.03 ± 3.39 . The

mean value of triglycerides level in intra-gastric balloon group was 133.15 ± 5.75 , while in triple therapy group, it was 106.6 ± 15.29 . The mean value of cholesterol level in intra-gastric balloon group was 227.0 ± 14.31 , while in triple therapy group, it was 199.75 ± 15.97 table (3) and figure (3).

Table (3): Comparison between all measurement in both groups after end of treatment.

	Body mass index(kg/m ²)		Triglycerides level(mg/dl)		Cholesterol level(mg/dl)	
	Group(1)	Group(2)	Group(1)	Group(2)	Group(1)	Group(2)
Mean	45.70	33.03	133.15	106.60	227.0	199.75
SD	± 4.78	± 3.39	± 7.75	± 15.29	± 14.31	± 15.97
Mean difference	12.67		26.55		27.25	
t-value	9.657		7.268		5.683	
p-value	0.000		0.000		0.000	
Level of significance	significant		significant		Significant	

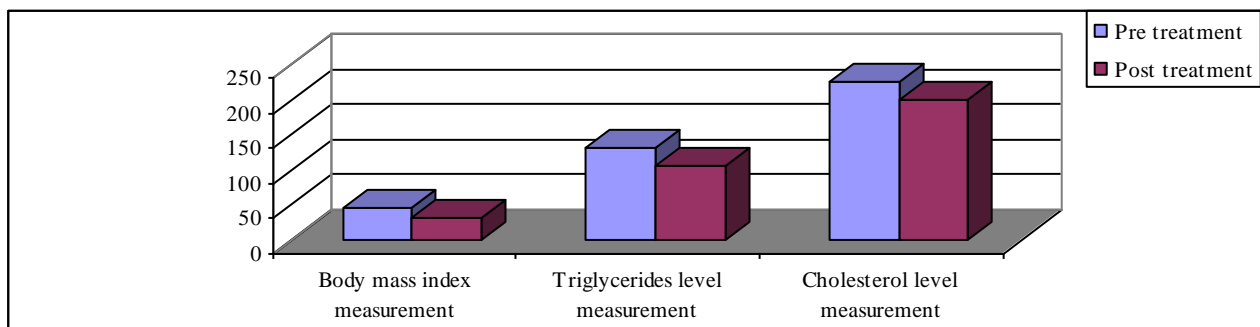


Fig. (3): Comparison between all measurements in both groups after end of treatment.

DISCUSSION

The aim of this work was to determine the effect of intra-gastric balloon, and triple therapy (diet, ex's and acupuncture), on morbid obese males & determine the best.

The measurements in this study included: body mass index (BMI), serum

cholesterol, and triglycerides. A comparison was made between the two groups on these parameters.

The results of the present study indicated that both groups induced significant reduction in BMI, serum cholesterol and triglycerides but this reduction was higher in triple therapy group than intra-gastric balloon group.

Firstly, for the intra-gastric balloon group:

In the present study twenty patients underwent intra-gastric balloon and showed significant reduction in BMI and serum cholesterol and triglycerides, these results were supported by:

Maggard et al.,¹⁵ studies included the loss of 14.7 kg at balloon removal, which is lower than bariatric surgery's 30–40 kg 1 year after treatment, In addition to this they estimated a loss of 12.2% of initial weight at the end of the treatment, a quantity considered sufficient to obtain health benefits because the loss of 10% of the weight improved some morbid conditions associated with obesity (hypertension, diabetes, hyperlipidemia), and also to reduce mortality. Genco et al.,⁸ estimated balloon efficacy as the lost 6.7 kg. at balloon removal, a result greater than the efficacy estimations for sibutramine (4.4 kg) or orlistat (2.9 kg).

Li et al.,¹⁴ reported that in regard to intra-gastric balloon safety, extracted data from 3,442 patients treated with that balloon and the majority of complications were mild. Although the early removal rate was significant (4.2%), half of these removals were voluntary. The estimate of intra-gastric balloon effectiveness at balloon removal came from 15 studies that summarized data from up to 3,608 patients. These estimates were the following: 14.7 kg lost; 12.2% of initial weight lost; 5.7 kg/m² lost; and 32.1% excess weight lost. These estimates were statistically heterogeneous. Two studies provided data on maintenance weight lost 1 year after treatment⁹. 143 patients included in studies lost a mean of 15.9 kg at balloon removal. Of these patients, only 133 patients were followed 1 year after balloon removal, and had recovered 6.3 kg, representing 39.6% of the weight lost at balloon removal. Two other studies provided follow-up data, but in these studies more than half of their patients were lost²⁴.

Svetkey et al.,²⁵ had an agreement with the results of this study as they reported that over their study on 30 patients with BMI 42.4 treated by intra-gastric balloon, hyperlipidemia observed in 8 patients with 4 patients showed normal levels, 2 lowered levels and 2 unchanged values post operatively.

Dhruva and Redberg⁵, suggested that 70% of intra-gastric balloon were successful in terms of weight loss maintaining excellent or good weight loss results.

The results of Weiss et al.,³² came in accordance with results of current study in that 60% of patients were off medications for related diseases as hyperlipidemia.

In the study of Dumonceau,⁶ over 18 patients with morbid obesity treated by intra-gastric balloon, the mean weight loss was 24 (range 1-39) kg at 6 month (P < 0.001 versus preoperative weight), representing a mean weight loss of 21.3 percent at 6 months. Expressed as percentage excess over ideal body-weight, this fell from a mean of 108 percent before operation to 64 percent at 6 months, while the mean body weight remained stable in the controls.

The results of the present study might be attributed to that the inflated balloon occupies a portion of the gastric volume and theoretically reduced capacity for food. This method is far less invasive than gastric surgery for reducing stomach capacity²¹.

Secondly, for triple therapy group (diet, ex's, & acupuncture):

In the present study twenty patients received selected diet program, aerobic exercises, and auricular acupuncture and showed the highest significant reduction in BMI and serum cholesterol and triglycerides, and these results were supported by many investigators as:

Tyo²⁸ who took biopsies of abdominal subcutaneous tissue before and immediately after two hours of exercises on bicycle to investigate the effect of long lasting boat of exercise on the lipolytic β - and antilipolytic and α -2 adrenergic receptors and the antilipolytic effect of insulin in obese subjects, they concluded that, after exercises, spontaneous lipolysis was significantly increased compared to the level before exercise. For the effect of insulin on lipolysis, there was no significant difference before and after exercises, the main finding of this study is the presence of significant exercise induced increase in β - adrenergic lipolytic effect in adipocytes obese subjects.

Fortunately, Rao,²³ had investigated the effect of eight months randomized trial

involving different amounts and intensities of exercise among overweight men and women with dyslipidemia. They found that low amounts of exercise at moderate or high intensity are associated with potentially beneficial changes in plasma lipid profile. However, higher levels of high intensity exercise resulted in more pronounced changes in lipoprotein and were required to increase the high density lipoprotein cholesterol level, without significant weight loss.

It was concluded that the highest amount of weekly exercise training, even with minimal weight change had widespread beneficial effects on lipid profile. They related such improvement to the amount of activity and not to the intensity of exercise training¹.

Hinderliter et al.,¹⁰ reported that aerobic exercise on obese women led to loss of weight and decreased in body mass index because exercise training is a major modifiable component of total daily energy expenditure.

It was found that after 8 weeks of aerobic exercise, there was significant decrease in body mass index. This was explained as cycle ergometer leading to increase energy expenditure. Total daily energy expenditure can be divided into several component: resting metabolic rate, which account for approximately 60-70% of 24 hour energy expenditure; the energy cost of feeding approximately 10% of 24 hour energy expenditure; and the thermal effect of physical activity or exercise, which is most variable component and may vary from 15% of 24 hour energy expenditure in sedentary people to even 400% in professional cyclists under extreme circumstances¹⁶.

Many of the improvements in lipid profile variables and insulin sensitivity that are associated with habitual exercise are also seen after a single session of exercise. This finding could indicates that the short term effects of exercise on insulin signaling in muscle are a fundamental mechanism underlying many of the observed changes in the lipid profile²⁶.

Despite the plethora of observations of exercise induced changes in the lipoprotein profile, there is limited understanding of the underlying mechanisms. Exercise conditioning is associated with an increase in lipoprotein lipase activity in adipose tissue and muscles.

According to Thompson,²⁷ increased lipoprotein lipase activities lower LDL and chylomicron triglyceride levels and enhance clearance of cholesterol-rich LDL and chylomicron remnant. LDL and triglycerides are exchanged for cholesterol ester in LDL and HDL, a process mediated by cholesteryl ester transfer protein, and the triglycerides in HDL and LDL is then hydrolyzed by lipases, causing a decrease in the size of the particles. Exercise and weight loss also reduce the level of cholesteryl ester transfer protein perhaps because a fraction of this protein is made in adipose tissue.

On the other hand, Wilmore et al.,³³ showed a decrease in body mass index and abdominal fat by training on a cycle ergometer for 3 days/week for 6 weeks because there was decrease in total amount of stored calories. This decrease in energy stores is obviously the results of a negative energy balance so that exercise produces decrease in energy intake leading to a reduction in weight.

Oppert and Balarac,¹⁹ demonstrated that cycling can be an effective form of exercise for weight loss and weight control. Also, improvements were seen in cardiovascular function with a reduction in total body weight and percentage of body fat.

Also the results of this study were supported with using acupuncture in treating adult obese subjects by Kan, et al.,¹¹, Cabvolgu, et al.,⁴ and Zhao, et al.,³⁵ where they found that using acupuncture with diet resulting in reducing the weight of adult obese intestinal motility and metabolism as well as emotional factors such as stress. They also found that acupuncture increases the neural activity in the ventromedial nuclei of the hypothalamus and in the levels of enkephalin, beta endorphin and serotonin in plasma which suppress appetite and has lipolytic effect.

It has been reported that acupuncture application therapy in obesity treatment is effective in producing weight loss. It can affect appetite, intestinal motility, and metabolism, as well as emotional factors such as stress²³.

Increases in neural activity in the ventromedial nuclei of the hypothalamus, in tone of the smooth muscle of the stomach and in the levels of enkephalin, beta endorphin serotonin in plasma and brain tissue have also

been observed with the application of acupuncture²⁹.

Acupuncture also stimulates the auricular branch of the vagal nerve and raises serotonin level, thus suppressing appetite³⁵.

It is thought that the increase in plasma levels of beta endorphin after acupuncture application can contribute to the body weight loss in obese people by mobilizing the body energy depots through lipolytic effect⁴.

The effect of application of acupuncture in obese women decrease the serum total cholesterol, triglyceride and LDL cholesterol levels by increasing the serum beta endorphin level. This lipolytic effect may also reduce the obesity by mobilizing the energy stored that result in weight reduction³.

Acupuncture combined with diet therapy is an effective method for reducing weight and metabolism of lipids which has a slimming mechanism²⁹.

The effect of acupuncture therapy on serum leptin level of the patient is possibly one of the mechanisms of acupuncture in reducing body weight¹¹.

Acupuncture, auricular point sticking combined with diet are a better program for slimming, decreasing appetite and promoting lipid decomposition metabolism⁴.

The combination of a low-calorie diet and acupuncture is characterised by a higher efficacy than a low calorie diet alone in lowering body weight, body mass index and waist-to-hip-ratio³¹.

Acupuncture can increase excitability of the satiety center, with a better long-term effect³⁵.

Caloric restriction has remained as the ministry of treatment for obesity. It improves most of the lipid abnormalities, except H.D.L. level which decreased further. Diet ranges from mild caloric restriction to total starvation, one of the best ways to achieve healthier weight is to adopt a healthful diet with an energy intake that doesn't exceed expenditure, is low in fat, and provides adequate amounts of all food groups, including whole grains and cereals, fruits and vegetables⁷.

Klien and Romijin,¹² concluded that, the more restrictive diet, the more rapid weight loss, but the greater the risk of non compliance. In general a caloric deficit of

about 7700 kcal leads to a loss of about one kilogram of fat. Estimation of total daily caloric needs (about 25-30 kcal per kg of body weight) allow one to calculate the daily caloric deficit required to achieve a given rate of weight loss.

Paul²⁰, studied the effects of 28 days, of a very low calorie diet (382 kcal/day) on the beta adrenergic lipolytic response and nutritive blood flow in adipose tissue. This study demonstrates an increase in the lipolytic responses to isoprenaline and dobutamine during the hypocaloric diet. One benefit of the very low calorie diet is the rapid loss, often 3-4 pounds or more per week, and the rapid medical improvement, such as significant reduction in blood pressure, decrease in serum cholesterol of 20% -25% and dramatic lowering of glucose level in diabetics.

It was concluded that, triple therapy in the form of (exercises, acupuncture and diet) had a significant effect on weight reduction in adult morbid obese men which is superior to intra-gastric balloon and in our opinion, it is the greatest choice for physiotherapists to deal with such cases with a non-invasive modalities and to avoid surgical interference.

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الملخص العربي

العلاج الثلاثي مقابل بالون داخل المعدة في علاج سمنة الرجال المفرطة

تهدف هذه الرسالة إلى دراسة تأثير العلاج الثلاثي مقابل بالون داخل المعدة في علاج سمنة الرجال المفرطة تم إجراء هذا البحث على أربعين مريضاً بالسمنة المفرطة وقد قسمت عينة البحث إلى مجموعتين متساويتين ، المجموعة الأولى : وتحتوي هذه المجموعة على عشرين مريضاً تم زرع بالون داخل المعدة لهم ، والمجموعة الثانية : وتحتوي هذه المجموعة على عشرين مريضاً والذين تلقوا برنامج العلاج الثلاثي والمكون من : (نظام غذائي، تمرينات هوائية ، وابر صينية) . تم التقييم كالاتي: قياس مؤشر كتلة الجسم وقياس نسبة الكوليسترول والدهون الثلاثية بالدم قبل بداية أي بروتوكول علاجي وبعد ستة أشهر، وذلك للمجموعتين. أظهرت النتائج وجود فروق ذات دلالات إحصائية عالية ووجود نقصان واضح بالنسبة لمؤشر كتلة الجسم ودهون المصل في المجموعة الثانية عنها في المجموعة الأولى . وبذلك فإن العلاج الثلاثي يأتي لاختيار أول لعلاج السمنة المفرطة و يليه زرع بالون داخل المعدة لاختيار ثاني .

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