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Beneficial effects of intragastric balloon therapy associated with hormonal changes on weight loss and serum metabolic, inflammatory and liver parameters**

Korzyści leczenia balonem dożołądkowym związane ze zmianami hormonalnymi na masę ciała oraz metaboliczne, zapalne i wątrobowe parametry krwi

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Keywords

obesity, gastric balloon, weight loss, adipokines

Słowa kluczowe

otyłość, balon dożołądkowy, utrata masy ciała, adipokiny

Conflict of interest
Konflikt interesów

None
Brak konfliktu interesów

Summary

Introduction. Beneficial effect of intragastric balloon (IGB) on weight loss and obesity-related complications is still questionable and may be related to serum hormonal changes.

Aim. The aim of the study was to assess the safety and benefits of IGB therapy associated with hormonal changes in peripheral blood.

Material and methods. This was a prospective, observational study of 25 obese patients treated with an IGB with assessment of safety, weight loss, gastroesophageal reflux, serum laboratory tests, and circulating leptin and omentin. The consent of bioethical committee of Medical University of Bialystok, as well as written consent from all subjects were obtained. The study was supported by the Polish National Science Center grant No. N N402 456839.

Results. A six-month IGB therapy resulted in a significant BMI decrease. The mean % total body weight loss at 6 months was 15.55 ± 8.96 and did not significantly change at 12 months. A 25% excess weight loss was achieved by 52 and 56% patients at 6 and 12 months, respectively. The therapy decreased mean levels of aminotransferases, glucose, C-reactive protein, hemoglobin A1c, and insulin resistance (HOMA-IR). Patients with % excess weight loss less than < 25 had significantly higher levels of leptin and lower levels of omentin. Leptin levels correlated with HOMA-IR, insulin, and alanine aminotransferase levels. Omentin levels correlated positively with HDL-cholesterol and negatively with alanine aminotransferase. Reflux esophagitis was found in 5 and 3 patients before and after therapy, respectively. The frequency of typical reflux symptoms did not differ significantly before and after therapy. There were no serious adverse events except one partial balloon deflation found on the day of its planned removal. Up to 80% patients were satisfied with therapy.

Conclusions. IGB therapy is a safe and effective weight loss procedure and its beneficial effects on weight loss and several serum metabolic and liver function parameters are associated with hormonal changes.

Streszczenie

Wstęp. Korzyści leczenia balonem dożołądkowym (ang. *intragastric balloon* – IGB) wywierane na masę ciała oraz choroby związane z otyłością są wciąż przedmiotem dyskusji i mogą być zależne od zmian hormonalnych.

Cel pracy. Celem badania była ocena bezpieczeństwa oraz korzyści leczenia IGB związanych ze zmianami hormonalnymi we krwi obwodowej.

Materiał i metody. Prospektywne, obserwacyjne badanie 25 otyłych pacjentów z oceną bezpieczeństwa IGB oraz wpływu na redukcję masy ciała, chorobę refluksową przełyku (endoskopia, objawy), badania laboratoryjne oraz zmiany stężenia leptyny i omentyny w surowicy. Uzyskano zgodę komisji bioetycznej Uniwersytetu Medycznego w Białym-

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stoku oraz pisemne zgody pacjentów. Badanie przeprowadzono w ramach grantu NCN nr N N402 456839.

Wyniki. Zaobserwowano duży spadek BMI po 6 miesiącach terapii IGB. %TBWL (ang. *total body weight loss*) wyniósł 15,55 ± 8,9 i nie zmienił się znacząco po 12 miesiącach. %EWL (ang. *excess weight loss*) wynoszący co najmniej 25% uzyskano u 53% chorych po 6 miesiącach i 56% chorych po 12 miesiącach leczenia. Po leczeniu zaobserwowano znacząco niższe stężenia triglicerydów, aminotransferaz, glukozy, HbA1c i HOMA-IR. Zauważalnie wyższe stężenia leptyny i omentyny w surowicy wykazano u pacjentów z %EWL < 25 niż u pacjentów z %EWL > 25%. Stężenia leptyny korelowały z HOMA-IR, stężeniem insuliny i aktywnością aminotransferazy alaninowej. Stężenia omentyny korelowały pozytywnie ze stężeniem cholesterolu HDL i negatywnie z aktywnością aminotransferazy alaninowej. Refluksowe zapalenie przełyku stwierdzono u 5 i 3 chorych odpowiednio przed leczeniem i po nim. Nie wykazano różnicy w częstości zgłaszanych objawów refluksowych przed terapią i po jej zakończeniu. Nie zaobserwowano poważnych powikłań z wyjątkiem przypadku częściowej deflacji balonu stwierdzonego w trakcie planowego usuwania balonu. Satysfakcję z leczenia podało 80% chorych.

Wnioski. Leczenie balonem dożołądkowym jest bezpieczną i skuteczną metodą redukcji masy ciała. Korzystny wpływ na masę ciała oraz metaboliczne i wątrobowe parametry laboratoryjne związane są ze zmianami hormonalnymi w surowicy krwi.

INTRODUCTION

Obesity has become a major public health problem as it is a chronic inflammatory disease associated with an increased risk of several diseases, higher medical costs, and decreased quality of life and productivity. Effective weight loss can significantly improve obesity-related complications such as hypertension and diabetes (1-3). Conservative treatments that include diets, physical activity, and pharmacology have limited efficacy. The most effective method of weight loss is bariatric surgery. However, it is not available for all obese patients, e.g. those with a higher surgical risk. In addition, younger patients commonly desire to lose weight using non-surgical methods and there are those who need to lose weight before non-bariatric procedures. Therefore, endoscopic therapy such as an intragastric balloon (IGB) fills the gap between conservative methods and bariatric surgery and has been added by the American Society for Metabolic and Bariatric Surgery (ASMBS) to the list of approved procedures for obesity treatment. IGB therapy potentially has fewer serious adverse events and costs less than bariatric surgery (4-6).

IGB therapy has been shown to be effective in weight loss and can improve obesity-related comorbidities such as hypertension, hyperlipidemia, and diabetes (4-9). However, the achieved weight loss is smaller and may be temporary without multidisciplinary management including lifestyle modification and consultations with dieticians (4, 5). The weight loss afforded by IGB is mostly due to increased satiety and delayed gastric emptying. However, the mechanism of weight loss seems to be more complex. Is it known that in the pathogenesis of obesity and obesity-related complications several mechanisms are involved such as, gastrointestinal hormones, cytokines, and growth factors, inflammatory and immune responses, gut microbiota, the gut-brain axis, or adipokines released by adipose tissue (1-3). Previously, we found that obese patients when compared to non-obese patients had higher leptin levels and lower levels of adiponectin, ghrelin, and omentin and that bariatric therapies had an impact on their blood levels (10). We found that the percentage of total body weight loss positively correlated with adiponectin levels and negatively with leptin levels. Patients with adequate weight loss had significantly lower leptin levels than patients who failed to respond to treatment (10).

The efficacy of IGB therapy, including weight loss and improvement of several conditions associated with obesity, may be related to changes in blood levels of adipokines as well as gastrointestinal hormones. This paper presents the results of a prospective, observational study of 25 obese patients treated with IGB that assessed: i) 6- and 12-month weight loss; ii) adverse events and quality of life; iii) changes in laboratory blood tests (lipids, liver enzymes, glucose, C-reactive protein, hemoglobin A1c) and insulin resistance; and iv) levels of ghrelin, leptin, and omentin before and after therapy as well as in relation to laboratory tests and weight loss.

AIM

The aim of the study was to assess the safety and benefits of IGB therapy associated with hormonal changes in peripheral blood.

MATERIAL AND METHODS

This was a prospective, observational study of 25 consecutive patients (17M/8F) with a mean age of 44.2 ± 12.2 yrs treated with a 6-month IGB therapy in the Department of Gastroenterology and Internal Medicine, Medical University of Bialystok, Poland. The consent of bioethical committee of Medical University of Bialystok, as well as written consent from all subjects were obtained. The study was supported by the Polish National Science Center grant No. N N402 456839.

We included adult patients with a body mass index (BMI) of 40 or 35 kg/m^2 with at least one obesity

concomitant disease who failed to lose weight through diet and exercise alone. The exclusion criteria were as follows: prior gastric or bariatric surgery, large hiatal hernia (≥ 5 cm), esophageal motility disorders, esophageal strictures, potential upper gastrointestinal bleeding conditions, malignancies, liver failure, concurrent use of anticoagulation or aspirin therapy, coagulopathy, alcoholism or drug addiction, and a lack of patient cooperation. All patients provided written informed consent and the study protocol was approved by the local ethics committee and conducted according to the 1975 Declaration of Helsinki guidelines.

The intragastric balloon (Orbera, Allergan, Irvine, CA) was endoscopically placed in the stomach and filled with 500-550 ml of normal saline dyed with methylene blue. At the day of balloon placement all patients received intravenous hydration, proton pump inhibitor therapy, and an antiemetic (if necessary). All patients received lifestyle modification instructions including diet and exercise recommendations. Patients were asked to consume only clear liquids for the first 2 days after balloon placement and a full liquid diet on days 3 to 14. Soft food (1200-1500 kcal/d) was introduced from day 15 and normal textured food after 3 weeks. The balloon was removed after 6 months. Patients were instructed to consume a liquid only diet for 2-3 days before balloon removal. All procedures were performed under conscious sedation. All procedure and patient-related adverse events were noted.

All patients were followed up to one year and had ambulatory control visits with clinical and physical examinations and (if necessary) consultations with a dietician and psychologist. We assessed BMI (kg/m^2), the percentage of total body weight loss (%TBWL), and the percentage of excess weight loss (%EWL) after 6 and 12 months. A threshold of a minimum 25% EWL was used to distinguish between success and failure of weight loss (11). Patients with insufficient weight loss were next referred for bariatric surgery. In addition, the 36-item Short Form survey 36 (SF-36) (12, 13), typical reflux symptoms (heartburn, regurgitation), GerdQ self-assessment questionnaire score (14), and the results of an endoscopy were analyzed before and after therapy.

The homeostatic model assessment insulin resistance (HOMA-IR) as well as several laboratory tests were analyzed before and after 6 months of IGB therapy. Laboratory tests included leukocytes, hemoglobin, alanine aminotransferase, aspartate aminotransferase, glucose, insulin, hemoglobin A1c (HbA1c), C-reactive protein (CRP), d-dimer, total cholesterol, high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol, triglycerides, and electrolytes. In addition, we assessed the concentration of leptin, ghrelin, and omentin-1 levels in peripheral venous blood also before and after 6 months of IGB therapy. All measurements of leptin (Human Leptin Elisa, Biovendor), ghrelin (Human Ghrelin Total, RIA, Millipore), and omentin-1 (Human Omentin-1 Elisa, Biovendor) were performed according to manufacturers' instructions.

Statistical analysis

The STATISTICA 10.0 package was used for all analyses. Patients' characteristics were described using relative (%) frequency. Results were described as mean and SD. Comparisons of variables before and after treatment were performed with the Wilcoxon matched-pairs signed-ranks test or the paired sample t-test. Comparisons between tested groups were analyzed with the Mann-Whitney U-test. Correlations were performed by means of Spearman's coefficient. A p value less than 0.05 was considered as significant.

RESULTS

Baseline patient characterization

We included 25 patients with a mean BMI of 47.36 ± 8.89 kg/m^2. There were 15 (60%) patients with hypertension, 3 (12%) patients with cardiac failure, 2 (8%) patients with obstructive sleep apnea, 4 (16%) patients with asthma, and 3 (12%) patients with hyperuricemia. Eight patients (32%) had a diagnosis of diabetes and received antidiabetic drugs. Hepatic steatosis was found in 7 (28%) patients.

All patients had an endoscopy before the IGB therapy. The study was normal in 18 (72%) patients. Reflux esophagitis was found in 5 (20%) patients and hiatal hernia in 2 (8%) patients. Typical reflux symptoms such as heartburn and regurgitation were reported by 7 (29.0%) and 17 (68%) patients, respectively. The mean baseline GERDQ questionnaire score was 6.36 ± 1.82.

Tab. 1. The impact of intragastric balloon therapy on body mass index, blood pressure, and serum hormones

Parameter, mean (SD)	Before therapy	After therapy	p
Body mass index (kg/m^2)	47.36 ± 8.89	40.16 ± 9.57	< 0.0001
Body mass (kg)	142.68 ± 33.55	122.44 ± 32.87	< 0.0001
Systolic blood pressure (mmHg)	127.60 ± 14.87	121.33 ± 8.27	0.1024
Diastolic blood pressure (mmHg)	82.00 ± 12.91	80.93 ± 6.45	0.8241
Serum hormones levels			
Leptin (ng/mL)	41.56 ± 24.12	24.12 ± 17.17	0.0021
Omentin (ng/mL)	496.88 ± 231.49	503.52 ± 201.00	0.9317
Ghrelin (pg/mL)	632.85 ± 209.06	617.95 ± 221.38	0.3967

Tab. 2. The laboratory tests before and after 6 months of IGB therapy

Parameter, mean (SD)	Before therapy	After therapy	p
Hemoglobin (g/dL)	14.26 ± 1.22	14.06 ± 1.21	0.5583
Mean corpuscular volume (f/L)	88.20 ± 4.37	88.05 ± 4.19	0.6389
Alanine aminotransferase (IU/L)	56.38 ± 38.56	30.52 ± 16.84	0.0017
Aspartate aminotransferase (IU/L)	37.58 ± 25.30	24.30 ± 8.24	0.0012
Total cholesterol (mg/dL)	200.04 ± 35.41	199.09 ± 46.98	0.8329
LDL cholesterol (mg/dL)	130.44 ± 33.22	130.36 ± 40.17	0.5316
HDL cholesterol (mg/dL)	45.32 ± 12.12	46.59 ± 13.10	0.3905
Triglycerides (mg/dL)	169.08 ± 76.89	124.14 ± 64.71	0.0113
Glucose (mg/dL)	102.84 ± 22.46	95.52 ± 12.46	0.0457
Hemoglobin A1c (%)	6.00 ± 0.85	5.5 ± 0.85	0.0002
Insulin (uIU/mL)	17.48 ± 10.62	12.43 ± 8.18	0.0152
C-reactive protein (mg/L)	6.78 ± 7.17	4.41 ± 5.36	0.0003
D-dimer (μg/mL)	0.28 ± 0.12	0.71 ± 1.96	0.8129
Na (mmol/L)	139.46 ± 1.32	139.04 ± 1.55	0.5862
K (mmol/L)	4.32 ± 0.25	4.21 ± 0.43	0.3301

Weight loss

The mean BMI significantly decreased compared to its baseline value after 6 months of IGB therapy (tab. 1). The mean %TBWL was 15.55 ± 8.96%. In addition, the 25% EWL was achieved by 13 (52%) patients, and a 10% EWL was achieved by 23 (92%) patients.

Weight loss was maintained by all patients after 12 months of IGB therapy except for one patient who had weight gain after removal of the IGB removal. However, there were no significant differences in the median BMI between 6 and 12 months (40.16 ± 9.57 vs 41.68 ± 10.72, kg/m^2, p = 0.4229) and %TBWL (15.55 ± 8.96 vs 15.83 ± 10.26, %, p = 0.9702). The 25% EWL was noted in 14 (56%) patients at 12 months.

Laboratory tests before and after 6 months of IGB therapy

Laboratory tests were assessed before and after 6 months of IGB therapy. We found a significant decrease in the mean levels of aminotransferases, glucose, CRP, HbA1c, and triglycerides. We did not observe significant differences in the levels of total, LDL, and HDL cholesterol (tab. 2). In addition, the mean HOMA-IR was significantly decreased after therapy (3.94 ± 1.90 vs 2.97 ± 1.89, p = 0.0106).

The levels of HOMA-IR after therapy correlated positively with alanine aminotransferase levels (R = 0.5064; p = 0.0162). The BMI after therapy also correlated positively with level of alanine aminotransferase (R = 0.4696, p = 0.0238), HDL-cholesterol (R = -0.4959, p = 0.0189), insulin (R = 0.4487, p = 0.0362), and CRP (R = 0.4316, p = 0.0397).

Ghrelin, leptin, and omentin concentrations before and after 6 months of IGB therapy

The mean concentration of leptin significantly decreased with therapy. There were no significant differences before and after therapy in the mean concentration of ghrelin and omentin (tab. 1).

However, the one patient who achieved 25% EWL compared to the remaining patients who did not achieved 25% EWL had significantly lower leptin levels (17.52 ± 12.92 vs 32.70 ± 18.81, p = 0.0178) and higher omentin levels (596.22 ± 211.15 vs 410.83 ± 145.60, p = 0.024).

The levels of leptin 6 months after therapy correlated positively with HOMA-IR (R = 0.5625; p = 0.0098), insulin (R = 0.5719, p = 0.0084), and alanine aminotransferase levels (R = 0.4563, p = 0.0038). The levels of ghrelin correlated negatively with insulin (R = -0.5906, p = 0.0078) and positively with total cholesterol (R = 0.5294, p = 0.0198) and triglycerides (R = 0.4649, p = 0.0449). Omentin levels correlated positively with HDL-cholesterol (R = 0.5057, p = 0.0323) and negatively with alanine aminotransferase (R = -0.5831, p = 0.0111).

Complications/adverse events

Vomiting (16/25, 64%), nausea (22/25, 88%), and abdominal pain (14/25, 56%) were the most common adverse events reported by patients after IGB placement and resolved within the first week. These symptoms were occasionally present in 48% patients one week after IGB placement and in 16% after 1 month. Only one patient was admitted to the hospital due to severe abdominal pain and vomiting at the end of the first month. Control tests, including abdominal CT, did not show signs of balloon deflation nor migration. Patient received proton pump inhibitor therapy and an antiemetic drug and remained asymptomatic to the end of the IGB therapy. However, this patient had abdominal pain while traveling by plane the day before the planned IGB removal. At the time of balloon removal, we found a partially deflated balloon that remained in the stomach. We did not observe any complications associated with balloon placement and removal.

At 6 months, there were no significant differences in the mean GERDQ questionnaire score (7.04 ± 2.39) compared to its baseline values (p = 0.4769). Typical reflux symptoms before as well as after therapy were reported by 10 patients while 4 patients did not report any symptoms. In addition, there were 8 patients with a typical reflux syndrome before therapy that were not present after therapy. In contrast, reflux symptoms presented in 3 patients after therapy.

Endoscopy after 6 months of IGB therapy was normal in 22 (88%) patients. Reflux esophagitis (*de novo*) was observed in 3 (12%) patients. All patients with baseline reflux esophagitis had normal endoscopy after therapy. We did not observe any adverse events such as stomach erosions and ulcers, bleeding, esophageal mucosal tears, and aspiration pneumonia.

Therapy satisfaction

The majority of patients (20/25, 80%) were satisfied with the therapy. Five patients were not satisfied due to insufficient weight loss (4 patients) and adverse events (vomiting, abdominal pain in 1 patient). Eight (40%) patients (including 7 patients who did not achieve 25% EWL) were further referred for bariatric surgery.

We did not find significant differences in the total SF-36 score before and after therapy. However, a significant improvement was observed in physical functioning score (67.0 ± 25.94 vs 74.9 ± 23.06, p = 0.0033).

DISCUSSION

Our study shows that IGB therapy is an effective weight loss therapy that decreases insulin resistance and inflammation as well as triglyceride, glucose, and aminotransferase levels. Its beneficial effects are associated with changes in peripheral blood hormones levels. We observed that patients with at least a 25% EWL had significantly lower leptin and higher omentin levels than patients with insufficient weight loss and also found several statistically significant correlations between their levels and laboratory test results.

IGBs have been used for the treatment of obesity for many years and thousands of balloons were implanted before their approval by the Food and Drug Administration (FDA) that was based on pivotal studies that studied their efficacy and safety profiles (6). Recently, more attention has been paid to these profiles after publication of two alerts by the FDA to all health care providers about cases of pancreatitis and deaths associated with the Orbera and ReShape IGBs (15). This resulted in several meta-analyses and new post-approval studies (16, 17). IGB therapy is an invasive procedure and careful patient selection and education including the details and nature of this procedure are key elements in decreasing adverse events. Although our study group was small, we did not have any serious complications except one case of a partially deflated balloon that was found during planned balloon removal. The most commonly observed adverse events in our study, and similarly described in other studies, were vomiting, nausea, and abdominal pain that occurred after balloon placement and resolved within the next few days. The impact of endoscopic and surgical bariatric procedures on gastroesophageal reflux has been assessed by several authors, but the conclusions are contradictive (18, 19). In this prospective study we did not observe an increase in gastroesophageal reflux based on the assessment of reflux symptoms and endoscopic reflux esophagitis. In addition, most patients were satisfied with therapy.

In this study, a 6-month IGB therapy resulted in a significant BMI decrease and the mean %TBWL was 15.55 ± 8.93. The weight loss was maintained 6 months after balloon removal in all except one patient who presented with weight gain. The recommended 25% EWL was achieved by 52 and 56% patients by 6 and 12 months, accordingly. Several studies have shown that IGB therapy results in a significant BMI decrease and can provide at least 10% TBWL (4-9). In contrast, a recent meta-analysis found a lower efficacy of IBG therapy. Based on a pooled weighted-mean %TBWL was 9.7% and the control-subtracted %TBWL was 5.6% at 6 months. The authors mentioned that similar weight loss can be achieved with the weight loss drug Qsymia (15). Several factors must be considered when analyzing the effects of IGB therapy on weight loss; e.g. short and long-term weight loss, additional therapies used, and patients cooperation and (self) motivation. IGB therapy is an effective weight loss therapy, but weight loss can be achieved and maintained only when IGB therapy is used in conjunction with lifestyle modification such as diet and exercise, and additional support of dieticians and psychologists. All patients in our study had outpatient clinic visits and received appropriate diet and exercise instructions.

Our study shows that IGB therapy has beneficial effects on several inflammatory, metabolic, and hepatic indices after 6-months. We observed a significant decrease of the levels of glucose, HbA1c, CRP, insulin resistance, aminotransferases, and triglycerides. Other authors also demonstrated that IGB therapy has beneficial effects on metabolic syndrome features and insulin resistance (8, 20, 21).

Gastrointestinal hormones and adipokines released by adipose tissue play a role in obesity and obesity-related complications. We have previously found that obese patients have higher leptin levels and lower levels of adiponectin, ghrelin, visfatin and omentin compared to non-obese controls (10). Leptin regulates energy hemostasis by controlling satiety, immune response as a proinflammatory factor, and insulin resistance (22, 23). Omentin is fat deposition-specific adipokine and its levels have been shown to be decreased in patients with obesity, diabetes, and polycystic ovary syndrome (24). Omentin has anti-inflammatory effects and its low plasma levels significantly correlated with an increase in the mean number of metabolic risk factors such as increased waist circumference, dyslipidemia, high blood pressure, and glucose intolerance (25).

Certain studies have described hormonal changes after IGB therapy (26-28). We previously observed a decrease of plasma leptin levels in patients treated with IGB, while the levels of hormones remained stable in patients treated with low-calorie diet and physical effort (26). In other study, we found that endoscopic and surgical bariatric therapies induced timeline changes in hormone levels in peripheral blood and that patients with adequate weight loss had lower leptin levels than patients with inadequate weight loss (10). In the current study, IGB therapy significantly decreased leptin levels but not ghrelin and omentin levels. However, the levels of hormones differed according to achieved weight loss. Patients with %EWL more than 25% had significantly lower leptin levels and higher omentin levels. Leptin and omentin levels correlated with several laboratory tests supporting their role in insulin resistance and lipid metabolism.

CONCLUSIONS

Although our study has some limitations including a small study group and short follow-up, its strength is its prospective design with complex assessment of the efficacy and safety of IGB therapy. We found that IGB therapy provides significant weight loss that is maintained up to 12 months. In addition, adequate weight loss and the observed beneficial effects on lipids and glucose levels, insulin resistance, and liver tests may be explained by changes in circulating hormones.

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