Gastric emptying and intragastric balloon in obese patients

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Abstract. – Background: Intragastric balloons have been proposed to induce weight loss in obese subjects. The consequences of the balloon on gastric physiology remain poorly studied. We studied the influence of an intragastric balloon on gastric emptying in obese patients.

Patients and Methods: 12 patients were included in the study, with BMI (mean ± SD) of 38.51 ± 4.32 kg/m². The balloon was inserted under light anaesthesia and endoscopic control, inflated with 700 ml saline, and removed 6 months later. Body weight and gastric emptying (T1/2 and Tlag) using 13C-octanoic acid breath test were monitored before balloon placement, during its permanence and 2 months after removal.

Results: Mean weight loss was: 6.2 ± 2.3 kg after one month; 12.4 ± 5.8 kg after 3 months; 14.4 ± 6.6 kg after 6 months and 10.1 ± 4.3 kg two months after BIB removal. Gastric emptying rates were significantly decreased in the first periods with balloon in place, and returned to pre-implantation values after balloon removal. T1/2 was: 87 ± 32 min before BIB positioning, 181 ± 91 min after 1 month, 145 ± 99 min after 3 months, 104 ± 50 min after 6 months and 90 ± 43 min 2 months after removal. T lag was 36 ± 18 min before BIB positioning, 102 ± 82 min after 1 month, 77 ± 53 min after 3 months, 59 ± 28 min after 6 months and 40 ± 21 min 2 months after removal.

Conclusions: BIB in obese patients seems to be a good help in following the hypo caloric diet, especially during the first three months when the gastric emptying is slower and the sense of repletion is higher. After this period gastric emptying starts to return to normal and the stomach adapts to BIB loosing efficacy in weight loss.

Key Words: Octanoic acids/diagnostic use/*metabolism, Gastric emptying/*physiology, Gastric balloon, Obesity, Weight loss.

Introduction

The Silicone Intragastric Balloon (SIB) was developed by Fred C. Gau in conjunction with INAMED Development Company (IDC) in 1986. In January 1996 the SIB IDE was transferred from IDC to BioEnterics Corporation (BEC) and the SIB was renamed the BioEnterics Intragastric Balloon (BIB).

The BIB is intended for temporary use in weight loss therapy for patients who are at least 40% above their ideal weight (as defined by the Metropolitan Life Insurance 1983 Weight and Frame Tables) and who have failed to achieve weight loss with a supervised weight control program.

The BIB is designed to be placed in the stomach in a collapsed form, then filled and expanded with saline to act as an artificial bezoar. As it is filled the BIB expands into an approximately spherical shape. A self-sealing valve permits detachment from external catheters. The BIB is designed to float freely within the stomach. The expandable design of the BIB is to permit adjustment of the fill volume (and thus the size of the balloon) at the time of placement as well as later in the treatment period.

The concept of an intragastric balloon evolved from observations of the effect of naturally occurring bezoars (large balls of ingested material) on weight; the presence of a bezoar causes weight loss and weight is regained when the bezoar is removed. The SIB (later BIB) was developed to incorporate the positive weight loss aspects of the bezoar concept with a physiologically and anatomically compatible design.

The BIB is designed to mechanically provide a sensation of fullness and a volume in
the stomach to decrease food consumption and to facilitate the learning of new dietary and behavioral routines. Patients using the BIB are able to eat normal food rather than special liquid or packaged diets. Because each person is different, the BIB is designed to be adjustable in volume (from 400 to 700 ml) to facilitate optimum weight loss. To further investigate the BIB action and to demonstrate that it also has a function in slowing gastric emptying of solid foods, we needed a simple test able to measure gastric emptying of solids.

The $^{13}$C-octanoic acid breath test (OBT) has been proposed as a reliable non invasive test to measure gastric emptying of solids, with results that can be comparable to those obtained with scintigraphy. Half emptying time (T 1/2) and lag time measured with OBT however are greater than those obtained with scintigraphy, a discrepancy that has been hypothesized to be due to absorption and oxidation of octanoic acid after it is emptied from the stomach.

However, scintigraphy and breath test are linearly correlated in such a way that the application of a correction factor to the breath test gives results similar to those scintigraphy in absolute values, assuming that absorption, oxidation and excretion are similar in each normal individual.

Real-time ultrasonography (RUS) has also been proposed as a good, reproducible method to measure gastric emptying of liquid and semisolid meals, and results obtained with this technique have also been comparable to those achieved with scintigraphy.

With real-time ultrasonography, gastric emptying is indirectly measured by observing gastric size, and no metabolic process is involved in this measurement. The data for gastric emptying of solid-liquid meals measured with ultrasonography are demonstrated to be linearly and significantly correlated with the ones obtained with OBT.

Therefore the OBT from 1993 has been proposed as non invasive, reliable and safe test for measuring the gastric emptying of solids.

Further studies performed in physiological as well pathological conditions are confirmed both the reliability and the accuracy of the OBT.

In clinical practice the OBT is definitively adopted as a validated test for measuring gastric emptying of solids with the advantage of non invasive, non operator dependent and performed several time in the same subject without biological hazard.

The aim of this study was to investigate if BIB has also a function in slowing gastric emptying of solid foods and not only to mechanically provide a sensation of fullness and a volume in the stomach. Moreover we measured the gastric emptying before, during and after BIB placement to analyze any variation and adaptation of the stomach's function. Finally we looked at correlations between gastric emptying and weight loss. In this paper we reported preliminary data about 12 patients who completed the study. Other patients are under examination.

**Patients and Methods**

Twelve patients (4 male and 8 female, mean age 39 years range 26-54 yr) were included in this study. Their body mass index (BMI) was 38.51 ± 4.32 kg/m$^2$ (range 32.21-43.22 kg/m$^2$) and all previous attempts with hypocaloric diets and drugs had failed. In all patients an accurate clinical investigation was performed in order to exclude any endocrine cause of obesity. Moreover a gastroscopy was performed prior to the balloon insertion in order to exclude any pathology of the mucosa of the oesophagus, stomach and duodenum.

The BIB was inserted under light anaesthesia and endoscopic control, inflated with 700 ml saline solution stained with methylene's blue. The balloon was removed endoscopically after a period of 6 months.

The $^{13}$C-OBT measurements were performed the day prior BIB’s insertion, 1 month after, 3 months after, 6 months after (the day prior BIB’s removal) and 2 months after BIB’s removal.

After an overnight fast, and at least 12 hours of no smoking, the patients ingested a test standard meal consuming in < 10 min, consisted of one scrambled egg with the yolk mixed with 100 mg of $^{13}$C-octanoic acid (So-far SpA, Italy), two slices of white bread, 10 g of butter and 300 ml of tap water, for a total amount of 250 Kcal.
Breath samples were collected at 15 min intervals during the first 2 hours and every 30 min for another 2 hours, control (baseline) samples were taken before the test meal.

Air collected in breath bas was analyzed for $^{13}$CO$_2$ by means of the isotope-selective nondispersive infrared spectrometry (IRIS) (WATV Bremen, Germany, provided by Altana, Milan, Italy).

Infrared spectrometry has been shown to give similar results, with good correlation with the standard isotope ratio-mass spectrometry (IRMS) both in the evaluation of the $^{13}$C-urea breath test$^{14}$ and the $^{13}$C-octanoic acid gastric emptying breath test$^{15}$.

The parameters of gastric emptying T1/2 and T lag were calculated for OBT starting from the model suggested by Ghoos et al$^7$. Gastric half emptying (T1/2) was established as the time at which half of the carbon labelled meal is retained in the stomach. Lag time (T lag) was the time needed for the antral contractions to grind solids into particles small enough to pass through pylorus.

Each subject gave written informed consesus to the study.

The ANOVA and correlations statistical analysis was performed using the Statview 5.1 software (Abacus. California-USA).

Results

Parameters of gastric emptying (T1/2 and T lag) before BIB placement were quite different in each patients. Therefore each patient was considered control of himself. There were no correlations between this variability of parameters recorded and BMI and/or sex. The T1/2 was (mean ± SD) 87 ± 32 min (normal up to 120 min) and the T lag was 36 ± 18 min (normal up to 52 min).

All patients had some nausea during the first days after the balloon placement. No other short-term complications occurred. The sensation related to the presence of the balloon (and to abdominal distension) dramatically increased after insertion and plateaued during the next 4 weeks. More important appears to be the delay of gastric emptying observed at this point (1 month after BIB placement): T1/2 was 181 ± 91 min and the Tlag was 102 ± 82 min. The increased values were significantly different ($p = 0.003$) compared with those before BIB.

After 3 months we recorded a slight decreasing of T1/2 (145 ± 99 min) and Tlag (77 ± 53 min). There were no significant differences ($p = 0.6$) compared with values recorded after 1 month, but it was still significant ($p = 0.004$) compared with those before BIB.

After 6 months (the day before BIB removal) we recorded an almost complete decreasing of times: T1/2 was 104 ± 50 min and the Tlag was 59 ± 28 min. There were no significant differences compared with values recorded before BIB placement.

Two months after BIB removal we recorded a further decreasing of T1/2 and Tlag and they were came back to pre BIB positioning values: T1/2 was 90 ± 43 min and the Tlag was 40 ± 21 min. Gastric emptying was completely came back to normal. Results are presented in Figure 1 and 2.

Mean weight loss was: 6.2 ± 2.3 kg (range 0 to 11) after one month; 12.4 ± 5.8 kg (range 5 to 20) after 3 months; 14.4 ± 6.6 kg (range 5 to 22) after 6 months and 10.1 ± 4.3 kg (range 1 to 18) two months after BIB removal (Figure 3).

No correlation was found comparing weight loss and gastric emptying at the same point, but a good correlation was found comparing gastric emptying and weight loss obtained at the successive point (Figure 4).

Discussion

Intragastric balloons have been used in adults with varying degree of success$^{16-18}$. Although all patients suffered medical consequences related to their obesity (hypertension, dyslipidemiae, orthopaedic abnormalities) none of them presented with symptoms suggestive of upper gastrointestinal pathology such as gastro-oesophageal reflux disease. Endoscopy of the upper gastrointestinal tract, including histology of oesophageal and gastric biopsies, before insertion of the BIB, was within normal ranges, confirming that the influence of untreated morbid obesity on acid reflux is less pronounced than expected$^{19}$.

Parameters of gastric emptying before BIB placement were extremely different in each patient but still included in a normal range
(up to 120 min for T1/2 and up to 52 min for Tlag). Therefore we did neither observe that gastric emptying rate is accelerated in obese patients versus controls with normal weight as reported by others\textsuperscript{20} nor delayed as reported by Jackson and coll\textsuperscript{21}. There were no correlations between this variability of gastric emptying recorded and BMI and/or sex.

One month after BIB placement every patient showed an increase of T1/2 and Tlag. T1/2 increase indicates that the gastric emptying is slowing down meanwhile Tlag increasing demonstrates that the balloon (influencing gastric mechanical function) increases the time needed for the antral contractions to grind solids into particles small enough to pass through pylorus. This delay of gastric emptying was constant during the first three months. This is the period we, as well as other authors\textsuperscript{18,22}, recorded the most important weight loss. Actually the sensation of fullness and the volume in the stomach together with a slower gastric emptying are really able to decrease food consumption and to facilitate the learning of new dietary and behavioral routines by the obese patient. Unfortunately from the fourth month of BIB permanence the stomach...
starts to adapt to the new situation (adaptation to BIB). After 6 months from BIB positioning T\(\frac{1}{2}\) and Tlag were decreasing and returning similar to those before BIB. The stomach returns more efficient in grinding solids and emptying; moreover it is accustomed to the volume of BIB and no delayed gastric emptying was evident. Therefore also the weight loss starts to decline since the patients return able to eat more. Some patient stop loosing weight meanwhile some others continue loosing a few more kilograms. Two months after BIB removal T\(\frac{1}{2}\) and Tlag have returned to their original values as well as the stomach has returned to its initial emptying capacity. But the most disappointing result is about weight loss. Patients slow down loosing weight after the

![Figure 3. Weight loss: Box = mean; Bar cap = Standard deviation.](image1)

![Figure 4. Correlation T\(\frac{1}{2}\)-weight loss.](image2)

Bivariate scattergram with regression

<table>
<thead>
<tr>
<th>Correlation analysis</th>
<th>Weight loss 3 months, 1 month T(\frac{1}{2})</th>
<th>11 observations were used in this computation</th>
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</thead>
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<tr>
<td>Correlation</td>
<td>P-Value</td>
<td>96% Lower</td>
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<tr>
<td>-.611</td>
<td>.0466</td>
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first four months and even recuperate weight after BIB removal (Figure 3). There was no correlation between weight loss and gastric emptying at the same point of the analysis, as described by others. But we considered that there is obviously a delay (in the order of a couple of months) between an event and a consequent weight loss and therefore we correlated T1/2 and Tlag of one step to the weight loss of the next step of the study and we found a good correlation (Figure 4).

We conclude that the positioning of BIB in obese patients seems to be a good help in following the hypocaloric diet, especially during the first three months when the gastric emptying is slower and the sense of repletion is higher. After this period gastric emptying starts to return to normal and the stomach adapts to BIB loosing efficacy in weight loss. Consequence of this is that it is very important during the period of BIB’s permanence to educate the patient to a new correct diet, as well as to a new life’s style. This should include space for the regular daily physical exercises and, if needed, the support of psychotherapy to improve stressful psychic conditions usually at the base of obesity. The poor or even nil results recorded in some patients suggest that an accurate psychological evaluation should be performed before BIB positioning in order to determine the patient’s compliance.

References

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