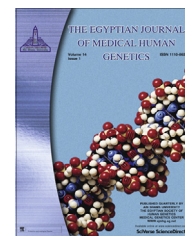




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## ORIGINAL ARTICLE

# Conservative therapy versus intra-gastric balloon in treatment of Prader-Willi Syndrome morbid obesity

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### KEYWORDS

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**Abstract** *Background and purpose:* Prader-Willi Syndrome (PWS) is a complex multisystemic disorder characterized by hyperphagia, severe obesity and muscular hypotonia. So, it is essential to seek an ideal program to help in solving such a widespread problem. The purpose of this study was to investigate the effect of conservative therapy (diet and exercises) versus intra-gastric balloon in PWS patients. Ten children born with PWS from both sexes ranging in age from 8 to 15 years were assigned into two groups of equal number. Study group I received conservative therapy in the form of diet regimen (a low caloric diet) and aerobic exercises on a stationary bicycle while study group II underwent intra-gastric balloon. Evaluation procedures in the form of initial evaluation and measurement of Body mass index (BMI) and lipid profile parameters were conducted for each child of the two groups before and after 6 months of treatment. The results revealed no significant difference when comparing the pre-treatment mean values of the two study groups (I and II), while significant improvement was observed in all the measuring variables of the two groups when comparing their pre- and post-treatment mean values. Significant difference was also observed when comparing the post-treatment results of the two groups in favor of the study group I. It concluded that conservative therapy could be the first choice of treatment of PWS morbid obesity, while BioEnterics Intra-gastric balloon (BIB) came in the second choice.

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## 1. Introduction

Prader-Willi Syndrome (PWS) is a genetically determined disorder that affects approximately one in 14,000 people of both

genders. The genetic basis is the absent expression of the paternally active genes in the PWS critical region on chromosome 15 [1]. It is characterized by muscular hypotonia, ligament laxity, hyperphagia, severe obesity, short stature, hypogonadism, and dysmorphic features. Both hypotonia and excessive body weight may affect the development of motor and functional skills of PWS individuals. A central feature of the syndrome is an excessive appetite, with overeating behavior apparent as early as 2 years of age. In addition, people with PWS usually require special help at school, due to the presence of mild learning disabilities, as well as having a short stature and other phenotypic characteristics [2]. A proposed pathophysiological

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explanation for the overeating behavior is hypothalamic dysfunction with failure of the feedback mechanism which would normally lead to feelings of fullness and loss of feelings of hunger after eating [3].

The most widely accepted definition of obesity relates to the body mass index (BMI): weight (kg)/height ( $m^2$ ). Children above the 85th percentile are classified overweight and those above the 95th percentile, obese [4].

Caloric restriction has remained as the ministry of treatment of obesity. It improves most of the lipid abnormalities. One of the best ways to achieve healthier weight is to adopt a healthful diet with an energy intake that does not exceed expenditure, is low in fat, and provides adequate amounts of all food groups, including whole grains and cereals, fruits and vegetables [5].

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 rhythmically, increasing heart rate and breathing. Specific aerobic activities include walking, jogging, bicycling, swimming, tennis and cross-country skiing [6].

Surgical treatment of obesity is based on two techniques gastric – restricting technique (gastric band, stapling, and balloon) and gastric restricting and malabsorptive technique (Gastric bypass) [7].

BioEnterics Intra-gastric balloon (BIB). It is a liquid-filled, intragastric balloon model that decreases preprandial hunger, increases postprandial satiety, and promotes weight loss in the short term [8]. Additionally, the intra-gastric balloon is thought to help individuals to modify their eating habits by providing a self-education tool [9].

A clinical trial was conducted on PWS patients to compare between the effects of conservative therapy in the form of diet regimen (a low caloric diet) plus aerobic exercises on a stationary bicycle and intra-gastric balloon in reducing patients' weight.

## 2. Patients and methods and procedures

### 2.1. Patients

Ten PWS patients from both sexes were eligible for participation according to the following criteria: their ages ranged from 8 to 15 years, they had a body mass index more than 35. All patients were conscious and ambulant. Five PWS patients had the same surgical technique done by the same surgeon for the intra-gastric balloon group. Children were subsequently excluded for any of the following reasons: they had BMI < 30, esophagitis > grade 1, and hiatal hernia > 5 cm and medically unstable as determined by history or medical records, as cardiac patients.

Patients were classified into two equal groups; study group I, five patients received conservative therapy in the form of diet regimen (a low caloric diet) a well-balanced diet of 1,200 kcal/day and aerobic exercises on a stationary bicycle, while study group II, five patients underwent bioenterics intra-gastric balloon.

Evaluation procedures in the form of initial evaluation and measurement of BMI and lipid profile parameters were con-

ducted for each child of the two groups before and after 6 months of treatment.

### 2.2. Methods

All procedures were explained to the parents and participants; the experimental protocol was explained in detail for caregivers of the children before the initial assessment. Each of them signed a consent form prior to participation.

#### 2.2.1. Initial evaluation procedures

A diagnosis of PWS was made according to the Holm and Cassidy criteria and confirmed by genetic analysis using methylation test and/or fluorescence in situ hybridization (FISH) for chromosome 15 [10].

Each child was examined medically in order to exclude any abnormal medical problem.

#### 2.2.2. Estimation of lipid profile

After fasting for at least 12 h, 3 ml of venous blood was extracted from the dorsal hand vein and allowed to clot at 37 °C in the water bath, then serum was separated using a centrifuge for the estimation of serum triglycerides and cholesterol level [11].

#### 2.2.3. Measurement of body mass index

Weight and height scale: A valid and reliable weight and height scale was used. Then the body mass index was calculated: [Body mass index = body weight (kg)/height ( $m^2$ )]. It is plotted on percentile charts [12].

### 2.3. Treatment procedures

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

#### 2.3.1. For study group I

Conservative therapy group (dieting and aerobic exercises).

**2.3.1.1. Recommended diet regimen.** Children received a low calorie diet. The caloric intake was below 1200 cal/day. This diet was used for 3 days at a time and followed by 4 days normal eating and then repeated for 6 months [13].

##### Day 1:

**Breakfast:** skimmed milk with tea, ½ grapefruit, 1 slice toast and 1 cup peanut butter.

**Lunch:** ½ cup tuna or 1 slice cheese, 1 slice toast.

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

##### Day 2:

**Breakfast:** skimmed milk with tea, 1 egg, slice toast and ½ banana.

**Lunch:** 1 cup cottage cheese or ½ cup tuna, 5 saltine crackers.

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

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