Effects of Intragastric balloon on obesity in obese Korean women for 6 months post removal

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Research article

Keywords: Obesity, Intragastric balloon, Eating habits, Skeletal muscle mass

DOI: https://doi.org/10.21203/rs.3.rs-35707/v1

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Abstract

Background: The prevalence of morbid obesity in Korean women has consistently been increasing, while the overall prevalence rate of obesity in Korean women seems to be stable. In addition to bariatric surgery, intragastric balloons (IGB), as a non-surgical therapy, have been reported to be effective in weight loss. However, the beneficial effects of IGB in Korean women with obesity have not been fully investigated. The aim of this study was to evaluate the changes in fat mass in Korean women with obesity who had undergone IGB treatment for 6 months.

Methods: Seventy-four women with obesity (BMI \(\geq 25.0\) kg/m\(^2\)) were recruited. Clinical data, including general information, comorbidities with obesity, anthropometric data, and changes in the body fat composition before and after IGB treatment, were obtained from the subjects.

Results: Most subjects had one or more comorbidities, such as osteoarthropathy and woman's disease, and had bad eating behaviors including irregular mealtimes, eating quickly, and frequent overeating. Body composition measurements showed that weight, fat mass and waist-hip circumference ratio decreased significantly at 6 months after IGB treatment. Especially, women with morbid obesity (BMI \(\geq 30.0\) kg/m\(^2\)) showed 33% excess weight loss. There was no significant difference in skeletal muscle mass and mineral contents after IGB treatment.

Conclusion: The present study suggested that 6 months of IGB treatment can be a beneficial treatment for obesity without muscle mass and bone mineral loss.

Background

According to the World Health Organization (WHO), obesity is defined as body mass index (BMI; body weight divided by height squared) \(\geq 25\) kg/m\(^2\) in East Asian populations, while overweight is defined as BMI between 23 and 24.9 kg/m\(^2\) \[1\]. The increasing rate of overweight and obesity in Korea, as well as Western societies, results in a serious public health problem. The prevalence of obesity has rapidly increased between 1998 (26.0%) and 2018 (34.6%) in Korean adults. The prevalence of obesity remained relatively stable from 25.2% in 2008 to 25.5% in 2018 for women, while the prevalence in men sharply increased from 2005 (35.3%) to 2018 (42.8%) \[2\]. Despite the stable findings on the overall prevalence rate of obesity in Korean women, a consistent increase in morbid obesity (BMI \(\geq 30.0\) kg/m\(^2\)) from 3.5% 2008 to 4.9% 2018 has been recorded \[2,3\].

Increased prevalence of obesity leads to a wide spectrum of diseases including hyperlipidemia, metabolic syndrome, hypertension (HTN), cardiovascular diseases (CVDs), type 2 diabetes mellitus (T2DM), cancer, and depression \[4,5,6\]. According to the 2019 Obesity Fact Sheet for Koreans, the incidence rates of T2DM, HTN, myocardial infarction, and stroke consistently increased as BMI increased between ages 20-39 years \[4\]. Seo et al. \[5\] also reported that T2DM, HTN, and hyperlipidemia were significantly higher in individuals with BMI \(\geq 25\) kg/m\(^2\). Additionally, the detrimental consequences of being obese have been
found to be especially harmful in women, elevating risks for mental health conditions, polycystic ovary syndrome (PCOS), endometriosis, and cancer, including endometrial and breast cancer [7,8,9].

The final goal of obesity treatment is to reach and stay at an ideal body weight. There are several methods that have been used to treat obesity, such as lifestyle modifications (diet and behavior), exercise, medications, endoscopic procedures, and surgery [10]. Diet and behavior modification and exercise are conventional treatment methods, but many studies reported that lifestyle modifications might fail at sustaining weight loss [11,12,13]. Some researchers also suggest that traditional therapy is not very effective in T2DM patients with severe obesity [14]. Diet and behavior modifications, and exercise, with or without medication is the best initial treatment method; however, methods such as bariatric surgery or endoscopic procedures, are needed for individuals with severe obesity [15]. Bariatric surgery, including gastric bypass (GBP), adjustable gastric band, sleeve gastrectomy, and duodenal switch, has been reported to be effective in the long-term for weight loss. Despite these advantages, surgery should be considered only for patients with BMI $\geq 35 \, \text{kg/m}^2$ who have failed non-surgical methods (with or without medications) and who have obesity-related complications. Further, the bariatric surgery is limited due to its serious complications, such as nutritional shortages, gallstones, ulceration, and hernias [16].

Intragastric balloons (IGB), a non-surgical therapy, are designed for weight loss and have minimal side effects compared to bariatric surgery [17]. The IGB filled air or saline solution of 400-700 mL is generally placed in the stomach to occupy space and reduce gastric capacity, resulting in weight loss [18]. The most common complications of IGBs include vomiting, nausea, and a treatment duration of 6 months, but treatment side effects are minimal compared to bariatric surgery. The End-ball approved by the Ministry of Food and Drug Safety, and the most generally used IGB treatment in Korea, is made of smooth spherical elastic polyurethane [19].

IGB could play a beneficial role in reducing obesity by reducing stomach volume with minimal side effect compared to surgery. However, the beneficial effects of IGB in Korean women have not been fully investigated. Therefore, this study aimed to evaluate the effects of IGB treatment for 6 months on obesity in Korean women.

**Methods**

**Subjects and study design**

This clinical study was a retrospective study, using subjects’ medical records. We analyzed data from 74 women patients with obesity (BMI $\geq 25 \, \text{kg/m}^2$) who received IGB treatment. The study included data collected during the period from February 2016 to July 2017. Data retrieved from subjects’ medical records included information on age, sex, weight, height, body composition, comorbidities with obesity, and health-related behaviors. We analyzed their medical records before IGB and 6 months after IGB. Subjects whose BMI was less than 25 kg/m$^2$, were under 18 years of age, were males, or had no medical records before and after IGB were excluded from the study. Changwon National University's Internal
Review Board (IRB) approved this retrospective medical record review (IRB No. 1040271-201711-HR-030). We analyzed their medical records before IGB, 1, 3, and 6 months after IGB treatment.

Anthropometric analysis

Anthropometric measurements were obtained from all subjects. Height and weight were measured with a digital scale. BMI was calculated by dividing subject’s weight (kg) by the square of subject’s height (m²). Body fat mass (BFM; kg), percent body fat (PBF; %), and skeletal muscle mass (SMM; kg) were measured using bioimpedance analysis (InBody 3.0; Biospace, Seoul, Korea). Waist circumference (WC) and hip circumference (HC) were measured with a flexible and substantial tape. Waist-to-hip ratio (WHR) was calculated as the waist circumference divided by hip circumference. Anthropometric measurements and body composition data were measured before and 1, 3, and 6 months after IGB treatment. Percentage of excess weight loss (%EWL) was generally calculated using the formula: %EWL = (preoperative weight − initial weight) ÷ (initial weight − ideal body weight (IBW)) ×100.

General characteristics, lifestyle, and eating habits questionnaire

For all the subjects, general characteristics, eating habits, and health related lifestyle habits, were analyzed using questionnaire surveys and medical interview on the first visit. The forms were prepared and consisted of two different categories: 1- General characteristics and lifestyle habits (marital status, occupation, smoke status, alcohol intake, presence of a disease related with obesity), 2- Eating habits (number of mealtimes, time of meal, meal speed, and overeating frequency).

Statistical analysis

All data are represented as mean ± standard deviation (SD) and the statistical significance was set at $P < 0.05$. The data from the questionnaire surveys were compared using the $\chi^2$ test. In addition, the changes in weight and body composition determined before and at 1, 3, and 6 months after IGB treatments were analyzed using one-way ANOVA and post-hoc Duncan’s test. The collected data of subjects were analyzed using IBM SPSS statistics version 24 software package (IBM Corp., Armonk, NY, USA).

Results

General characteristics

A total of 74 subjects were enrolled in this study, general characteristics are shown in Table 1. The mean BMI of subjects was 31.0 ± 4.2 kg/m². A total of 43.2% of the subjects had a BMI and age within $25 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ kg/m}^2$ and $30 \text{ years} \leq \text{age} \leq 39 \text{ years}$, respectively. With regard to alcohol drinking, 60.8% of the subjects responded “yes”. The smoking response rate for “no” was 70.3% in the subjects. According to the questionnaire, 42 subjects (56.8%) had obesity related complications. Osteoarthropathy (20.3%) and woman’s disease (18.9%) were more frequently found in these subjects. All subjects had tried
non-surgical therapy, such as pharmacotherapy (89.2%), exercise (85.1%), and diet modifications (71.6%) before the IGB treatment (Table 2).

Table 1

Table 2

**Eating habits**

Results from the eating habits of the study subjects are shown in Table 3. With regard to meal frequency per day, 35.6% and 42.4% of the subjects reported with “Irregular” and “2 times”, respectively. Furthermore, the mealtime response rate for “Irregular” was also 49.3%. Most (46.5%) subjects finished their meals within 10 minutes and 52.2% of the subjects reported overeating 2-3 times per week. Thus, most subjects tended to eat at irregular times, ate fast (within 10 minutes), and had overeaten 2-3 times per week.

Table 3

**Changes in body composition in subjects**

Body composition analyses before and after IGB are presented in Table 4. The results from anthropometrics indices before and after IGB showed significant reduction in body weight, BMI, BFM, PBF, and WHR at 6 months after IGB treatment. There were no statistically significant differences in skeletal muscle mass and mineral contents after IGB treatment. The rate of weight loss, BFM loss, and WHR loss were 8.8%, 14.3%, and 2.6%, respectively, at 6 months after IGB treatment. Especially, the decrease rate of the PBF was highest among the anthropometric measurements (Figure 1). The decreasing rate of PBF was significantly higher from 1 month to 3 months after IGB, whereas the decreasing rate of body weight and WHR were significantly higher from baseline to 1 month after IGB (Figure 2). Particularly, severely obese subjects (35 kg/m$^2$ ≤ BMI < 40 kg/m$^2$) showed greater weight loss (-11.7%, Figure 3).

Table 4

Figure 1, 2, 3

**Changes in body composition according to marital status and degree of obesity**

According to their marital status (Figure 4), the ratio of changes in body weight tended to decrease after IGB in the not married group (-7.4 ± 8.4%), compared to the married group (-9.1 ± 5.6%). However, there was no significant difference in the ratio of changes in body weight between the two groups. Changes in BMI between baseline and after 6 months in morbidly obese (BMI ≥ 30.0 kg/m$^2$) subjects are presented in Table 5. The rate of morbidly obese subjects decreased after IGB treatment from 56.8% to 36.5%. The %EWL of morbidly obese subjects (BMI ≥ 30 kg/m$^2$) was presented at 33.0 ± 28.4%.

Figure 4
Table 5

Conclusions

During the past few decades, the prevalence rates of obesity have been rapidly increasing worldwide and had reached a serious point. According to WHO, over 650 million (13%) of the world's adult population were obese in 2016 [20]. Thus, obesity has become a serious public health problem worldwide and can result in obesity-related diseases. We investigated the beneficial effects of IGB treatment on obesity in Korean women with obesity. Seventy-four women were recruited, and their general characteristics, eating habits, and health related-life style body composition, were analyzed.

As a result of the analysis of general characteristics and health-related lifestyle factors, more than half of the subjects had one or more comorbidities, such as osteoarthropathy and woman's disease. Osteoarthropathy is a syndrome that includes clubbing of the toes and fingers, periostitis of joint and long bones (radius, distal tibia, femur), and osteoarthritis [21]. Obesity is characterized by a systemic low-grade inflammatory status, leading to the development of metabolic diseases [22]. Obesity and pathogenesis of osteoarthropathy are not known; imbalanced adipokine expression leading to the remodeling and destruction of joint tissue has been reported [23,24]. Reyes et al. [25] reported that as the BMI increased, the risk of knee osteoarthritis increased. Compared to normal weight, as the degree of obesity increased, the risk of irregular menstruation increased; at 20-24 years, the risks increased by 33.3%. BMI was also strongly associated with the risk of breast cancer among postmenopausal women. Maternal complications with increase in BMI in women [26]. Our results are in line with those of previous studies that showed that increase in obesity greatly elevated the risk of obesity-related complications [25,26]. Thus, weight loss after IGB treatment is thought to effectively alleviate obesity, suggesting an improvement in osteoarthritis and women's disease.

The lack of exercise, sedentary lifestyle, and unhealthy eating habits are reported as the main causes of excess body fat accumulation [27,28]. In a study by Hassan et al. [27], most obese and overweight Egyptian women, were engaged in health risk behaviors and unhealthy dietary patterns (the low intake of fruits, vegetables, and milk, the increasing consumption of snacks, sweets, salts, and soft drinks). Korean children in the overweight group were also significantly more likely to overeat and ate rapidly compared with the normal group [28]. In a study by Kang et al. [29], regarding the eating habits, high response rates for “Consumed meal quickly (less than 10 minutes)”, “Preference of oily foods”, and “A tendency to eat until the stomach is full” were observed in metabolically abnormal obese women. Our study also showed that most obese subjects had negative eating habits, including eating at irregular times, eating fast (within 10 minutes), and overeating frequently (2-3 times per week), which was consistent with previous studies [27-30].

The Garren–Edwards Gastric Bubble was the first United States Food and Drug Administration-approved IGB in 1985 [30]. IGBs that were more effective in helping promote weight loss have consistently been developed over the last 20 years. The effect of IGB on obesity is not fully understood. IGB with a volume
of 400 mL or greater may also lead to feelings of satiety by delaying gastric emptying and finally reducing their food intake [18]. Additionally, evidence suggests that IGB suppresses food intake through the vagal signaling by modulated gastric mechanoreceptors [31]. The Bioenteric intragastric balloon (BIB), also known as ORBERA, has been most widely used in IGB treatment. BIB is made of silicone, which is thicker than polyethylene, and the balloon volume is thus significantly bigger and has a high incidence of complications [32]. Buzga et al. [32] reported a mean weight loss of 13.9 kg with an EWL of 37.9% in 20 patients in 6 months after End-ball treatment. Keren and Rainis [33] reported a mean weight loss of 23.5 kg and 39.2% EWL in 114 subjects who were treated the End-ball; the weight loss significantly continued for 1 year after End-ball removal. Our study also showed that body weight, body fat, and WHR significantly decreased at 6 months after IGB treatment. Especially, patients with morbid obesity (BMI ≥ 30 kg/m²) showed a mean %EWL of 33.0%.

The results of this study also showed that SMM and mineral contents were not significantly different after IGB treatment with adverse reduction in body fat mass. Obesity is negatively associated with muscle mass, which detrimentally affects muscle function. Obesity may induce an increase in intramuscular adipose tissue resulting in impaired muscle strength and mobility [34]. Reduced muscle function is a crucial predictor of serious problems, including the restriction of physical activity, mobility disability, hip fracture, falls, and increased mortality rate [35]. Thus, subjects with obesity also tended to be have an increased risk of fracture in peripheral sites [34]. Bone mineral loss can accelerate the risk of hip fracture and osteoporosis in women. Nevertheless, excessive weight loss can also add to the increasing risk of fracture by inducing muscle mass loss and imbalance in bone metabolism [36]. Thus, maintenance of muscle and bone mineral should be the main focus of therapeutic strategies for obesity. Previous studies have reported that bone mineral contents significantly decreased after bariatric surgery. Bone mineral density (BMD) at the hip tended to decline to an extent of 1 year after GBP [37]. Carrasco et al. [38] reported that GBP results in a significant loss in BMD with changes in body composition in women with obesity. Therefore, IGB, which has less side effects, muscle mass loss, and mineral reduction, is considered to play a key role in obesity treatment as compared to pharmacotherapy and surgery, especially in patients with mild to moderate obesity who failed previous treatment methods.

However, this study had some limitations. First, we did not investigate the improvement of obesity-related complications after IGB and metabolic parameters before and after IGB. Therefore, we could not assess how IGB helps with the improvement of metabolic status related obesity, maintenance of SMM, and bone mineral with sustained weight loss in subjects with obesity. Additionally, the time of exercise or physical activity on weekends was not included in the questionnaire survey. In conclusion, most Korean women with obesity had comorbidities related with obesity, such as osteoarthropathy and woman's disease and had negative eating habits. Additionally, IGB can be of beneficial effect in ameliorating obesity without adversely decreasing SMM and bone mineral. We suggest that further studies be conducted to evaluate the changes in metabolic and inflammatory biomarkers in Korean women with obesity who have received IGB treatment.
Abbreviations

WHO: World Health Organization; BMI: body mass index; HTN: hypertension; CVDs: cardiovascular diseases; T2DM: type 2 diabetes mellitus; PCOS: polycystic ovary syndrome; GBP: gastric bypass; IGB: intragastric balloons; BFM: body fat mass; PBF: percent body fat; SMM: skeletal muscle mass; WC: waist circumference; HC: hip circumference; WHR: waist-to-hip ratio; %EWL: percentage of excess weight loss; IBW: ideal body weight; BMD: bone mineral density.

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Changwon National University’s Internal Review Board (IRB) approved this retrospective medical record review (IRB No. 1040271-201711-HR-030). Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (NRF-2016R1D1A1B03935660). The funding body played no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Authors' contributions

Review concept and design: JYE, HCL; drafting of the manuscript: HJP, HNC; critical revision of the manuscript: JYE.

Acknowledgements

Not applicable
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Tables

Table 1. General characteristics of the subjects
| Age (year) | Total (N=74) |
|-----------|-------------|
| 20~29     | 23 (31.1%)  |
| 30~39     | 32 (43.2%)  |
| 40~49     | 13 (17.6%)  |
| ≥ 50      | 6 (8.1%)    |
| Height (cm)| 163.37 ± 5.41 |
| Weight (kg)| 82.74 ± 12.70 |
| Body mass index (kg/m²) | 30.95 ± 4.21 |
| 25~29.9   | 32 (43.2%)  |
| 30~34.9   | 28 (37.8%)  |
| 35~39.9   | 12 (16.2%)  |
| ≥ 40      | 2 (2.7%)    |
| Marital status |         |
| Married   | 27 (36.5%)  |
| Not married | 47 (63.5%) |
| Occupation |               |
| Manual worker | 12 (17.4%) |
| Office clerk | 50 (72.5%) |
| Students   | 6 (7.9%)    |
| Unemployed | 1 (1.3%)    |
| Alcohol drinking |         |
| Yes       | 45 (60.8%)  |
| No        | 29 (39.2%)  |
| Smoking   |               |
| Yes       | 22 (29.7%)  |
| No        | 52 (70.3%)  |
| Complication |         |
| 42 (56.8%) |               |
| Osteoarthropathy | 15 (20.3%) |
| Condition                  | Count (Percentage) |
|----------------------------|--------------------|
| Woman disease              | 14 (18.9%)         |
| Sleep disturbance          | 5 (6.8%)           |
| Diabetes                   | 5 (6.8%)           |
| Psychical disorder         | 5 (6.8%)           |
| Hypertension               | 5 (6.8%)           |
| Asthma                     | 4 (5.4%)           |
| Fatty liver                | 4 (5.4%)           |
| Others                     | 3 (4.1%)           |

Values are presented as mean ± SD or number (%). The data from the questionnaire surveys were compared using the $\chi^2$ test.

### Table 2. Experience Of non-surgery treatments of the subjects

| Treatment                                      | Count (Percentage) |
|-----------------------------------------------|--------------------|
| Weight control experience                     | Total (N=74)       |
| Yes                                           | 74 (100.0%)        |
| Diet therapy                                  | 53 (71.6%)         |
| Exercise therapy                              | 63 (85.1%)         |
| Behavior modification therapy                  | 1 (1.4%)           |
| Pharmacotherapy                               | 66 (89.2%)         |
| Others                                        | 24 (32.4%)         |

Values are presented as number (%). Multiple choices are available. The data from the questionnaire surveys were compared using the $\chi^2$ test.

### Table 3. Eating habits of subjects
Eating habits

| Meal number of times | Total (N=74) |
|----------------------|-------------|
| Irregular            | 21 (35.6%)  |
| 1 time               | 1 (1.7%)    |
| 2 times              | 25 (42.4%)  |
| 3 times              | 12 (20.3%)  |

| Mealtime               |             |
|------------------------|-------------|
| Fixed time             | 10 (14.9%)  |
| Sometimes irregular    | 24 (35.8%)  |
| Irregular              | 33 (49.3%)  |

| Meal speed (minutes)   |             |
|------------------------|-------------|
| More 20                | 10 (14.1%)  |
| 10~20                  | 28 (39.4%)  |
| Within 10              | 33 (46.5%)  |

| Overeating (per a week)|             |
|------------------------|-------------|
| Rarely (≤ 1 time)      | 2 (3.0%)    |
| Sometimes (2-3 times)  | 35 (52.2%)  |
| Often (≥ 4 times)      | 30 (44.8%)  |

Values are presented as number (%). The data from the questionnaire surveys were compared using the $\chi^2$ test.

Table 4. Changes of body composition in baseline and after IGB treatment
|                      | Baseline (N=74) | 1 Month (N=74) | 3 Month (N=74) | 6 Month (N=74) |
|----------------------|----------------|----------------|----------------|----------------|
| Weight (kg)          | 82.74 ± 12.70<sup>a</sup> | 78.93 ± 12.26<sup>ab</sup> | 77.66 ± 11.75<sup>ab</sup> | 74.97 ± 12.22<sup>b</sup> |
| BMI (kg/m<sup>2</sup>)| 30.95 ± 4.21<sup>a</sup> | 29.62 ± 3.98<sup>ab</sup> | 29.21 ± 4.03<sup>ab</sup> | 28.24 ± 3.90<sup>b</sup> |
| Body fat (kg)        | 34.97 ± 9.18<sup>a</sup> | 32.86 ± 8.93<sup>ab</sup> | 31.02 ± 8.64<sup>ab</sup> | 29.20 ± 8.81<sup>b</sup> |
| PBF (%)              | 41.70 ± 5.53<sup>a</sup> | 41.06 ± 5.71<sup>ab</sup> | 39.37 ± 6.14<sup>ab</sup> | 38.30 ± 5.94<sup>b</sup> |
| WHR (%)              | 0.94 ± 0.04<sup>a</sup> | 0.93 ± 0.04<sup>ab</sup> | 0.92 ± 0.44<sup>ab</sup> | 0.91 ± 0.76<sup>b</sup> |
| SMM (kg)             | 26.14 ± 0.49 | 25.38 ± 0.46 | 25.19 ± 0.53 | 24.86 ± 0.47 |
| Protein (kg)         | 9.38 ± 1.03<sup>a</sup> | 9.04 ± 1.02<sup>ab</sup> | 9.15 ± 1.10<sup>ab</sup> | 8.96 ± 1.00<sup>b</sup> |
| ICW (L)              | 21.70 ± 2.38<sup>a</sup> | 20.90 ± 2.35<sup>ab</sup> | 21.16 ± 2.55<sup>ab</sup> | 20.74 ± 2.33<sup>b</sup> |
| ECW (L)              | 13.63 ± 3.42 | 12.84 ± 1.43 | 13.01 ± 1.51 | 12.78 ± 1.42 |
| Mineral (kg)         | 3.40 ± 0.40 | 3.31 ± 0.37 | 3.31 ± 0.37 | 3.29 ± 0.41 |

All values are means ± SD. Analyzed using ANOVA followed by the Duncan's multiple range test.

BMI, Body mass index; PBF, percent body fat; WHR, waist-hip ratio; SMM, skeletal muscle mass; ICW, intra cellular water; ECW, extra cellular water

*a, b values with different superscript letter are significantly different at \( P < 0.05 \).

Table 5. Changes of percent in initial morbidly obese women and excess weight loss percent.

|                      | Baseline (N=42) | After 6 Month (N=27) |
|----------------------|----------------|---------------------|
| Severe obesity       | 56.8%          | 36.5%               |
| %EWL                 |                | 33.0 ± 28.4%        |

Values are presented as number (%). % EWL, excess weight loss percent.
Figure 1

Changes of percent in weight, body fat, and waist-hip ratio at 1, 3, and 6 months after IGB treatment. *a, b values with different superscript letter are significantly different at P < 0.05.
Figure 2

Changes of percent in weight (A), waist-hip ratio (B), and body fat (C) according to duration after IGB treatment.
**Figure 3**

Changes of percent in weight according to baseline BMI.

**Figure 4**

Changes of percent in body weight according to marital status.