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Review

Position of Intragastric Balloons in Global Initiative for Obesity Treatment

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A B S T R A C T

Obesity is chronic disease with multiple health consequences and among the most severe health problems worldwide. According to public health records around 65% of population in Croatia are overweight and 20% obese. National physicians chamber with support of Health and Social Welfare Ministry gave recommendations on diagnosing and treating of obesity in form of national consensus. Treatment of obesity is complex and enrolls multiple clinical specialties. Change of life style, strenuous physical activity and pharmacotherapy are part of conservative treatments. Patients are treated more efficiently by minimally invasive endoscopic procedures or bariatric surgery depending on starting body mass index score. Implantation of intragastric balloons is conceptually simple method of obesity treatment. Modern devices as Bio-Enterics intragastric balloons (BIB®), (Inamed Health, USA) are gaining wide popularity among both patients and physicians. BIB intragastric offers the best gains with individuals ranging BMI from 35 to 40. Efficiency has relative timeline dependance from 85% at 6 months to 24% at 36 months. BIB offers substantial ameliorative influence on obesity comorbidities, particularly cardiovascular risk. Treatment with BIB is also efficient but transient treatment modality in morbidly and superobese individuals to reduce preoperative risks of general and bariatric surgery. Obesity treatment with BIB is well tolerated and safe, offering better quality of life. Nevertheless, due to relative poor results of conservative obesity treatments on long term follow up further investigations defining new clinical parameters for solving treatment resistance. In order to provide resourcefully individualized approach modern perspectives are focused on endocrine constitutes of obesity. Hormonal effects of BIB treatment in compare to bariatric surgery are potentially interesting for the prospect studies.

Key words: *body mass index, BMI, obesity, bariatric surgery, intragastric balloon, BIB, cholesterol*

Introduction

Obesity is chronic disease among the most severe health problems in both developed and transitional civilizations. According to Croatian public health records 58.2% of female and 68.3% of male are overweight (BMI>25 kg/m^2), with 22.7% female and 21.6% male being obese (BMI>30 kg/m^2). Even more concerning is the fact that 11% of school age children is overweight and 5% obese. World Health Organization (WHO) reported global epidemic of Obesity in 21st century, tending to outspread to 50% of global population by 2025[1].

Secondary effects of obesity

Obesity brings multiple consequences on global health status. It affects functional changes in performance of different organs and altering for the worse quality of life. Series of epidemiological studies have shown that obesity represents crucial risk factor of impaired glucose tolerance, diabetes, dyslypoproteinemia, cardiovascular diseases and advancement of degenerative changes in musculoskeletal system[2–4]. Total mortality is higher in obese patients and significantly correlates to body mass index BMI (5). Within pathological BMI

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range (25 to 50 kg/m^2), a 5 kg/m^2 raise in BMI was shown to be related with a significant increase in mortality from: coronary artery disease (hazard ratio [HR] 1.39), cerebrovascular insult (HR 1.39), diabetes (HR 2.16) and chronic kidney disease (HR 1.59). The mortality from number of cancers was found to be associated to BMI (HR 1.10) (liver, kidney, breast, endometrial, prostate, and colon)[5]. Swedish Obese Subjects Study showed positive connection of several comorbidities with BMI excess (hypertension — 13.6 percent, diabetes mellitus — 6.3 percent, hyperinsulinemia — 6.3 percent, hypertriglyceridemia — 7.7 percent, low serum high-density-lipoprotein (HDL) cholesterol concentration — 8.6 percent, hypercholesterolemia — 12.1 percent)[6].

Main Outcome Measures and Methodology

The body mass index (BMI) is the most commonly used tool for initial screening giving different grades of obesity (BMI>25 overweight, BMI 30–34.9 grade I obesity, BMI 35–39.9 grade II obesity, BMI>40 grade III i.e. morbid obesity, BMI>50 so called »superobesity«)[6]. The treatment side is also closely related to initial BMI[1].

Waist and hip circumference are especially useful for detecting »central« adiposity linked to higher mortality from obesity comorbidities[8,9]. Waist circumference greater than 102 cm for men and 88 cm for women was found to be related with a higher risk for diabetes, dyslipidemia, hypertension and coronary disease individuals from grade I obesity group[8].

Absolute weight reduction (AWR) represents weight reduction in kilograms, representing baseline body weight minus after-treatment body weight.

Excess body weight (EBW) is the actual weight pre--treatment minus the ideal body weight according to the individual's height.

Ideal body weight in most of study was defined as BMI of 25 kg/m^2[2,10,11].

Percentage excess weight reduction (%EWL) is the percentage reduction in excess body weight after the BIB treatment, at a given time, it equals absolute weight reduction (AWR) divided by excess body weight and at a given time multiplied by 100.

Percent of excess body mass index loss (%EBL) is the percentage of BMI change and is calculated as pre-treatment BMI minus post-treatment BMI and divided by preoperative BMI-25 and multiplied by 100[12].

Percentage of loss of total weight (%LTW) represents percentage of reduction in total weight at a given time i.e. after BIB treatment, and is calculated as post – treatment weight loss in kilograms divided by pre-treatment body weight in kilograms and multiplied by 100.

Modern perspectives are focusing on endocrine part of obesity, considering the gut as hormone factory; »the home of hormones« and potentially interesting from therapeutic view[13].

There is still relatively insufficient knowledge in regard to adequate methodology for treatment analysis and long term follow up. Different measures are particularly targeting various major events of obesity, primary or secondary complications and comorbidities. New clinical parameters that could offer more individualized and patient orientated from perspective of efficiency are being studied widely.

Treatment of Obesity

Croatian physicians' chamber initiated organization of Croatian Obesity Society in 2002, with 4 congresses (2002, 2006, 2008, 2010) giving Recommendations on diagnosing and treating of obesity in form of national consensus[14] (Table 1).

National plan for prevention and treatment of Obesity and weight reduction was initiated by Ministry of Health and Social Welfare in 2007[15].

Treatment of obesity is complex and enrolls multiple clinical specialties (internal medicine, gastroenterology, endocrinology, surgery, nutrition and psychology). Clinical objective of medical treatment(s) should be focused at a sustained 5–10% weight loss in order to prevent and reduce cardiovascular risks[16] or other secondary complications of obesity[17].

First steps enroll noninvasive methods and change of life style in manner of regular strenuous physical activity, reduced calories diet, and eventually by adding pharmacotherapy (orlistat, sibutramin). Upon failure of conservative treatments (in 90–95%) patients are left with

TABLE 1
RECOMMENDATIONS ON DIAGNOSING AND TREATING OF OBESITY

Therapy	BMI 25–26.9	BMI 27–29.9	BMI 30–34.9	BMI 35–39.9	BMI >40
Diet, physical activity, behavioral therapy	With cardiovascular risk factor	With cardiovascular risk factor	Yes	Yes	Yes
Pharmacotherapy		With comorbidity of obesity	Yes	Yes	Yes
Intragastric balloon (BIB)			With comorbidity of obesity	Yes	Yes
Surgery				With comorbidity of obesity	Yes

possibilities with more invasive methods according to their health condition and class of obesity (Table 1).

The most efficient therapy for lessening body weight seems to be bariatric surgery. Bariatric procedures are generally indicated for morbidly obese (BMI>40) and superobese individuals (BMI>50) respectively, since those are burdened with greater complications on a natural course. Ameliorative effects on major comorbidities secondary to obesity were well documented in prolonged follow up of 10 years post bariatric surgery[18].

Minimally invasive non surgical methods on the other are acquiring attractiveness more and more. Endoscopic implantation of intragastric balloon reduces volume of ingested food i.e. total reduction of caloric intake, causes space occupying fill effect with additional neurohumoral changes that are being investigated currently. Studies from minimally invasive endoscopic procedures also report on ameliorated metabolic profile as significant treatment effect[19–22].

Due to pandemic growth of obesity and modest total treatment success additional investigations are being taken. Those are mostly concentrated around patophysiologic moments and genetic background with exploring potential clinical use of at least couple dozens of pharmacological substances[23–27]. Preclinical animal studies are investigating anti-ghrelin vaccine[28,29], so far burdened with relative inefficiency due to host response on generated autoantibodies. Since ghrelin is found likewise in central nervous system and heart, beside gut and adipose tissue, anti-ghrelin effects of treatment might cause pleiotropic unwanted sideeffects. Investigations came somewhat further with diacylglycerol acyl transferase-1 (DGAT1) inhibitors, which are now being teted for obesity and diabetes in phase II clinical studies[30].

History of Intragastric Ballons

Implantation of intragastric balloons is conceptually simple method of obesity treatment. Weight loosing effect was observed to a large extent earlier in patients with bezoars[31]. First therapeutic implantation of space engaging device was reported in 1980 by Neiben[32]. Since then wide range of balloons regarding volume, material, filling etc (Table 2). Two earliest balloons were The Garren-Edwards (GEGB) and the Ballobes. Garren Edwards are 220 mL air filled plastic container looking like tin, with sharp edges and was implanted for 3 months. Those were introduced in the United States in 1985. and remarkable 25.000 were implanted in period of couple of years, when they were pulled off the market by FDA due to relative inefficiency and complications (decubital ulcers (3–14%), erosions (26%), Mallory-Weiss (11%), deflations (31%). Ballobes were rubber ballons, with an air-tight valve, upon insertion was inflated with 450 cm^3 of air (Table 2).

Following the world trends the series of intragastric air filled rubber balloons were implanted in »Sestre Milosrdnice« University Hospital Center among first in this region and Croatia in 1991. A new generation liquid filled balloons (The Bioenterics) were employed on from 2007.

Present Intragastric Ballons

Since a large scale of complications and technical issues was noticed with first intragastric balloons in despite their proven effectiveness, a scientific conference was held in Tarpon, Springs, Florida in 1987. It was a team of 75 experts liaised with obesity treatment from various backgrounds as gastroenterologists, surgeons, psychologists and general physicians. Recommendations were given that therapeutic intragastric balloons should hold certain characteristics (Table 3).

Over 10 000 liquid filled balloons (Bioenterics Intragastric Balloon (BIB)) were implanted until recently and series published in literature. On the other hand there are just a few studies regarding two lately existing air filled devices Heliosphere Bag and Endogast[33,34] so they will not be included in this review.

TABLE 3
RECOMMENDATIONS REGARDING INTRAGASTRIC BALLOONS CHARACTERISTICS FROM CONFERENCE IN TARPON, SPRINGS, FLORIDA IN 1987

Targeted characteristics of intragastric balloons
Effectiveness in promoting weight loss
Filled with liquid (not air)
Capability of adjustment to various sizes
With smooth surface and low potential for causing erosions, ulcers or obstructions
Marked with radiopaque marker that allows proper follow up e.g. the device if it deflates
Constructed of durable materials that do not leak

TABLE 2
THE PRINCIPAL CHARACTERISTICS OF INTRAGASTRIC BALLOONS THROUGH HISTORY

	Garren-Edwards	Ballobes	Taylor	Wilson Cook	BioEnterics
Shape	Cylindrical	Oval	Oval	Oval	Spherical
Matherial	Elastomer	Elastomer	Silicone	Elastomer	Silicone
Filling	Air	Air	Fluid	Air	Fluid
Volume	250 mL	500 mL	500 mL	300 mL	500–600 mL
Reference	Lindor 1987	Ramhamadany 1989	Marshall 1990	Mathus Vliegen 1990	Galloro 1999

Bioenterics Intragastric Balloon (BIB)

The BIB is endoscopic intragastric balloon used as method for obesity treatment by achieving restriction intake of food. It is spherical, saline-filled intragastric device filled with fluid and designed for nonsurgical treatment of obesity and morbid obesity[35]. Second generation of BIB (onwards 2000) was made smooth surface durable elastic silicone, with a fill range of 400–800 mL of physiological saline colored with methylene-blue (Figure 2).

The BIB is routinely implanted following certain indications (Table 4) under conscious sedation or exceptionally in total anesthesia. Procedure begins as upper diagnostic gastroscopy and if there are no abnormalities or local contraindications present, placement in stomach is done under endoscopic guidance. Balloon is filled with sterile saline (cca 400–800 mL) and 10 mL of methylene blue through attached small filling tube catheter. Once the device is filled the operator pulls out the catheter, and balloon is left floating freely in the stomach (Figure 3).

Position of BIB is controlled by transabdominal ultrasound (Figure 4), native abdominal radiograph or by control upper gastrointestinal endoscopy.

During short postimplantation period patients receive parenteral fluid and symptomatic therapy in order to cover gastric hypersensitivity and adaptation on balloon presence. First three days are the most commonly burdened with complications as dyspepsia, vomiting, abdominal cramps. Pharmacological treatment includes proton pump inhibitors, metoclopramide, scopolamine butylbromide. Patients are discharged after normal peroral liquid nutrition is tolerable. A proton pump inhibitors are mandatory during complete implantation treatment period influencing protective both for gastric mucosa and balloon surface[20].

BIB is inserted in stomach for 6 months and patients receive BIB identification card (Figure 5). Patient is followed by gastroenterologist routinely in time periods from 1–3 months. Routine outpatient control includes abdominal ultrasound, anthropometrics, and blood chemistry laboratory exams.

TABLE 4
INDICATIONS AND CONTRAINDICATIONS FOR INTRAGASTRIC BALLOON TREATMENT

Recommended indications
BMI<35 with comorbidities and resistance to conservative treatment
BMI >35 with resistance to conservative treatment and refusal or present contraindication to surgical treatment
BMI >50 super-obese individuals with very high operative risk as preparation of further surgery
BIB test- evaluation and selection of patients for restrictive procedures
Reduction of anesthetic risk (all surgery)
Absolute contraindications
Previous gastric surgery
Hiatal hernia >5 cm
Coagulation disorder
Potentially bleeding lesion of the upper gastrointestinal tract
Pregnancy or desire to become pregnant, breast feeding
Drugs/alcohol abuse
Obesity of secondary origin (hormonal, genetic)
Malignancy within 5 years
Drugs/alcohol abuse
Severe liver disease
On active treatment of obesity with pharmaceuticals
Any contra-indication to endoscopy
Relative contraindications
Previous abdominal surgery
Active gastritis, H pylori infection, duodenal ulcers
Hiatal hernia <5 cm, mild esophagitis
Severe esophagitis (class III and IV)
Hemorrhage from upper gastrointestinal system
Nonsteroidal antiinflammatory drugs, anticoagulants and antiaggregators
Crohn's disease
Psychiatric illness
Malformations of esophagus or larynx
Inflammatory bowel diseases

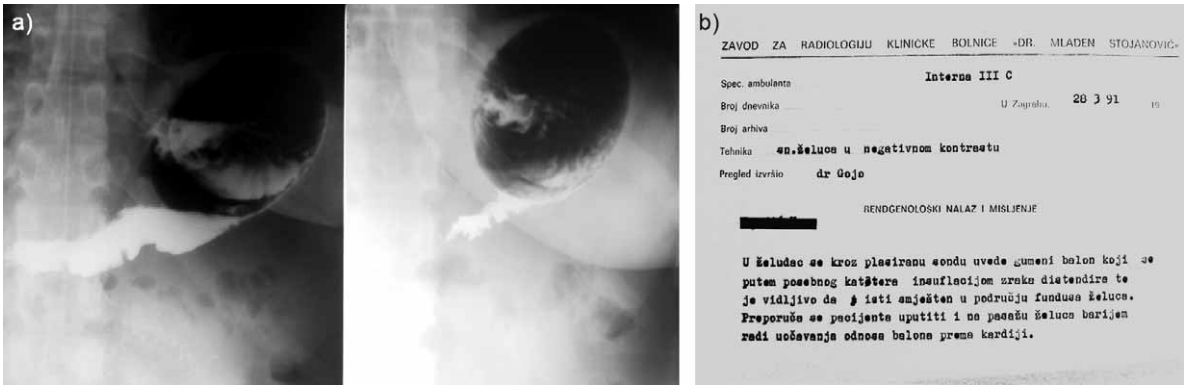

Fig. 1. First series of intragastric balloons implanted in »Sestre Milosrdnice« University Hospital Center (formerely Mladen Stojanovic) 20 years ago; a) native abdominal X-ray, b) radiology report.

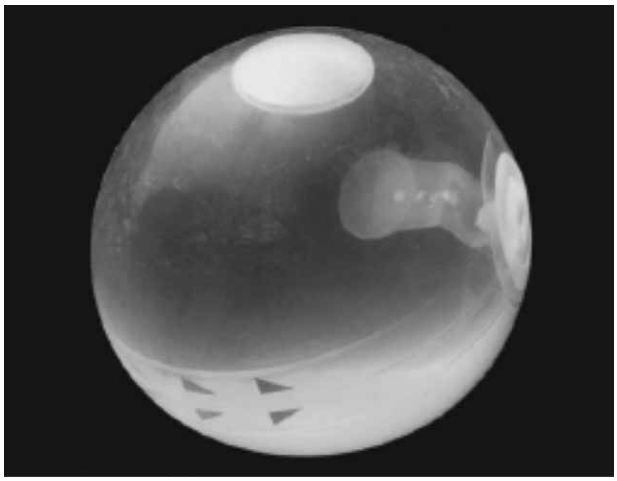

Fig. 2. BIB intragastric balloon (BIB, Inamed Health, Santa Barbara, CA, USA).

Before removal patient must be kept on a liquid diet for 1 day. Removal is done by upper gastrointestinal endoscopy. After diagnostic examination of mucosa and balloon, punctuation is done with needle. Containing fluid is completely drained through catheter connected to pump with negative pressure. Extraction is done by foreign body grasper.

Experiences with Bioenterics Intragastric Balloons

Since the first generation of BIB was developed in 1998, and enhanced in 2001 year it was outspread within the world. Series of patients consider it quite popular because is simple, minimally invasive, with short insertion/removal duration and is effective form of obesity treatment.

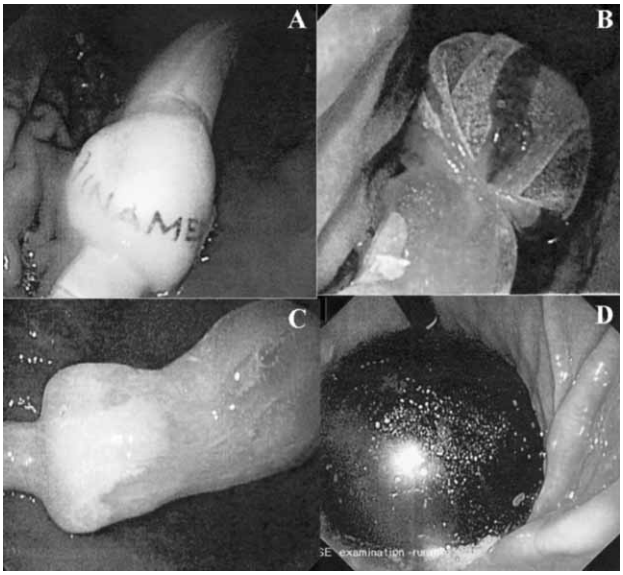

Fig. 3. Upper gastrointestinal endoscopy: different stages of balloon implantation.

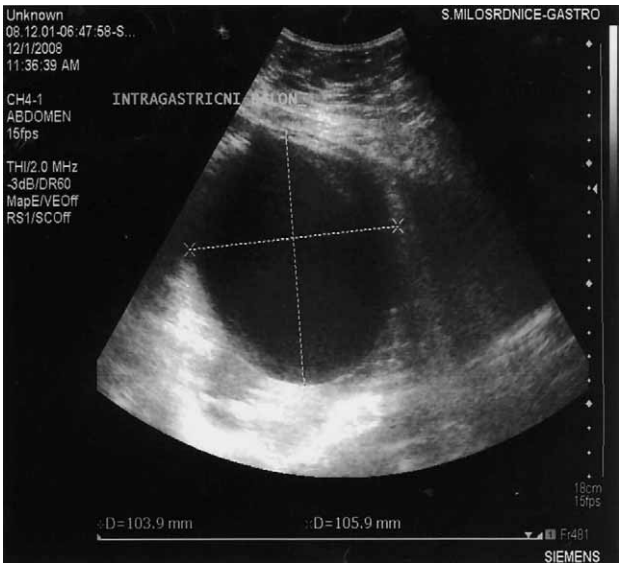

Fig. 4. Transabdonimal ultrasound (t-USD) control of balloon's position and morphology i.e. fuction.

BIB intragastric balloon treatment analyses of clinical series showed the most optimal outcomes in patients within BMI range 35 to 40[19]. Is also found to be very efficient in the short term as a treatment modality for morbidly obese (BMI >40) and superobese (BMI>50) patients reducing constitutive preoperative risks of general or bariatric surgery.

Weight Loss Effect of BIB Treatment

Up to date there is avalilable over 160 studies, of which 30ish were used multiple times in meta analyses[36,37]. Meta analysis from 22 studies with 4371 patients reported mean weight loss on BIB 17.8 kg (4.9–28.5 kg), but with immense differences among studies[37]. A randomized crossover trial showed difference of 12 kg within group placebo and balloon[38].

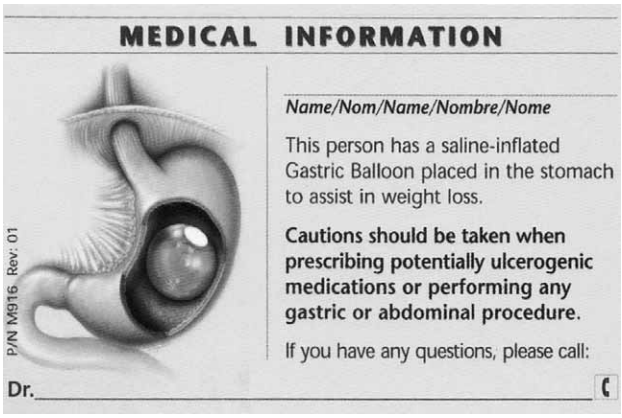

Fig. 5. BIB – patient identification card.

Weight loss among studies has a propensity to be superior in patients with greater BMI (22 kg with BMI >40 and 12 kg in BMI <40). On the other hand, when considering the percentage of excess weight loss, better results were reported with patients that had lesser BMI (non-morbid obesity) and smaller % EWL[37]. Standard intragastric balloon treatment lasts for 6 months, although major of percentage weight loss was reported within first 3 months (48.6%) in compare to completed 6 months period (50.83%)[39]. However these observations need further clarifications in regard to hormonal change, influence on obesity comorbidities and long term follow up with weight regain. Report from Italy by Genco et al.[21] included remarkable 2515 patients and showed average decrease of 5 BMI units, with largest weight loss of 9 BMI with preoperative morbidly obese patients (Table 5).

Reproducibility and Comparability among Studies

Significant deal of published studies could not be compared fairly due to different settings. In a report by Ganesh et al. from Singapore[40], treatment with intragastric balloons gained less efficiency in Asian individuals, which might partially be due to different anthropometric parameters, particularly because of lower volume of balloon filled, lower volume capacity of stomach and significantly greater intolerance rates with premature removal. Conversely, in a report from Ohta et al.[41] on 21 obese patient results from similar settings regarding population gave 12±5kg, and 27±9% (% LTW) which is pairing to our series and other reports on Caucasians[36,37,42] which might bring additional point for clarification. Study from 6 clinics with private medical care and the second biggest study published so far by Sallet et al., and reported % EWL of 48.3±28.1[20]. Although outcomes were superior than average from meta-analyses[36,37,42] due to inclusion of substantial share of addressees with from morbidly obese group that are better candidates for bariatric surgery. In despite to more efforts made around follow up only a third of patients were finally included in analyses, which might be dubious for reproducibility.

Long Term Weight Loss and Maintenance with BIB Treatment

Concrete effects on comorbidity with BIB treatment with sustained responses should be judged in prolonged follow up period longer than one year via Herve et al.[22], to assess real significances[37].

There are several available studies (Table 6) in regard to prolonged follow up of patients with intragastric balloon treatment. Maintenance of weight loss after balloon treatment was reported in 8 studies, of which 3 had follow up period of one year with 28–40% return of the total lost weight[36,37].

In a study by Dumonceau et al. in a prolonged follow up of 5 years whole tested population had lost a median of 2.0 kg or 6.2 %EWL. Significant treatment effect (>or=10% baseline weight loss) was some better with bariatric surgery (32%) than BIB (26%)[43]. Interestingly repeated BIB treatment had no relation to proportions of subjects with sufficient baseline weight loss or bariatric surgery.

Dastis et al. reported 100 patients with average follow up 4.8±1.6 years, with 3% dropout[44]. At 6 months treatment i.e. BIB removal average weight loss was 12.6±8.3 kg, 63 individuals with > or =10 % baseline weight loss. Weight regain was 4.2±6.8 in first year post-BIB and 2.3±6.0 kg in second. At 36 months after BIB, treatment was efficient with 24 participants. Nearly one third of patient had over 10% LTW, and 35 took bariatric surgery mostly due to weight gain over half in compare to initial BMI.

Sallet et al.[20] presented series of 323 patients from Brazil treated for 6-months treatment with 1 year follow up with significant outcomes, which might partially be due to different motivation of patients, regarding it was performed in private clinics. There was noted a significant change in body weight reduction (15.2–10.5 kg), % of excess weight loss (48.3±28.1), BMI (–5.3±3.4 kg/m^2), while 85 of patients remained 90% of their BMI reduced with intragastric balloon-treatment. There was also observed excellent effect on reducing of obesity related comorbidities in over ¾ of treated individuals, with resolution or improvement of hyperlipoproteinemia as one among the most influential cardio/neurovascular risk factor in bit over half of patients. However, probably due to biometrical differences among patients in series from Singapore by Ganesh et al.[40] treatment for obesity with intragastric balloons was seen as insufficiently efficient with maximal weight loss 5.9 kg (1.4–13.4), % of excess weight loss 32.4% (6.7–87). What is more important, after the 1 year follow up mean weight loss compared to pre-BIB was 1.5kg, mean % of excess weight loss 10.9% (15.1–31.3), with only 20% of 20 patients were overall

TABLE 5
WEIGHT LOSS WITHIN STUDIES

	Age	BMI	Change /kg	Change BMI	Change % EWL
Non morbid obesity – 5 studies N 665	33–37.5	31–39	9.5–18.6	5.3–5.7	38.1–50.8
Morbid obesity – 5 studies N=573	31–43	41–46.6	13–15	4.8–5.3	18.7–35.0
Preoperative wight loss 2 – studies N=58	38.8–43.3	58.4–60.2	18.1–26.4	6.4–9.4	21–26.1
Genco et al. N=2515	38.9	44.4		4.9	33.9

TABLE 6
BIB TREATMENT FOLLOW UP

	N-start	BIB Weight loss	Control period without BIB	N-control	Weight regain
Non morbid obesity					
Sallet et al.	323	48.3% EWL	6 months	85	+6.5 % EWL
Herve et al.	100	12 kg	12 months	100	+3.4 kg; 56 remained
Morbid obesity					
Doldi et al.	132	14.4 kg	6 months	38	14–7.8 kg; 17 + 8.4 kg; 7 remained
Loffredo et al.	64	14.3 kg	6 months	34	28+5.5 kg; 4 start; 2 remained
Mathus-Vliegen	43	21.3 kg	12 months	43	+8.6 kg
	33	25.6 kg	12 months	33	+11 kg
Negrin Dastis et al.	100 Non morbid obese 86% Morbidly obese 14%	12.6±8.3 kg	36 months	98	Regain 4.2±6.8, (18months) Regain 2.3±6.0 kg (30months) 24 % remained with LTW>10% at 36 months
Preoperative loss of kg					
Weiner et al.	15	18.1 kg	1 months	15	+2.4 kg
Busetto et al.	43	26.4 kg	1 months	43	+1.6 kg

satisfied with treatment. Through a few of studies retreatment showed not to be efficient as nascent BIB treatment.

Post BIB treatment long term follow up outcomes vary even more and are indeed difficultly for comparison or drawing more solid conclusions, so additional points as including endocrinology part might be the necessity.

Metabolic and Endocrine Effects of BIB Treatment

During BIB is implanted a hormonal changes as decrease in plasma leptin and a transient elevation of plasma ghrelin[45], without changes in adiponectin[46]. Intragastric balloon treatment beyond primer weight loosing effects offers significant alleviation of endocrinologic comorbidities of obesity, as follows: diabetes (54.4%), hypertension (48.9%), osteoarthritis (46.1%), hyperlipoproteinemia (36.5%)[21] and liver steatosis[47].

Obesity is closely related with multiple hormonal disturbances, which are not fully understood with respect to primary origin. The optimal time-line and criteria for assessing secondary effects in relation to post BIB-treatment still have not been defined or concerned unanimously.

Complications and Safety of BIB Treatment

Meta analysis of 16 trials on a sample of 3429 balloons (Table 7) reported by Imaz et al.[42] noted complications as follows: Nausea / vomiting after first week 8.6%, Abdominal pain and minor digestive disorders 5.0%, Deflation/displacement 2.5%, Inflammation or lesion in digestive lining 2.1%, Gastro-esophageal reflux 1.8%, Dehidration 1.6%, Deflation without displacement of the balloon 0.9%, Obstruction in the digestive tract 0.8%, Diarrhea / constipation 0.7%, Gastric ulcer 0.4%, l Gastric perforation 0.1%, Mortality related to balloon treatment (perforation of stomach) 0.1%. Early removal of balloon was detected in 4.2% of patients (143/3442), of which 43% were voluntary procedures. Regarding safety of BIB treatment (table 8) in a meta analyses by Vieglen et al. that in-

TABLE 7
COMPLICATIONS OF BIB TREATMENT

Reports 1999–2006	Ezophagitis	Esophageal erosions	Gastric ulcer	Gastric erosions	Gastric perforation	Mortality
16 studies; N=1402						
n	62	10	12	7	3	0
%	4.4	0.71	0.86	0.5	0.2	0
Genco et al. N=2515						
n	32		5		5	2
%	1.27		0.2		0.2	0.08

TABLE 8
BIB TREATMENT SAFETY

Reports 1999–2006	Deflation	Endoscopic removal from stomach	Rectal evacuation	Emergency surgery	Difficult removal
16 studies; N=1402					
N	123 (8.1%)	31	87	5	9
%		25.2	70.7	4.1	0.64
Genco et al. N=2515					
N/%	9 (0.36%)	9 (100%)			

cluded 4037 patients deflation occurred in 8.1% (123/1522)[36]. Immense series[21] also observed particular comorbidities as previous gastric surgery, hiatus hernia and gastritis/severe esophagitis that were all linked to major complications (generally in need for surgery) linked to intragastric balloon treatment. Majority were evacuated *per* rectum in 70.7% (87 balloons) while only 25.2% (31 balloon) were extracted from the stomach, with emergency surgical removal in 4.1% (n=5). Life threatening risks requiring an operation occurred in 5 patients from 4037.

Need for early removal due to substantial subjective intolerance occurred in 6.7%[36]. Gastrointestinal complications present in 5.5% could be treated conservatively, except for perforations (n=3). Balloon deflation rate was 8.1% generally without additional complications.

Quality of Life

We earlier reported of the relationship regarding intragastric balloon treatment effect on weight loss in manner of patients' treatment satisfaction[19]. Although subjectively expected this difference in health quality were not earlier described as typical[39]. However, it could be interest category for including in future studies from the similar backgrounds.

There are still quite some lacks available with questionnaires in regard to separating quality of life changes in relation to obesity[48,49], its commorbidities[50] treatment and posttreatment periods.

Treatment Failure and Related Parameters

A therapeutic difference of %LTW <10 is considered as a treatment failure. Genco et al. defined a successful weight loss being at least 20% of excessive weight loss, with a failure rate of 15% treated[21]. Additional psychological assessment prior to treatment might offer benefit regarding excluding individuals with binge eating disorder, or transferring those to different protocols for since they showed to obtain lesser BMI with intragastric balloons with loss 3.3 *vs*. 5.7 in non-binge controls[51]. Individuals with non-morbid obesity generally have higher usefulness of BIB treatment, on the origin of the % EWL, attributable to the fact that comparable AWR represented a greater difference in BMI. Morbidly obese patients on BIB treatment have paradoxically similar AWR and % LTW. Greatest part (90%) of patients with BMI≥40 have associated metabolic syndrome and represent better candidates for bariatric surgery. Candidates from morbidly and super-obese groups who had success with BIB treatment mostly do not agree to take recommended surgery[19]. Substantially more efforts must be applied with patients that do not comply to bariatric surgery or have contraindication, in order to gain clinically significant achievement particularly around medical history, continuous psychological and nutritionist support. This is important in both prior treatment and during follow up periods.

The Position of Intragastric Ballon Therapy for Treatment of Obesity

Intragastric balloons are a valuable minimally invasive endoscopic therapy option for treatment of obesity between pharmacotherapy and surgery. BIB intragastric balloon treatment showed to offer the best gains with individuals ranging BMI from 35 to 40[19]. Even though timeline efficiency drops from 85% at 6 months to 24% at 36 months, it offers substantial positive influence on comorbidities (over 50%), particularly cardiovascular risk factors, altering for the better quality of life[37,44]. BIB treatment is also efficient but transient modality of treatment in morbidly obese and superobese individuals to reduce preoperative risk on general and bariatric surgery. Obesity treatment with BIB is well tolerated and safe, offering better quality of life.

There are great variances among general obesity treatment or appliance of intragastric balloons. In this manner further studies that would define new clinical parameters reproducible for treatment resistance in order to provide resourcefully individualized therapy. One must not forget the ameliorative influences of lifestyle changes and implementation of physical activity, particulary in relation to obesity[52].

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POZICIJA INTRAGASTRIČNIH BALONA U GLOBALNOJ INICIJATIVI LIJEČENJA PRETILOSTI

SAŽETAK

Debljina je kronična bolest s višestrukim učincima za zdravstveno stanje pojedinca i među najvažnijim zdravstvenim problemima današnjice. Prema javnozdravstvenim podacima oko 65% populacije Hrvatske je preuhranjeno, a od toga oko 20% pretilo. Hrvatska liječnička komora u suradnji s Ministarstvom Zdravstva i socijalne skrbi izdali su smjernice o dijagnostici i liječenju debljine u obliku nacionalnog koncenzusa. Liječenje debljine je kompleksan problem i uključuje više kliničkih struka. Promjena životnih navika, energična tjelesna aktivnost i farmakoterapija dio su konzervativnog liječenja. Djelotvorniji se rezultati postižu primjenom barijatrijske kirurgije ili minimalno invanzivnih endoskopskih zahvata, koji se propisuju obzirom na početni indeks tjelesne mase (ITM). Ugradnja intragastričnih balona

predstavlja konceptualno jednostavan princip liječenja debljine. Suvremeni intragastrični baloni od kojih je najzastupljeniji BioEnterics-ov(BIB®) (Inamed Health, USA) postaju sve popularniji među bolesnicima i liječnicima. BIB nudi najbolje rezultate za pojedince sa ITM od 35–40. Učinkovitost intragastričnih balona pokazuje vremensku zavisnost od 85% nakon 6-mjesečnog tretmana do 24% nakon praćenja od 36 mjeseci. BIB poboljšava stanje komorbiditeta debljine, pogotovo kardiovaskularnog rizika. Liječenje BIB-om također je djelotvorno, ali samo kao privremen oblik liječenja morbidno i super pretilih osoba na način da smanjuje perioperativni rizik za predstojeću barijatrijsku ili opću kirurgiju. Liječenje debljine uz pomoć BIB-a je djelotvorno, dobro podnošljivo, sigurno i nudi bolju kvalitetu života. Ukupni rezultati konzervativnih oblika liječenja debljine mogu se smatrati nezadovoljavajućim na dulji rok, te su potrebna nova istraživanja za identifikaciju dodatnih kliničkih parametara rezistencije. Kako bi se ponudio učinkovit, prema bolesniku individualiziran terapijski pristup suvremena istraživanja više su fokusirana na endokrinološke stavke debljine. Hormonalni učinci BIB liječenja, te usporedba prema barijatrijskoj kirurgiji su potencijalno interesantni za buduća istraživanja.