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Original

Intragastric balloon and multidisciplinary team

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Abstract

***Background*: The intragastric balloon is widely used for weight reduction in obese patients, but results are variable. We describe our results enhancing the importance of a Multidisciplinary Team (MT) taking part in the treatment.**

***Methods:* A retrospective review was done concerning a total of 119 balloons , placed in 116 patients, under endoscopic control and conscious sedation, from May 2001 until August 2006. 49 patients were prepared and recommended to be followed by a MT in a physical unit, at least every 15 days during 6 months. 67 were indicated and followed by other colleagues, without MT. Removal was performed 6 months later.**

***Results:* Concerning our 49 patients, mean age was 38, 1 years, 31 female and 18 males, with BMI ranged between 32 and 63, average of 42. The average decrease of weight excess was 31, 85% (-4, 45-80, 4%), and the BMI diminished 5,3 points (from 13,6 to gain of 0,9). The treatment failed in 34,6 % of our patients —including 4 patients lost of follow-up (8, 16%)—, compared with 53, 8% of patients without structured MT for selection and follow-up. Physical exercise enhanced markedly the results with 45, 8% of excess of weight loss in women and 39, 7% in males, compared with 14, 6 and 15, 6% in patients who didn't follow the program. The weight loss was mostly fat mass, 89,9% in men and 75,6% in women.- The results maintenance was obtained in 40% of patients one year later. There were no major complications; one balloon had to be removed at 3 weeks because of intolerance, another at 5 months because of gastroesophageal reflux.**

***Conclusions:* BIB is an effective help to achieve a short term weight loss in obese patients; nevertheless, good and long lasting results will depend on the modification of life style obtained by a multidisciplinary approach.**

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Key words: *Intragastric balloon. Obese patients. Multidisciplinary.*

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BALÓN INTRAGÁSTRICO Y EQUIPO MULTIDISCIPLINAR

Resumen

***Antecedentes:* el balón intragástrico se usa ampliamente para la reducción de peso de pacientes obesos pero sus resultados son variables. Describimos nuestros resultados resaltando la importancia de la implicación del equipo multidisciplinar (EM) en el tratamiento.**

***Métodos:* Se realiza una revisión retrospectiva correspondiente a 119 balones colocados a 116 pacientes bajo control endoscópico y sedación consciente desde mayo de 2001 a agosto de 2006. Se preparó a 49 pacientes a los que se recomendó seguimiento por un EM en una unidad física, al menos cada 15 días durante 6 meses. Se indicó a 67, que fueron seguidos por otros colegas, sin un EM. Se realizó la retirada 6 meses después.**

***Resultados:* Con respecto a nuestros 49 pacientes, la edad media fue de 38,1 años, hubo 31 mujeres y 18 hombres, con un IMC en el rango de 32-63, media de 42. El descenso medio de exceso de peso fue de 31,85% (-4,45-80,4%), y el IMC disminuyó en 5,3 puntos (desde 13,6 a una ganancia de 0,9). El tratamiento fracasó en el 34,6% de nuestros pacientes —incluyendo 4 pacientes (8,16%) en quienes se perdió el seguimiento— en comparación con el 53,8% de pacientes sin un EM estructurado para la selección y el seguimiento. El ejercicio físico aumentó significativamente los resultados con un 45,8% de exceso de pérdida de peso en las mujeres y un 39,7% en los hombres, en comparación con el 14,6 y 15,6% en los pacientes que no siguieron el programa. La pérdida de peso fue sobre todo de masa grasa, 89,9% en los hombres y 75,6% en las mujeres. Los resultados se mantuvieron en el 40% de los pacientes un año después. No hubo complicaciones importantes; se tuvo que retirar un balón a las 3 semanas por intolerancia, y otro a los 5 meses por reflujo gastroesofágico.**

***Conclusiones:* El BIG es una ayuda eficaz para conseguir una pérdida de peso en el corto plazo en pacientes obesos; sin embargo, los resultados buenos y duraderos dependerán de la modificación del estilo de vida obtenida mediante un abordaje multidisciplinar.**

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Palabras clave: *Balón intragástrico. Pacientes obesos. Multidisciplinar.*

Introduction

The Bioenterics Intragastric Balloon (BIB) was introduced almost a decade ago, and tested in a preliminary study of patients by Dr. Mathus-Vliegen,[1] demonstrating its innocuousness and efficiency helping to achieve an around 10-15% weight loss. Later, several published series obtained in general good results, especially at a short delay.[2-9]

Certainly a lot of questions subside, especially concerning patients' selection, results at long term, and the influence of specialized teams in the achievement of good results.

Since 1991, the INH enunciated the procedure to indicate the suitable surgical treatment for the obese patient.[10] It includes the need of a Multidisciplinary Team (MT). Nevertheless, the Intragastric Balloon (BIB), a more recent invasive therapeutic modality, suffers still poorly definite protocols, the influence of MT not being known yet in the results and its maintenance.

We analyze our results with regard to the application of the BIB in EM'S context.

Patients and methods

Patients

From May 2001 until August 2006, a total of 119 balloons were placed in 116 patients. Of these, 49 were treated entirely by our team. We placed the other 67 as well but they were indicated and followed by other colleagues, in MT'S absence. We proceed to review retrospectively the data of all these patients, and evaluate results of the technique in both groups in term of weight loss, and the eventual benefit of a MT following in our own patients.

We indicate the BIB to patients with an obesity of more than 2 years of evolution in which the non invasive methods have failed, if they promise to submit to the discipline of our MT, and if they are considered to be suitable by our psychologist.

There are contraindications like mental problems, drug or alcohol addiction, non stable cardiovascular disease, or the presence of previous gastric surgery. An active ulcerous gastro-duodenal disease is a temporal contraindication as well as known or detected disorders of food behavior, except advice of psychologist foreign to the team (table I).

The lack of availability to the follow-up or the denial of the patient to accept the practice of the physical exercise as part of the treatment was also at least temporary contraindications.

Table I
Contraindications to the gastric balloon treatment

a) Psyquiatric disorders
b) Drug addiction, alcoholism.
c) Active gastro duodenal disease.
d) Inflammatory bowel disease, malignancies.
e) Hematologic disorders.
f) Pharmacologic treatments like anticoagulants, antiinflamatories, corticoids, AAS.
g) Hearth or renal diseases able to be decompensate by first days vomiting. In general, medical contraiindicacions to bariatric surgery.
h) Lack of guaranties to be able to retire de balloon in the next 48 hours in case of deflation.
i) Extreme ages, being accepted in general 18 and 65 years.

Multidisciplinary Team and Follow-up

Our team, whose composition is considered essential in the treatment of the obese patient, consists of a medical coordinating surgeon, endoscopist, a psychologist specialized in cognitive-behavioral skills, a dietitian and a physical trainer specialized in the obese patient treatment.

The follow-up consists of reviews at least fortnightly, of sequential form for all the members of MT in a physical unit.

Contrary to other tendencies,[2,4,5,8,9] our dietitian does not impose predefined diets of 800 or 1,000 calories. Departing from the culinary preferences and habits of the patient, the dietician proceeds to their progressive modification.

The psychologist provides a preliminary study of personality, test of anxiety, detection of disorders of food behavior, and cognitive-behavioral support to the proposed changes of life; the patient continued to be evaluated and followed every 15 days during 6 months and more recently, every 3 months for 2 years, allowing application of psychotherapy if needed in some cases, relaxation techniques in case of stress or anxiety, and, in any case, promoting the application of life habits changes.

The physical trainer evaluates the patient at the beginning and at 6 months: a complete anthropometry is done with measure of 6 perimeters and 6 folds, as well as dynamometry and anaerobic limit. The patient was individually trained during 6 months, twice weekly and recommendation was done to train at least 40 minutes 6 days per week.

The surgeon is the medical coordinator and takes care of the clinical aspects of the obese patient, studies carefully the metabolic syndrome and eventual vitamin and mineral deficiencies, to optimize patient's general health. Body composition was determinate by impedantiometry, and repeated at each patient's visit.

Every patient was evaluated by the whole team, and the strategy carefully discussed with the patient who was prepared and meanwhile informed of all the possibilities of improvement of his obesity, including surgical techniques.

Table II
49 patients followed with intragastric balloon

Sex	*Females*	*Males*
Number	31	18
Mean age	37.7 (20-63)	39.5 (24-60)
Initial BMI	41.88 (31.8 -63)	41.63 (33-62.3)
BMI loss	5.77 (-1.1-13.6)	4.43 (-0.6-9.4)
% Ew loss	35.2 (0-120)	23.4 (0-50)
% Ew loss with physical exercise	39.7% (22 patients)	45.8% (11 patients)

Once the balloon was the elected technique, it was introduced by the endoscopist, assisted by the medical coordinator.

Balloon Placement and Removal

BioEnterics's BIB is a globe of silicone with capacity from 400 to 700 cc according to the manufacturer, whose filling is usually done with 500 cc, to achieve a partial occupation of the stomach, creating a sensation of precocious satiety, and decrease of the appetite. Indeed, its mechanism of action is not well known, but it seems to work mainly through expansion of the antral gastric wall,[11] as well as of a marked slowing down of the gastric digestion.[12]

To the filling, we add to the saline serum 10 cc of blue of methylene, in order to detect an eventual escape through the valve, before its retreat foreseen before 6 months of its application. All the balloons were filled by 500 cc, except in patients to whom the second or third balloon was applied, or in a patient's case with precedents of bulimia, in which, the globe was filled by 550 cc.

The introduction of the BIB is done by endoscopy, and under sedation, as well as its retreat, routinely planned for 6 months. In two patients general anesthesia was used because of phobia to the introduction of objects oral route.

We tried to avoid the complications described up to the date:

1.º BIB's migration and bowel occlusion[3,5] by means of retreat before 6 months and addition of 10 cc of blue of methylene to the saline serum. In case of precocious deflation, the BIB would be withdrawn before 48 h.

2.º Nauseas and vomits tried to be weakened by means of systematic administration of ondasetron during the procedure and 8 mg every 12 hours during the first 3 days. Liquid diet was delayed up to 24-36 h.

In spite of it, the tolerance was very changeable and we encourage the patients to overcome these days trusting that these symptoms correspond to the stomach adjustment to the BIB and they will yield spontaneously.

3.º The initial aggravation of a previous gastroesophagic reflux (RGE) was well controlled increasing Omeprazol to 40 mg daily.

4.º The episodes of possible food retention and/or transitory gastroparesis were managed with dietetic modification.

Data Analysis

We choose to express our result attending to the percentage of lost overweight, taking as ideal weight the correspondent to the Body Mass Index(BMI), preferring the reference of 25[6] to the more demanding 22.[13] The immediate success was defined as a loss of weight excess superior to 20%.[8] We analyze likewise the variation of corporal composition, attending principally to the proportion of fat lost with regard to the global weight decrease, and therefore fat free mass conservation.[14]

Results

With regard to the 49 own patients, there were 31 women with a mean age of 37,7 years and 18 males with average of 39,5 years. The BMI ranged between 31,8 and 63 for women and 33 and 62,3 for the men with average of 41,88 and 41,63 respectively.

There were no such technical complications as viscous injuries or precocious deflation. There was a case of globe extraction before 3 months because of intolerance in a patient under antidepressant treatment. We observe a case of reflux esophagitis aggravated by the BIB, as well as gastritis with erosive diffuse injuries[2] in a patient with episodes of gastric retention, and therefore, globe withdrawal at 5 months.

In 5 patients, it was necessary to postpone the retreat because gastric solid remains were observed at endoscopy. Two male patient and three young women insisted on the sensation of ineffectiveness of the balloon.

The nauseas, vomits and transitory constipation in most patients were considered to be collateral effects of the treatment, and were controlled partially by pharmacological treatment. They were not assessed therefore as complications.[6]

Other minor problems like constipation and halitosis were easily treated by conventional methods.

We do not observe any case of candidiasis on the BIB at its retreat.

There was a case of late abdominal pain due to biliary stones, which was controlled and treated surgically after balloon was retired.

The tolerance to the physical exercise was excellent, without injuries, and with marked positive effect on state of mind and motivation, as well as with a degree of adherence of the 67, 34%, which was especially high in the 2ª half of our experience reaching 80%.

The average decrease of the weight excess was 31, 85% with a great variability, from gain of 4, 45% up to

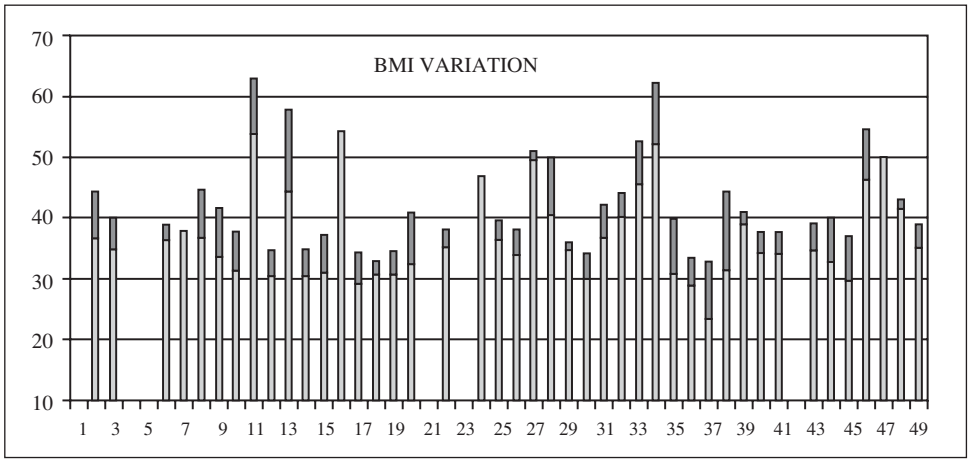

Fig. 1.—Each column indicates decrease of a patient BMI after balloon retraction, colored in red.

loss of 80% excess of weight. In the consulted studies,[2-9] the average decrease of the weight excess ranged from 10 to 48.3%.

In terms of BMI, after de balloon was removed, it decreased 5, 3 points, varying from a loss of 13, 6 to a gain of 0, 9. The final average BMI was 36, 4 between 23, 4 and 54, 6 (fig. 1).

The loyalty of the patients to the program of physical exercise produced a marked implementation of the results: in the women, the percentage of weight excess loss was 45, 8% in contrast with those who did not expire with the program, which lost only 14, 6% of their weight excess. In the males, there was 39, 7% of loss of weight excess with exercise, opposite to 15,6 % without it (fig. 2).

Seventeen —34.6%— of our patients lost less than 20 % of their weight excess, which means failure of the treatment (we include here the patients lost of follow-up).

Comparing roughly our casuistry with 62 patients deprived of multidisciplinary follow-up, the index of failure in these reached 53, 8%.

The successive utilization of 2.º balloon in 3 patients did not really improve the results.

We suffered a total loss of follow-up of 8, 16% (4 patients) in our group compared to the published results of 7.4-33.1%.[2-9] The patients came to remove their balloon, but refused to be weighted (we assumed then no weight loss).

The results were kept at least during a year in 40% of the patients.

We obtained favorable results in relation to the impedanciometry: a preponderant decrease of fat was observed with regard to the total lost weight, being 89, 8% in males and 75, 6% in women (fig. 3). This aspect has not been described in the literature with regard to the BIB, although it has been done in bariatric surgery by authors like Metcalf.[14] In this respect,

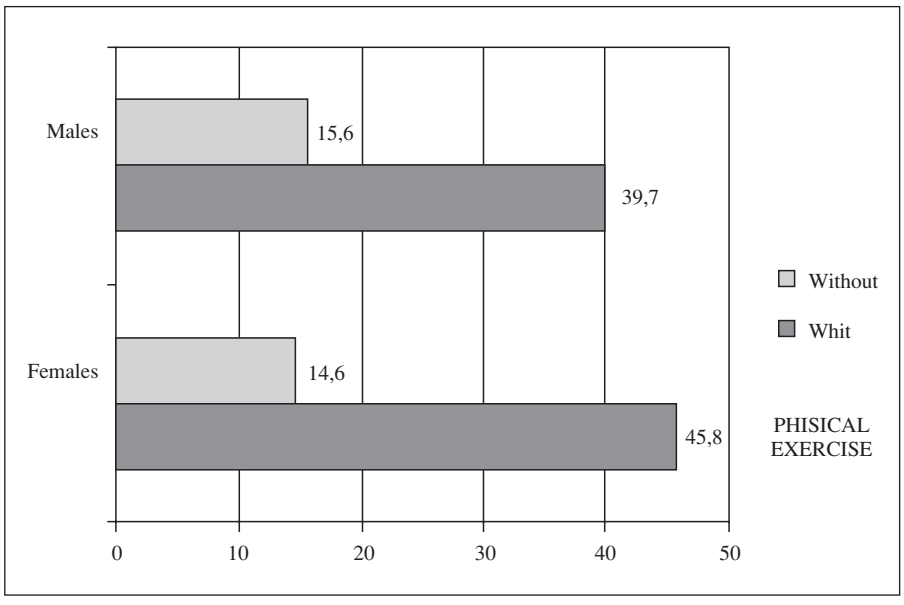

Fig. 2.—Percentage of excess of weight loss.

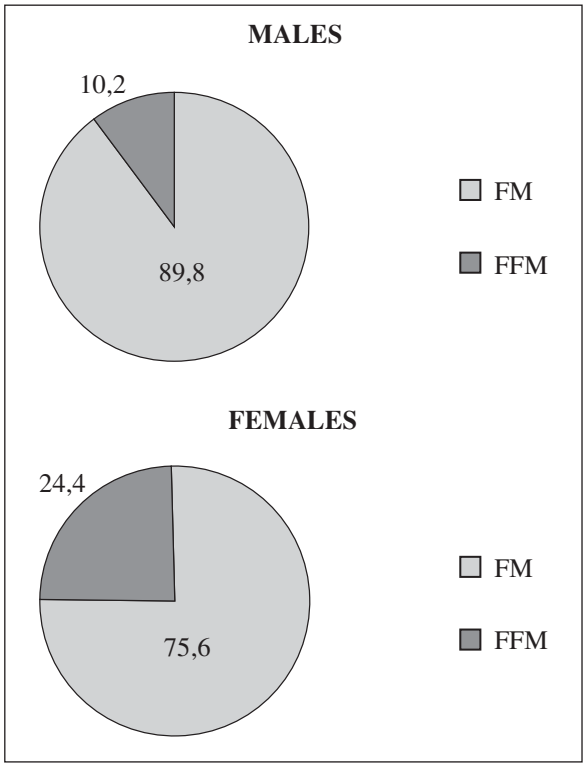

Fig. 3.—Percentage of fat mass (FM) and fat free mass (FM) loss.

we consider key the participation of personal trainers in MT.

Discussion

The BIB has demonstrated to be an effective and slightly invasive method in the treatment of the obesity. Its principal disadvantage takes root in the eventual sharp and short lasting weight loss. This may create problems like frustration and aggravation of patient's psychosocial problems, as well as others like colelithiasis, nephritic colic, or dehydration with risk of cardiovascular complications, besides the metabolic consequences still badly known concerning these changes.

We understand that this technology has to be applied only in case of previous failure of not invasive methods to lose weight, and exclusively in the context of a Multidisciplinary Team capable of modifying, if possible in the space of 6 months, the patient's habits of life.

Because of this, the Team must be expert and the patient disciplined.

In the checked works, stands out the scanty precision relating to the follow-up of the patients treated by means of BIB.[2,3,5,6,7,9] The multicentre Brazilian series is the only one that precise the intervention of a personal trainer in the MT[8].

In two of these series, the weight loss average was less than 20% of the overweight, which suggests failure of the technique.[3,4] It would be important to analyze the reasons of variability of results of the same technique used by different groups.

Our own experience shows an implementation of the results if the technique combined with the monitored physical exercise: in this case, the loss of overweight obtained was more than double than in the most sedentary patients.

Of equal way, the lack of a multidisciplinary team in the treatment of the patient, enhance the percentage of failures to the unacceptable number of 53, 8%.

We rise this way a double problem: the selection of the patient, with absence of current suitable criteria (apart the acquaintances BMI, age and eventual contraindications); on the other hand, the training of the professionals who indicate and/or apply the BIB.

This way applied, the technique provokes very scanty complications: there were neither migrations nor perforations, nor dehydrations nor fluid imbalances clinically significant. We attribute a case of balloon intolerance with retreat at 3 months because a lack of selection.

Nevertheless, our main problem was the lack of response of some patients to the treatment: in 3 cases we believe that it was due to non diagnosed food behavior disorder; nevertheless in 2 males, there was a total lack of perception of the presence of the BIB, and the weight loss was owed exclusively to the will of the patient and to the support of MT. We understand that a great variability exists in the mechanical efficiency of the BIB depending on the degree of antral distension generated. We do not know the way of foreseeing this situation.

On the other hand, the contribution of an intensive program of physical exercise carried out by personal specializing trainers, had the double advantage of promoting a weight loss fundamentally based on fat mass, and further, we know with a C degree of evidence that it contributes decisively to the supported weight loss. A 40% of maintenance of results a year is similar to the reported one for HERVE,[15] who insists on the need of modification of habits by a MT, which begins 8 to 12 weeks before the insertion of the BIB.

Our therapeutic approach is based on the conviction that the obesity is a chronic disease, which does not have a known curative treatment, with a persistent tendency to the weight increase independently of the applied treatment. The treatment is therefore based on the alteration of habits, with major or minor therapeutic support.

We consider that MT is basic in the treatment of our patients, whereas the complementary applied treatment, being dietetic - pharmacological, an Intragastric Balloon or a gastric band, is based on the principle of the "minimal effective dose". We apply the less invasive procedure for every patient, trying to avoid side effects tied to these techniques, and to involve as much as possible the effort of the own patient in his treatment.[16]

We have to clarify that the time invested by patient and Team in this type of treatment is considerable:

approximately 73 total hours in 6 months of attention for the Team, to which there would be necessary to add up the time for the regular practice of physical exercise. We have to admit that this approach is difficult to apply nowadays in the Public Health, for what it is probable that the minimally invasive technologies are less successful in this area.

Of equal way, the terrible results described in those patients deprived of multidisciplinary follow-up suggest us that it is not correct to propose this technique without to rely on a MT. The lack of motivation to follow this methodology must be a contraindication for the procedure.

With regard to the results, we do not believe suitable to qualify a weight loss superior to 50 % in 6 months as "very good" as suggests Wahlen,[17] provided that it might represent in some cases a relative intolerance to the BIB, accompanied by retention vomits or sometimes a turn towards a disorder of food behavior type anorexia.

Let's not forget, that has been demonstrated that the loss of the fat free mass (FFM) is correlated in a linear way by the degree of weight loss, indicating that a rapid loss of weight can result in a disproportionately high loss of muscular mass.

On the contrary, if we accept that the correct weight loss should be an average of half to one kilo per week, the total should range at 6 months between 12 and 24 kilos, independently of the initial weight.

We think also that it is important to mention, not only the average percentage of lost overweight and his range, but the number of patients who achieved a good result. The consensus seems today to express as failure a weight loss lower than 20% of the weight excess. In effect, the variability of response is very wide, and the average of percentage of weight loss is obtained on the basis of an average of bad results and maybe some excesses of weight loss.

Likewise, it is important to achieve a weight loss concerning a maximum of fat mass (FM), with conservation, or ideally increase, of fat free mass (FFM).

Ideally, the results of the obesity treatments should concern the qualitative aspect of weight loss, instead of the gross weight. In a recent controlled series of 39 patients treated by gastric By-Pass, we can observe a loss of 59, 7% of the weight excess at 6 months, but also a decrease of 7, 8 kg of FFM, which is not desired. In this study, the body composition was measured up on the basis of the total body water measured by means of deuterium oxide isotopic dilution.[18] Our problem is that today the method we have used, the impedanciometry, is undoubtedly comfortable in the practice, but of scanty precision.

The weight maintenance at one year has been obtained in 40% of the patients: this information compared with non invasive methods is excellent, but he has to be improved. Our first measure has been to the follow-up, for all treated patients, up to 2 years.

In conclusion, treatment by means of BIB is useful in the context of a MT. It has to include if possible a physical trainer, provided that he seems to have a marked influence on the degree and the quality of the weight loss.

References

1. Mathus-Vliegen EM, Tygat GN. Intragastric balloons for morbid obesity: results, patient tolerance and balloon lifespan. *Br J Surg* 1990; 77: 76-9.
2. Totte E, Hendrickx L, Pauwels M, Van Hee R. Weight reduction by means of intragastric device: experience with the Bio-Enterics's intragastric balloon. *Obes Surg* 2001; 11: 519-23.
3. Evans JD, Scott MH. Intragastric balloon in the treatment of patients with morbid obesity. *Br J Surg* 2001; 88: 1245-8.
4. Hodson RM, Zacharoulis D, Goutzamani E, Slee P. Management of obesity with the new Intragastric Balloon. *Obes Surg* 2002; 11: 327-9.
5. Doldi SB, Micheletto G, Perrini MN, Librenti MC et al. Treatment of obesity with intragastric balloon in association with diet. *Obes Surg* 2002; 12: 583-7.
6. Al-Momen A, El-Mogy I. Intragastric balloon for obesity: A retrospective evaluation of tolerance and efficacy. *Obes Surg* 2005; 15: 101-5.
7. Roman S, Napoleon B, Mion F, Bory RM et al. Intragastric balloon for "non-morbid" obesity: a retrospective evaluation of tolerance and efficacy. *Obes Surg* 2004; 4: 539-44.
8. Sallet JA, Marchesini JB, Paiva DS, Komoto K et al. Brazilian multicenter study on the intragastric balloon. *Obes Surg* 2004; 14: 991-8.
9. Genco A, Bruni S, Doldi B, Forestieri P et al. Bioenterics Intragastric Balloon: the Italian experience with 2,515 patients. *Obes Surg* 2005; 15: 1161-4.
10. Gastrointestinal Surgery for Severe Obesity. NIH Consensus Statement 1991; 9 (1): 1-20.
11. Geliebter A, Hashim SA. Gastric capacity in normal, obese and bulimic women. *Physiol Behav* 2001; 74: 743-6
12. Bonazzi P, Petrelli MD, Lorenzini I, Peruzzi E et al. Gastric emptying and intragastric balloon in obese patients. *Eur Rev Med Pharmacol Sci* 2005; 9: 15-21
13. Lemmens HJ, Brodsky JB, Bernstein DP. Estimation ideal body weight. *Obes Surg* 2005; 15: 1082-3.
14. Metcalf B, Rabkin RA, Rabkin JM, Metcalf L et al. Weight loss composition: the effects of exercise following obesity surgery as measured by bioelectrical impedance analysis. *Obes Surg* 2005; 15: 183-6.
15. Herve J, Wahlen CH, Schaeken A, Dallemagne B et al. What becomes of patients one year after the intragastric balloon has been removed? *Obes Surg* 2005; 15: 864-70.
16. Mazure Lehnhoff RA, Salgado Mijail G, Valencia A, Villarreal P et al. Ejercicio físico y cirugía bariátrica. *Nutr Hosp* 2007; 22: 397-401.
17. Wahlen CH, Bastens B, Herve J, Malm Endier C et al. The Bioenterics Intragastric Balloon (BIB): how to use it. *Obes Surg* 2001; 11: 524-7.
18. Carrasco F, Papapietro K, Csendes A et al. Changes in resting energy expenditure and body composition after weight loss following Roux-en-Y gastric bypass. *Obes Surg* 2007; 17: 608-616.