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Original article

Intragastric balloon as an alternative restrictive procedure for morbid obesity

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SUMMARY

This study was done to evaluate the intragastric balloon in Greek population suffering from the morbid obesity. From December 2003 to February 2006, 240 individuals with a body mass index [BMI] of 44.1±8kg/m^2, initial excess weight [EW] of 62.8±24.9 and mean %EW of 48.5±9.3, were enrolled in a 6-m using weight reduction programme, an intragastric balloon.

Balloon placement was uneventful. There were 7 patiens who stopped treatment earlier [2 to proceed for obesity surgery, 2 after achieving their desired body weight and 3 because of continuous vomiting]. Another 2 cases experienced a sudden balloon disruption and rejection, one through the anus and one by vomiting.

The remaining 231 patients had a BMI reduction of 38.4±8.3 kg/m^2, that means an %EW reduction of 28.5±19.4. This result led us to conclude that the intragastric balloon is a safe and effective procedure for weight loss in the case of patients strongly motivated to lose weight.

INTRODUCTION

Obesity is steadily becoming one of the most widespread pathologies in western countries, with considerable morbidity and mortality. Although a body mass index [BMI] of more than 25 can be associated with reduced life expectancy and a risk of exacerbating many diseases, it is now usual to consider a BMI of 30 as the cutoff–the point at which the accumulation of fat becomes a major health hazard.[1,2]

The first choice of treatment for patients with a BMI=30 is obviously medical; calorie-restricted diet, physical activity, behavior modification[3] and eventually psychotherapeutic support. For patients who seriously attempt but fail to achieve a weight loss, pharmacotherapy is also recommended. A surgical approach is restricted to the extremely obese [BMI=40]. However, there is a group of patients who refuse anaesthesia for bariatric surgery, or refuse bariatric surgery, or are considered to be high risk for anaesthesia and surgery, or just need to achieve limited weight reduction prior to surgery of whatever kind and for whatever reason.[4] For all such individuals, a restrictive type procedure, being non-invasive and also being both effective and reversible, namely the intragastric balloon, may be the ideal treatment.

The aim of this study is the evaluation of the efficacy of this device in the Greek population, in terms of weight loss and its influence on co-morbidities.

MATERIAL-METHOD

Patients: From December 2003 to February 2006, 240 patients consulting for a weight reduction plan and refusing any kind of actual surgery or suffering from obesity but not meeting the IFSO standards for surgery[5] were included in this study.

A pre-procedure interview was conducted with all patients, concerning medical history, co-morbidity factors, previous treatments for weight reduction and the social, psychological and relational impact of obesity. Additionally, patients were asked to describe in a few words the main reason for strongly desiring weight loss [i.e., to become pregnant, to be married, to find a hus-

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band, to resolve the problem of sleep apnea, against diabetes, etc]. Another interview was then conducted by the dieticians on the dietary habits, as well as consultation given about „the new way of eating". Weight control and assessment of body composition by bioelectrical impedance were also done, for BMI, initial excess weight [EW] and %EW to be estimated.

All patients were checked for a hormonal or genetic cause of their obese state, a known malignancy, pregnancy or the desire to become pregnant in the next 6mo, and alcohol or drug abuse. Additionally, GI tract lesions, known or recognized at endoscopy, such as a large >5cm hiatus hernia, grade C-D esophagitis, peptic ulcer and varices were considered as contra-indications.

Technique: The Bioenterics Intragastric Balloon, Inamed® Corporation, Santa Barbara, CA, was used in all cases. A specially designed informed consent form was signed by all enrolled patients. All procedures were performed by the same fully trained endoscopists. After midazolam conscious sedation [max 5mg], endoscopy was performed to rule out abnormalities that would preclude the patient from participation.

On removal of the endoscope, the balloon placement assembly [consisting of a sheath with the collapsed balloon and a balloon fill tube] was inserted into the gastric fundus. The inflation, using saline solution, was performed under direct endoscopic vision. A volume of 700mL was used for patients having a BMI of more than 35 and 600mL for individuals with a BMI between 30 and 35. After filling the balloon, gentle suction exerted by withdrawing the plunger of the syringe created a vacuum which sealed the valve and the balloon was released by a short pull on the filling tube, which was then totally removed via the mouth. The patient then remained in the recovery room for 2hrs, to verify awareness from sedation, and was then discharged.

Instructions for a 3-day liquid diet were provided, and antiemetics, antispasmodic and PPI's were prescribed for systematic use. After the 3-day period, or until vomiting, abdominal cramps or acid reflux ceased, patients were instructed to follow a semi-liquid and then normal balanced diet of between 800-1000Kcals. Medication was continued when necessary. A phone help-line was available on a 24hrs basis; advisory assistance and support to adherence to the calorie-restricted diet as well as diet adjustment was also provided if requested.

At monthly intervals, the participants were invited for interview, during which dietary habits, in respect to the effort for re-education of eating habits were discussed, and body weight loss [and BMI] and bioelectric impedance assessed and new advice given.

Upon completion of the 6mo period, endoscopic removal was performed, the patient being under deep intravenous anaesthesia, in a lateral decubitus position, without tracheal intubation. For safety reasons, to minimize the risk of residual food entering the trachea through the esophagus during balloon withdrawal, a clear-fluid diet was prescribed for the 48hrs prior to the procedure.

For removal, the endoscope was inserted into the stomach to aspirate thoroughly all gastric fluid and to inspect mucosa for any lesion. Then, the balloon was punctured by a specially designed catheter with a needle, the fluid was totally suctioned and the balloon grasped with long rat-tooth forceps and gently removed with the endoscope.

Statistical analysis: All data were expressed as mean±sd, except as otherwise indicated. Statistical assessment was performed by means of paired t-test for comparisons within the treatment period. Differences were considered significant at $p<0.005$ level.

RESULTS

A total of 240 patients were eventually eligible for the study, comprising 76 males and 164 females, aged 40±11, range 14 to 69. They had a mean body weight of 127.2±27.6. Mean BMI was 44.1±8kg/m^2. Mean initial EW was 62.8±24.9 and mean %EW was 48.5±9.3.

Balloon placement was mainly uneventful. During implantation there were 2 technical problems: one defective valve and one immediate deflation. The balloons were immediately removed and replaced by new one, during the same anaesthesia. Mean duration of the procedure was 12min [range, 10 to 18min]. Extraction of the balloon prior to the end of the treatment period was requested and performed in 7 cases: 2 patients to proceed for bariatric surgery after a 2mo period and having lost 30 and 18 kg; 2 patients being satisfied with the result of 25 and 53 Kg lost at 3mo and 4mo, respectively; 3 patients who refused to continue after continuous vomiting for 10, 25 and 45 days, post-implantation. One further individual, failed to experience any satiety. On examination by plain abdominal radiography and CT there was no evidence of the balloon configuration or of the radiopaque valve. It was concluded that the balloon had probably ruptured and been evacuated through the anus. Finally, a few days prior to the programmed day of re-

moval, one patient experienced vomiting violently, during which the balloon was removed. All these 9 patients were excluded from the final assessment.

A number of transient side-effects occurred: vomiting during the 1st week in 92% of the cases; occasional vomiting during the 1st month, 20%; gastroesophageal reflux needing PPI's treatment throughout the 6month period, 3%.

Balloon removal was uncomplicated in all but two cases: one patient experienced a sudden respiratory arrest due to upper airway obstruction after the balloon was released from the grasping forceps midway to the upper esophageal sphincter. The balloon was immediately and successfully removed by grasping it with a Magyl forceps through the mouth, under direct vision by a rigid laryngoscope; the other patient required removal of the deflated balloon by a rigid esophagoscope after impaction of the balloon in the upper esophagus. Finally, in respect to minor complications due to its use, 5 cases of esophagitis [grade A or B] were prominent during endoscopy for balloon removal, but no peptic ulcers at all.

Upon completion of the 6 months period, data from the 231 patients were as follows: mean body weight loss was 16.5±11kg. Mean BMI was reduced to 38.4±8.3kg/m^2; mean EW was reduced to 46.3±25.5 and mean %EW was reduced to 28.5±19.4 [p=0.001]. No or unsatisfactory weight loss [between 1 and 10kg] occurred in 38 [15.8%] patients. This event is clearly attributable to the poor compliance of the obese individuals to the restricted-calorie diet and the failure to meet the monthly follow-up appointments, despite repeated invitation.

DISCUSSION

Obesity is steadily becoming our worst pathogen. It is a side-effect of an evolving life-style characterized by ready access to copious amounts of attractive food, high in fat, carbohydrates and, in particular, simple sugars, in collaboration with little physical activity. Numerous diseases are caused or worsened by obesity, shortening life expectancy, affecting quality of life and increasing health care cost. An effective solution, resulting in volume restriction, but being non-invasive, irreversible, cheap and safe, is thus clearly needed. At this moment, the intragastric balloon meets all the above criteria: it theoretically affects both the stretch receptors and the gastric capacity, it increases satiety while decreasing the residual stomach volume available for food and could, therefore, be considered a non-invasive restrictive procedure to treat obesity. Compared to surgical procedures, the intragastric balloon can be attractive to patients, as it is non-invasive, can be repeated and is totally reversible.[6,7]

The Bioenterics Intragastric Balloon has all the characteristics needed to be considered as an „ideal gastric balloon".[8] It is filled with liquid [not air] to induce an accentuated feeling of satiety to support patients in reducing food intake and adopting new dietary habits. It is adjustable to a variety of sizes; it contains a radiopaque marker that allows proper follow-up; it is constructed of fine durable silicone fine material that does not leak, but has a smooth surface, thus avoiding creation of pressure/ischemia–induced gastric ulcers.

The balloon itself, as well as the technique for positioning and removal, are safe in experienced hands. In the present study, the array of complications encountered in previous studies did not occur.[9,10] The rates for spontaneous deflation [2 out of 240 balloons] and the side-effects related to its use were low and far fewer than those reported by others. Extensive clinical experience has shown that the complication rate is very low.[11-14]

The results achieved in respect of weight reduction was statistically significant; a reduction of BMI form 44.1±8kg/m^2 to 38.4±8.3kg/m^2, or more representatively, a reduction of %EW from 48.5±9.3 to 28.5±19.4 clearly indicates that the intragastric balloon is effective as an adjuvant device for weight reduction, with the absolute prerequisite of close adherence to the restrictive-calorie diet and physical exercise.

Similar good results have been reported by the Italian Group on 2515 individuals,[10] this being the largest published study to date, as well as by others, in smaller series of patients.[6,7,13,16,17]

We observed that weight loss was not related to side-effects and especially to vomiting. Patients who experienced prolonged periods of vomiting did not achieve a higher percentage of excess weight loss, as Herve[6] also observed. We have recently documented [as yet unpublished data] that the highest percentage of excess weight lost was pure fat, excluding the case of dehydration of individuals, either due to drinking water restrictions or loss of water due to vomiting.

The health benefits of weight loss on co-morbidities are not so easy to evaluate, in such a small number of patients and with no follow-up at the present assessment. We did, however, observe a favourable outcome in diabetes-type-2 patients. Insulin therapy was greatly reduced and oral hypoglycemic agents were reduced or stopped. Kuhlmann[15] has reported a 30% decrease in diabetes-

associated mortality in the morbidly obese after a 10kg weigh loss. Similarly, good results were prominent in the 8 obese suffering sleep apnea. They experienced a need for less pressure support for breathing. Similar results were reported by Herve[6] and Doldi.[7]

The careful monthly follow-up is of primary importance in supporting adherence to the restricted-calorie diet, in creating a consultation continuity and stricter collaboration, and in psychological reinforcement of month by month successful weight loss, the final objective being the patient's life-style re-education.

In conclusion, the intragastric balloon is a simple, non-invasive and effective procedure for weight loss, if applied to a strictly selected population of patients prepared to follow a restricted diet and adopt a new way of thinking about feeding needs and habits.

REFERENCES

1. O'Brien PE, Dixon JB. The extent of the problem of obesity. Am J Surg 2002; 184(6B):4S-8S.
2. Gardner G, Halweil B. Underfed and overfed: the global epidemic of malnutrition. Washington DC; Worldwatch Institute, 2000.
3. Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults. The evidence report. National Heart, Lung and Blood Institute Education Initiative [review]. Obes Res 1998; 6 [Suppl 2]:51S-209S.
4. Gostout CJ, Rajan E. Endoscopic treatments for obesity: past, present and future. Gastroenterol Clin North Am 2005; 34:143-150.
5. International Federation for the Surgery of Obesity - European Chapter (IFSO-EC). Obes Surg 2006; 16:948-950.
6. Herve J, Wahlen CH, Schaeken A, Dallemagne B, Dewandre JM, Markiewicz S, Monami B, Weerts J, Jehaes C. What becomes of patients one year after the intragastric balloon has been removed? Obes Surg 2005; 15:864-870.
7. Doldi SB, Micheletto G, Perrini MN, Rapetti R. Intragastric balloon: another option for treatment of obesity and morbid obesity. HepatoGastroenterology 2004; 51:294-297.
8. Schapiro M, Benjamin S, Blackburn G, Frank B, Heber D, Kozarek R, Randall S, Stern W. Obesity and the gastric balloon: a comprehensive workshop. Gastrointest Endosc 1987; 33:323-327.
9. Mathus-Vliegen EM. Treating morbid and super-morbid obesity. Int J Gastroenterol 2000; 5:9-12.
10. Genco A, Bruni T, Doldi SB, Forestieri P, Marino M, Busetto L, Giardiello C, Angrisani L, Pecchioli L, Stornelli P, Puglisi F, Alkilani M, Nigri A, Di Lorenzo N, Furbetta F, Cascardo A, Cipriano M, Lorenzo M, Basso N. BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. Obes Surg 2005; 15:1161-1164.
11. De Waele B, Reynaert H, Urbain D, Willems G. Intragastric balloons for preoperative weight reduction. Obes Surg 2000; 10:58-60.
12. Doldi SB, Micheletto G, Perrini MN, Librenti MC, Rella S. Treatment of morbid obesity with intragastric balloon in association with diet. Obes Surg 2002; 12:583-587.
13. Totte E, Hendrickx L, Pauwels M, Van Hee R. Weight reduction by means of intragastric device: experience with the bioenterics intragastric balloon. Obes Surg 2001; 11:519-523.
14. Al-Momen A, El-Mogy I. Intragastric balloon for obesity: a retrospective evaluation of tolerance and efficacy. Obes Surg 2005; 15:101-105.
15. Kuhlmann HW, Falcone RA, Wolf AM. Cost-effective bariatric surgery in Germany today. Obes Surg 2000; 10:549-552.
16. Sallet JA, Marchesini JB, Paiva DS, Komoto K, Pizani CE, Ribeiro MLB, Miguel P, Ferraz AM, Sallet PC. Brazilian multicenter study of the intragastric balloon. Obes Surg 2004; 14:991-998.
17. Roman S, Napoleon B, Mion F, Bory RM, Guyot P, D'Orazio H, Benchetrit S. Intragastric balloon for "non-morbid" obesity: a retrospective evaluation of tolerance and efficacy. Obes Surg 2004; 14:539-544.