Original article

Effective intragastric balloon treatment in obese adolescents

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SUMMARY

Introduction: The intragastric balloon is a minimally invasive technique used to treat obesity by reducing hunger and inducing satiety as a result of gastric volume restriction, thus it could be ideal to treat young people who are thought to be easier to change their eating behavior. Aim: The purpose of this prospective clinical study was to investigate the effectiveness of intragastric balloon on obese adolescents, after a six-month period of treatment. Material: Fourteen adolescents -aged 18,5±2,5 yrs- treated by intragastric balloon were studied prospectively. Mean baseline Body Mass Index [BMI] was 39,8 ± 5,8kg/m^2 and %Fatty Mass [FM] 41,7 ± 5,4. The data collected every month for the 6mo period was: Body Weight [BW], BMI, Resting metabolic Rate [RMR] by indirect calorimetry, %FM, %Excessive Weight Loss [%EWL] and %Actual Caloric Intake [%ACI]. Appetite related sensations scores [hunger, satiety, desire for food] were also assessed monthly by visual analogue scales [VAS]. The number of follow-up visits was considered as a marker of compliance. Results: Median baseline values were as follows: BM 118kg [range 80 to 174], BMI 39,1kg/m^2 [range 33 to 54] [>95th percentile], %FM 42 [range 33 to 49] and %ACI 116,6 [range 60 to 200,5]. After a 6mo period, just before the removal of the balloon, all measured parameters exhibited a statistically significant reduction: the median BW was found to be 108kg [range 62 to 162, p=0,002], the BMI 37kg/m^2 [range 26 to 50, p=0,001], %FM 40 [range 20 to 49, p=0,009], the %EWL was 14,29 [range 3,33 to 69,23, p=0,021] and the %ACI=86 [range 33 to 153,96, p=0,02]. Appetite related sensation score was unchanged. The median number of follow-up visits was 4 [range 2 to 7]. Conclusions: Although the number of follow-up visits during the 6 month treatment generally reveals poor compliance, a small though significant weight loss, as a consequence of reduction in the energy intake is prominent. Based on the above findings, a better pre-procedure screening for the appropriate candidates for treatment as well as a better scheduled approach by a multi-disciplinary group, including a dietician and a psychologist is considered mandatory.

Key Words: morbid obesity, adolescents, intragastric balloon

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INTRODUCTION:

The obesity epidemic, which is the most common nutrition disorder, is rising rapidly worldwide, not only among adults, but also among children and adolescents. The prevalence of obesity in the European Region is rising rapidly and it is expected to include 150 million adults and 15 million children by 2010.[1] The annual rate of increase in the prevalence of childhood obesity has been growing steadily, and the current rate is 10 times that in the 1970s. This contributes to the obesity epidemic in adults and creates a growing health challenge for the next generation. Greece is among the 10 countries of Europe with the highest prevalence of overweight and obesity in children and adolescents.[2]

It has already been proven that many of the obesity-related co-morbidities recognized in adulthood begin to develop in childhood. The health consequences of childhood obesity include an increased risk for metabolic ab-

normalities, such as type-2 diabetes mellitus and cardiovascular diseases, hypertension, gallstones, non-alcoholic fatty liver disease, as obstructive sleep apnea syndrome and orthopedic complications.[3-6]

The methods in use so far in the treatment of obesity in children and adolescents are almost the same as those used for adults. These are: dietary modification, both conventional and non-conventional, physical activity increase and reduction of sedentary behaviors, behavior change, parental involvement, pharmacotherapy, and bariatric surgery.[2-8]

A technique that is currently considered to be in the group of surgical methods to treat obesity, is the intragastric balloon [IB]. In contrast to bariatric procedures, this is a minimally-invasive technique, as IB is introduced endoscopically under conscious sedation. It is placed in the gastric fundus and works on reducing intragastric volume and thus producing satiety and suppressing hunger. In adults, it has been proved to be successful, the excessive weight loss reported to range from 16 to 50,8%.[9-10]

Since it is a non-invasive and reversible method it is ideal for young people, aiming primarily to changing of their eating behavior. Thus the purpose of this clinical study was to prospectively investigate in obese adolescents subjected to balloon treatment, the changes in eating behavior as well as its effects on weight loss and body composition, after a six-month period.

PATIENTS AND METHODS

A small group of 14 obese adolescents referred to our Department for IB treatment were analyzed. These subjects were part of a group of over 450 severe and morbidly obese adults studied prospectively after IB placement. The patients presented herein were included in the study only after they – as well as their parents – were found to really desire and be committed to loosing weight. This was tested twice, by briefing both parents and the adolescent together, and then separately. Finally, both signed an informed consent. No balloon was inserted in the case of a parents' decision.

The 14 obese subjects studied were 6 males and 8 females, with a mean age of 18,5±2,5 years. They were classified as obese on the basis of their BMI, which was above the 95th percentile.

The intragastric device used [Bioenterics Intragastric Balloon, Inamed Health, Santa Barbara, CA, USA] fulfilled all requirements defined for the safety and efficiency of intragastric balloon designs[11]. It was placed endoscopically in the stomach and filled with a volume of 700ml normal saline. After the IB placement and before hospital discharge, all patients received written nutritional instructions, as well as a model diet, in order to avoid any symptoms and to ensure maximum weight loss, and were instructed to attend monthly follow-up visits. After the first month, they were encouraged to follow a normal, well balanced diet in accordance to the model diet.

Data collected monthly -over the six month period- during the follow-up visits were: body weight [BW], body mass index [BMI], resting metabolic rate [RMR] by the use of indirect calorimetry [MedGem, Healthetech Inc., USA], body composition [%FM], by the use of BIA [Bodystat-1500, Bodystat® Ltd, Isle of Man GB], weight loss as a percentage of excessive weight [%EWL] and actual caloric intake [%ACI], which was calculated as a percentage of the RMR with the use of a 24h food recall questionnaire, analyzed by Food processor [ESHA Research, Salem, Oregon, USA]. Appetite related sensations score [hunger, satiety, desire for food] was assessed by a visual analogue scale [VAS], monthly, after overnight fasting.[12]

The number of follow-up visits was also recorded, as a marker of compliance. According to this, having, adolescents with up to 4 visits were categorized as having poor compliance while those with 5 to 7 visits had good compliance, the maximum being 7 visits.

Statistical analysis: All data were expressed as median [range] except as otherwise indicated. Statistical assessment was performed by means of paired t-test for comparisons within the treatment period [MINITAB Release 14.1, Statistical Software, Minitab Inc., USA]. Differences were considered significant at $p<0.05$ level.

RESULTS

In all cases balloon placement and removal was mainly uneventful. Additionally, there were no significant balloon related adverse effects during the 6 month period of treatment.

Baseline values [median] were as follows: body weight was 118kg [range 80–174], BMI was 39,1 kg/m^2 [range 33 to 54] and %FM 42 [range 33 to 49]. Median baseline value of RMR [n=13] was 1594Kcal/day [range 1193 to 2279], and %ACI 116,6 [range 60 to 200,5].

At the end of the 6 month treatment period, all the teenagers, except one, lost weight. A 17yrs old girl, having a baseline BMI of 37kg/m^2, gained 3kg, as a result of poor compliance both to the nutritional instructions and

the monthly calls for follow-up sessions. This subject was excluded from the final statistical assessment.

Statistical analysis was thus performed on the data of the remaining 13 patients. All measured parameters exhibited a statistically significant reduction in relation to baseline [Table 1]: the median BW was found to be 108kg [range 62 to 162, p=0,002 – Figure 1], the BMI 37kg/m^2 [range 26 to 50, p=0,001 – Figure 2, 3], the %FM 40 [range 20 to 49, p=0,009 – Figure 4], the %EWL was 14,29 [range 3,33 to 69,23, p=0,021] and the %ACI 86 [range 33 to 153,96, p=0,02]. There were no differences between genders.

Despite the statistically significant results obtained in weight loss, neither hunger suppression, nor satiety effect was documented. However, energy intake and %ACI were decreased in relation to baseline values [p=0,021, Figures 5, 6]. The changes of %ACI displayed a positive correlation with age [r^2=0,273, p<0,05, Figure 7].

Although the balloon was inserted after the full consent of obese individuals, the overall compliance to follow-up visits was rather poor, during the six-month period. The median number of follow-up visits was 4 [range 2 to 7], including the placement and the removal visits. The category distribution of patients was of poor compliance n=7 and of good compliance n=6. However, there was no statistical difference between those who conformed and those who did not, among the two groups of poor or good compliance.

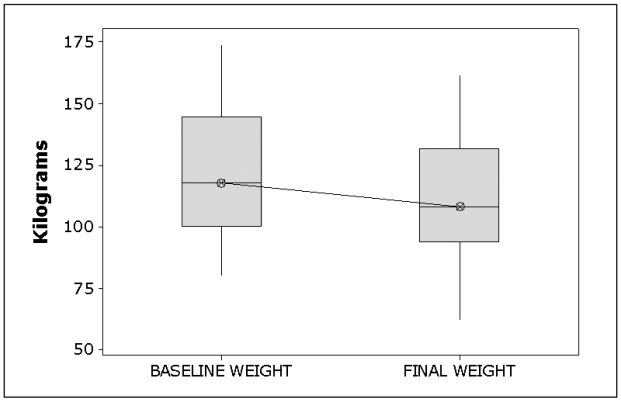

Figure 1. Boxplot of Weight [p=0,009]

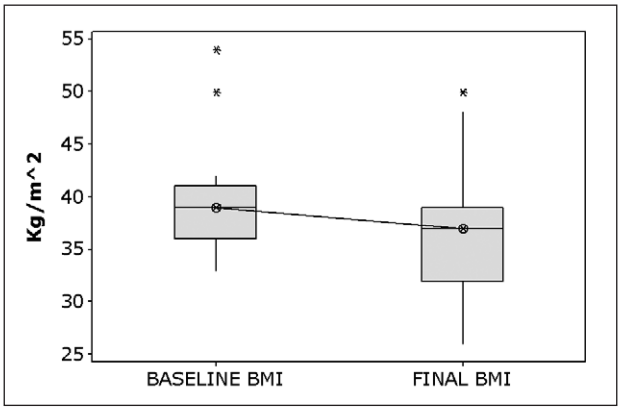

Figure 2. Boxplot of BMI [p=0,002]

DISCUSSION

A growing number of morbidly obese pediatric patients are treated surgically. However, bariatric surgery of any kind is by itself a major procedure involving multiple perioperative risks and life-long post-operation implications that must be considered carefully[13-14]. Patients who undergo such procedures and mainly those subjected to different types of bypass may suffer malnutrition and various metabolic consequences, and as a result they must comply with lifelong use of vitamin and mineral supplements.[15-16]

This is of particular concern for children and adoles-

Table 1. Cumulative data of patients at baseline and at the end of the treatment period.

	Baseline values	Removal values	Difference[δ]	P
BW [kg]	118 [80 – 174]	108 [62 – 162]	7,00 [1,10 – 33,00]	0,002
BMI [kg/m2]	39,1 [33 – 54]	37 [26 – 50]	2.00 [0,4 – 9]	0,001
%FM	42 [33 – 49]	40 [20 – 49]	2.00 [0 – 13]	0,009
%EWL		14,29 [3,33 – 69,23]		
RMR [n=13]	1594 [1193 – 2279]	1585 [1173 – 2236]	20 [0 – 110]	0,006
Hunger [VAS]	2.00 [0 – 10]	2.50 [0 – 10]	-0.5	NS
Satiety [VAS]	8.00 [0 – 10]	7.00 [0 – 10]	1.00	NS
EN. INTAKE [kcal]	2330 [1325 – 4296]	1414 [617 – 2740]	458 [-827 – 1880]	0,01
%ACI	116,60 [60 – 200,5]	86 [33 – 153,96]	27,48 [-54,81 – 147,9]	0,021

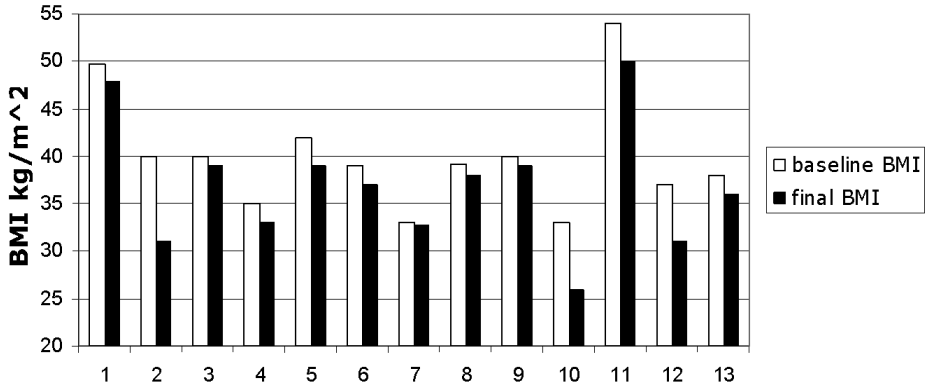

Figure 3. Body mass index changes before and after the 6mo period of treatment in each individual

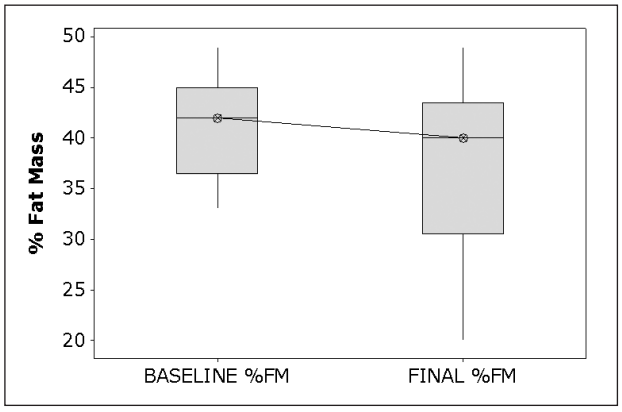

Figure 4. Boxplot of %Fat Mass [p=0,009]

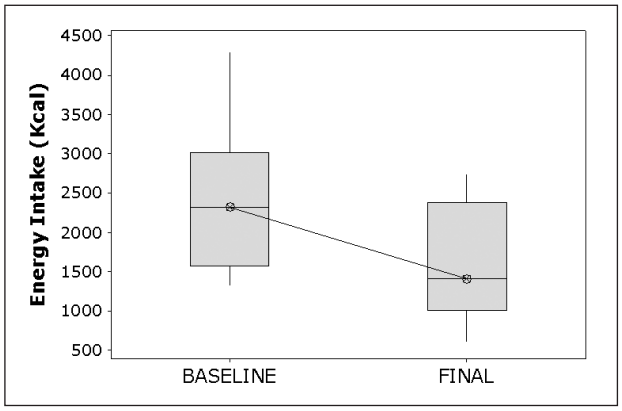

Figure 5. Boxplot of Energy Intake [p=0.01]

cents who may not have reached their full growth potential. Several factors in the pediatric patient must be considered in order to decrease medical risk after surgery, maximize compliance and follow-up after surgery and ensure adequate growth and development.

The intragastric balloon is a non invasive procedure: it does not disrupt the continuity of the digestive tract and it is reversible. However, there is a limited experience of its use in pediatric patients, and the first reported application in pediatric patients at 1993 was disappointing.[17] On the contrary, a Brazilian study, which includes 21 adolescents treated by IB,[18] suggests that obese adolescents may be a promising indication for the IB, because the shorter duration of obesity allows a greater possibility for them to change their eating behavior and lifestyle. They support the theory that morbidly obese teenagers with no satisfactory results on clinical management are the proper candidates for IB treatment.[19]

In the present study, although the number of subjects is generally small not allowing the potential of drawing strong results, a statistically significant reduction of BW, BMI, EWL% is evidence. Generally speaking, the loss of excessive weight was not as high as expected, compared to that of adults treated by the same medical group.[20, 21] This fact could be related to the poor compliance observed in our series. However, the good compliance subjects [n=6] were found to have similar results.

These findings support the need for further pre-procedure screening of parents and adolescents before a decision is made for IB insertion. Additionally, consultation by a psychologist specializing in adolescents seems to be mandatory.

Poor compliance is also a constant problem in all series of pediatric patients undergoing bariatric surgery[8]. Pediatric patients exhibited poor compliance following the post-operative dietary regimen. A small study of adolescents with a Roux-en-Y gastric bypass also revealed that only 14% took the recommended supplements.[22]

The subjective feelings of hunger and satiety of each

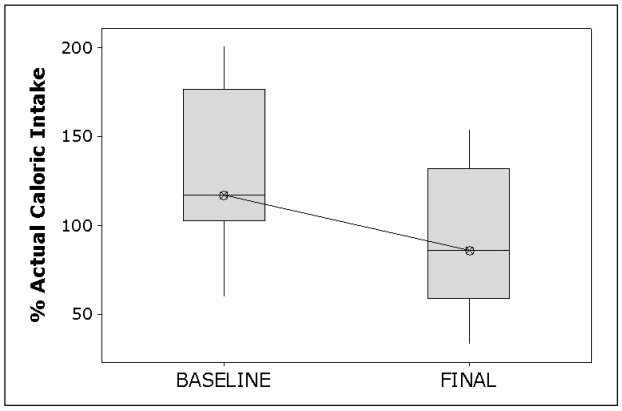

Figure 6. Boxplot of actual caloric intake %ACI [p=0.021]

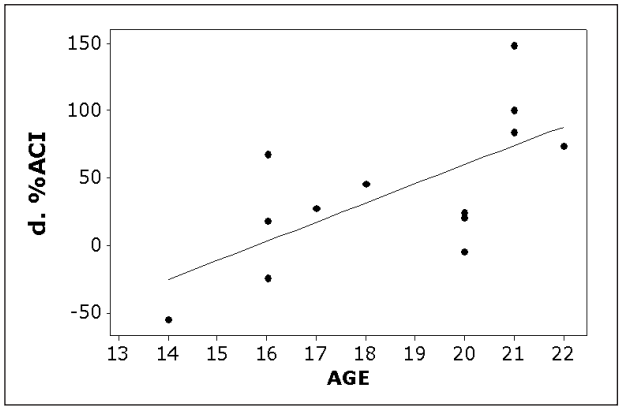

Figure 7. %Actual caloric intake [%ACI] changes with age [r2 =0,446, p<0,05]

individual before, during and after IB treatment were assessed by a visual analogue scale which is the only validated method[12]. Taking into consideration that neither hunger suppression nor satiety was reported, as in adults treated by the same group[20], it is not clear whether compliance was the major problem. According to the self-reported data on 24h food intake, it appears that they significantly reduced their energy intake, which means, either that they had a very high energy intake before balloon placement and even if its reduction was significant it was not enough to induce significant weight loss, or they were not sincere about their food intake when answering to the 24h food recall questionnaire. This is also supported by the correlation of the percentage of actual caloric intake reduction with age: it suggests either a more responsible attitude towards the treatment or a better disguise of their real intake in their reports of 24 h food intake.

Based on the above data, we concluded that although IB proved to be safe it was not as effective in adolescents as it was in adults. Even though it induces a significant weight loss, it neither substantially suppressed hunger nor induced satiety helping to modify of eating behaviour.

Thus it is proposed that for future studies the total concept of IB application to adolescents should be re-scheduled: a better pre-procedure screening of the appropriate candidates for treatment is considered crucial for good results, as well as a better scheduled approach by a multidisciplinary group including a dietician and a psychologist for a closer monitoring as the successful Brazilian pattern suggests.

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