

Assessment of weight loss after non-adjustable and adjustable intragastric balloon use

Maíra L SCHWAAB¹, Eduardo N USUY JR², Maurício M de ALBUQUERQUE¹, Daniel Medeiros MOREIRA¹, Victor O DEROSI¹ and Renata T USUY²

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ABSTRACT – Background – Intragastric balloon (IGB) use is indicated for patients whose BMI precludes the option of bariatric surgery or who need to lose weight prior to undergoing surgery. It is a minimally invasive procedure and currently there are two main models of IGBs in use, the non-adjustable intragastric balloon (NIB), implanted for six months, and the adjustable intragastric balloon (AIB), implanted for up to 12 months. **Objective** – Analyze clinical characteristics between patients receiving non-adjustable gastric balloon and the adjustable (prolonged implantation) intragastric balloon. **Methods** – This was a cross-sectional study of 470 patients diagnosed as obese or overweight who had balloon implantation from October 2011 to July 2018. The associations between percentage excess weight loss versus clinical and demographic variables were calculated using the chi-squared test. Independent samples were submitted to the Student's *t* test to determine the quantitative variables, with a confidence interval of 95%. Calculation of excess weight was based on an estimated ideal weight that would correspond to a BMI of 24.99 kg/m². **Results** – A total of 414 patients completed the treatment achieving an average total body weight loss (%TBWL) of 15.4±7 with the NIB and 15.5±9.6 with the AIB. Overweight patients achieved higher excess weight loss (%EWL) values using AIBs (157.2±82.5) and obese patients did so with NIB use (56±29.7). Women achieved higher %EWL values (65.6±62.2) than men (48±27.1). Individuals who attended >4 consultations with a nutritionist (60.8%) achieved TBWL >18%. All of those *P*-values were <0.001. **Conclusion** – Obese individuals and women registered the greatest weight losses. Overweight patients achieved greater losses using AIB and obese patients did so using NIBs. NIB use was associated with higher EWL percentages. Nutritional accompaniment had a positive impact on the %TBWL.

HEADINGS – Obesity. Gastric balloon. Weight loss.

INTRODUCTION

Obesity is a global epidemic associated with a series of comorbidities that can be readily prevented by a 5% to 10% loss of weight⁽¹⁻³⁾. Clinical treatment restricted to dietetic do not have the best long-term effect⁽⁴⁾. For patients with a body mass index (BMI) ≥40 kg/m² or BMI ≥35 kg/m² with the presence of co-morbidities^(2,5), bariatric surgery is a valid treatment option. However, for patients with lower BMIs who do not achieve weight loss with clinical therapy, endoscopic therapies are treatment options^(6,7).

Intragastric balloon (IGB) use is indicated for patients whose BMI precludes the option of bariatric surgery⁽⁸⁻¹⁰⁾, who have other contraindications, or who need to lose weight prior to undergoing surgery^(10,11). It is a minimally invasive procedure approved by the Food and Drug Administration (FDA) and Brazilian Public Health Surveillance Agency (ANVISA). Factors influencing its efficacy are balloon volume, patients' gastric capacity, and treatment duration^(12,13).

Currently there are two main models of IGBs in use, the non-adjustable intragastric balloon (NIB), implanted for six months, and the adjustable intragastric balloon (AIB), implanted for up to 12 months⁽¹⁴⁾.

The main factors associated with weight loss are initial BMI, female gender, adherence to diet, and the placebo effect, as shown by sham endoscopy studies^(7,11,15). There are considerable diver-

gences in the IGB literature regarding the effects on excess weight loss (%EWL) and BMI reduction, as well as the possible initial influence of BMI on final treatment result⁽¹⁶⁻¹⁹⁾. Furthermore, there is a scarcity of nationally or internationally published studies, not only evaluating the results of AIBs and NIBs individually, but also in comparison.

The present study aims to contribute to the literature by comparing the adjustable and non-adjustable balloons in terms of demographics characteristics, initial BMI, interdisciplinary follow-up, total body weight loss (%TBWL), %EWL, to investigate possible intolerance, and to demonstrate the results of IGBs use for obesity and overweight treatment.

METHODS

This cross-sectional study is based on data gathered from a gastroenterology and endoscopy clinic in *Universidade do Sul de Santa Catarina*.

The patients included were 18 age or older, male and female, and those who were overweight (BMI >27 kg/m²) or obese with a history of failed medical treatment at some time between October 2011 and July 2018. The only criterion for exclusion was precocious removal of the IGB. The research project was approved by the Research Ethics Committee of the *Universidade do Sul de Santa Catarina*.

The IGBs used in this study were the ORBERA® (B-50000)

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¹ Curso de Medicina da Universidade do Sul de Santa Catarina, Palhoça, SC, Brasil. ² Usuy Clínica Médica, Florianópolis, SC, Brasil.

Corresponding author: Maíra L. Schwaab. E-mail: maira.schw@gmail.com

intragastric balloon manufactured by Apollo Endosurgery, Inc. and the Spatz3® Adjustable Intragastric Balloon manufactured by Spatz FGIA, Inc.

In this study, the dependent variables were total body weight loss and excess weight loss⁽²⁰⁾, both expressed as percentages. The independent variables were gender, balloon type (adjustable or non-adjustable), age, and number of interdisciplinary consultations (with a nutritionist and/or psychiatrist). Each patient's excess weight was calculated based on an ideal weight that would give a BMI of 24.99 kg/m².

Diagnosis of patients' overweight or obese status was made during a consultation prior to treatment by weighing the patient (in kilos) using a regularly calibrated professional mechanical scale (Filizola 300 kg) and a stadiometer to obtain the patient's height (in centimeters). On the occasion of balloon implantation and its removal, measurements were repeated using the same instruments.

Data were tabulated in Windows Excel and analysis was performed using the Statistical Package for the Social Sciences (SPSS) Version 13.0. Chicago: SPSS Inc; 2009.

The association between the dependent variables (%EWL and %TBWL) and the independent demographic and clinical variables was calculated using the chi-squared test. The Student *t*-test was applied to the independent samples to determine quantitative variables with the respective confidence intervals. The level of significance was set as *P*<0.05. The researchers declared no conflicts of interests.

RESULTS

Between October 2011 to July 2018, 470 individuals underwent the implantation and removal of intragastric balloons – 326 with NIBs balloons and 144 with AIBs. Individuals who had their balloons removed before the planned time were excluded from the study.

The average patient age was 38, ranging from 18 to 74. Among patients using the NIB, mean age was 40, ranging from 19 to 69. In the AIB group, it was 39.7, ranging from 18 to 74.

A total of 322 (77.8%) individuals were females and they accounted for 79.9% of the patients using NIB and 72.4% of those using AIBs. Males accounted for 20.1% of NIB users and 27.2% of AIB users.

TABLE 1 displays patients' demographic characteristics and the FIGURES 1 and 2 the initial BMI according with each IGB. Average initial excess weight was 29.2 kg for the 298 patients using NIB and 32 kg for the 116 patients using AIB. Average weight loss was 9.07% for patients with NIBs implanted and 19.89% for those with AIBs. Female patients presented the best results for %EWL, 65.6±62.2%, and %TBWL, 15.5±7.8%. The corresponding figures for male patients were 48±27.1% and 15.1±7.9%, considering *P*<0.001 for the %EWL values.

TABLE 1. Demographic and clinical characteristics of the study participants.

Characteristics	NIB (n=298)	AIB (n=116)	P
Age*	40±10.84	39.7±11	0.78
Gender – n (%)			0.09
Female	238 (79.9%)	84 (72.4%)	
Male	60 (20.1%)	32 (27.6%)	
Initial excess weight*	29.2±15.8	32±19.22	0.16

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon. *Mean %/ standard deviation. Source: elaborated by the authors, 2019.

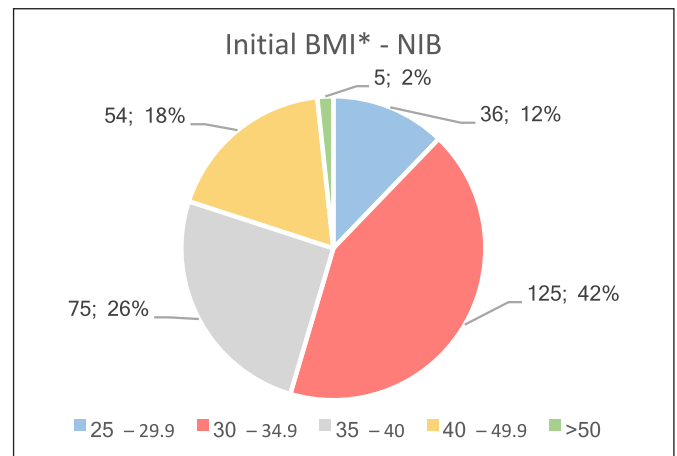


FIGURE 1. Initial BMI (NIB).

Average BMI – NIB: 35±5.6. *P* value comparing initial BMI of both IGB: 0.18.

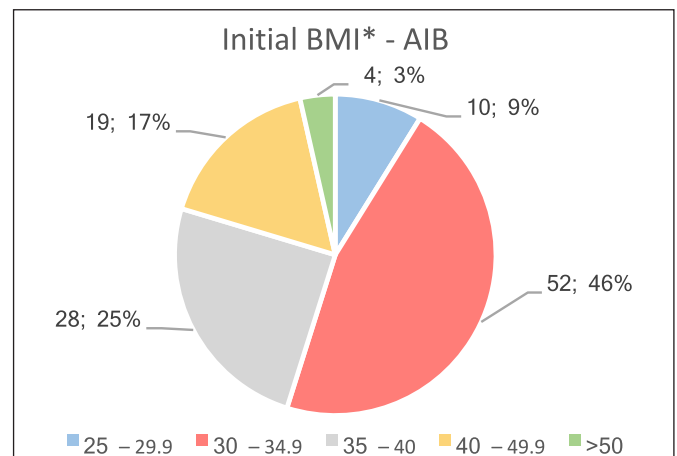


FIGURE 2. Initial BMI (AIB).

Average BMI – NIB: 36.3±6.3. *P* value comparing initial BMI of both IGB: 0.18.

FIGURES 3 and 4 details the early balloon removal according to balloon type. Respectively, 28 and 27 patients underwent premature removal of NIBs and AIBs. The major reason for removal was intolerance – NIBs (22) and AIBs (8). One AIB was removed due to an ulcer. One patient with an NIB and five with AIBs abandoned the treatment.

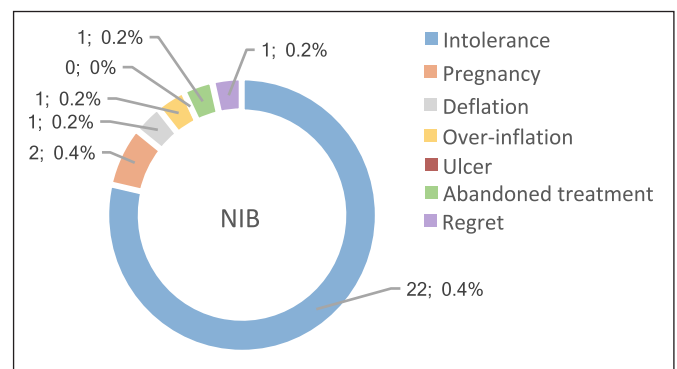


FIGURE 3. Early removals of NIB (Δ).

NIB: non-adjustable balloon; Δ (n%). Source: elaborated by the authors, 2019.

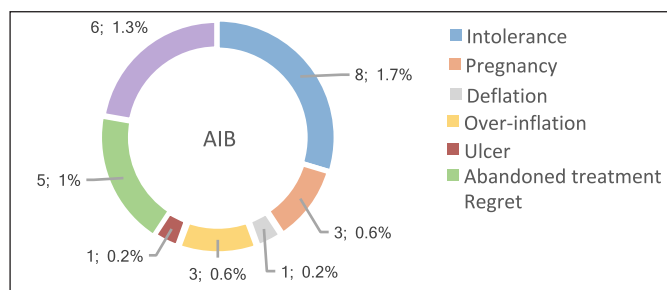


FIGURE 4. Early removals of AIB (Δ).

AIB: adjustable intragastric balloon; Δ (n%). Source: elaborated by the authors, 2019.

TABLE 2 details the numbers of consultations with nutritionists and/or psychologists divided into one group below and a second above the 50th percentile.

TABLES 3 and 4 set out details of the response to intragastric balloons^(21,22) in terms of total body weight losses equal to or greater than 10% and excess weight losses equal to or greater than 25%. Among patients with NIBs and AIBs, 88.6% and 80.2%, respectively, achieved excess weight losses of over 25% ($P < 0.05$).

TABLE 2. Interdisciplinary accompaniment discriminated by consultation numbers.

Variables	NIB	AIB	P
Nutritional consultation			0.32
≤4 – n (%)	159 (53.4%)	55 (47.4%)	
>4 – n (%)	139 (46.6%)	61 (52.6%)	
Psychological consultation			0.91
≤3 – n (%)	151 (50.7%)	60 (51.7%)	
>3 – n (%)	147 (49.3%)	56 (48.3%)	

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon. Source: elaborated by the authors, 2019.

TABLE 3. Response to treatment with NIB and AIB.

Response to IGB implantation	NIB	AIB	P
Total body weight loss (%)			0.082
≥10% – n (%)	242 (81.2%)	85 (73.3%)	
<10% – n (%)	56 (18.8%)	31 (26.7%)	
Excess weight loss (%)			0.038
≥25% – n (%)	264 (88.6%)	93 (80.2%)	
<25% – n (%)	34 (11.4%)	23 (19.8%)	

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon. Source: elaborated by the authors, 2018.

TABLE 4. Response rates to AIB with and without readjustment during treatment.

Response to AIB implantation	With readjustment (n=79)	Without readjustment (n=37)	P
Total body weight loss (%)			0.173
≥10% – n (%)	61 (78.2%)	24 (64.9%)	
<10% – n (%)	18 (21.8%)	13 (35.1%)	
Excess weight loss (%) – n (%)			0.203
≥25% – n (%)	67 (85.9%)	27 (73%)	
<25% – n (%)	12 (14.1%)	10 (27%)	

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon. Source: elaborated by the authors, 2019.

Results of the separate analyses of data for the non-adjustable and adjustable balloons are displayed in FIGURES 5 and 6. Obese patients using NIBs achieved significantly greater %EWLs than obese patients using AIBs. Among overweight patients, those using adjustable balloons achieved greater %EWL than NIBs, with all P values < 0.001 .

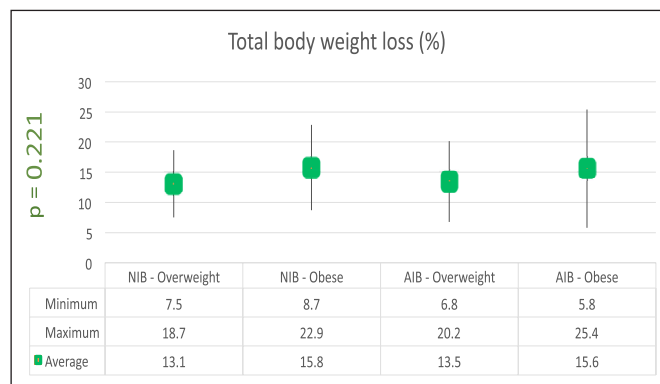


FIGURE 5. Relationship of balloon type to total body weight loss and classification as overweight or obese.

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon; $P = 0.221$ comparing NIB with AIB. Source: elaborated by the authors, 2019.

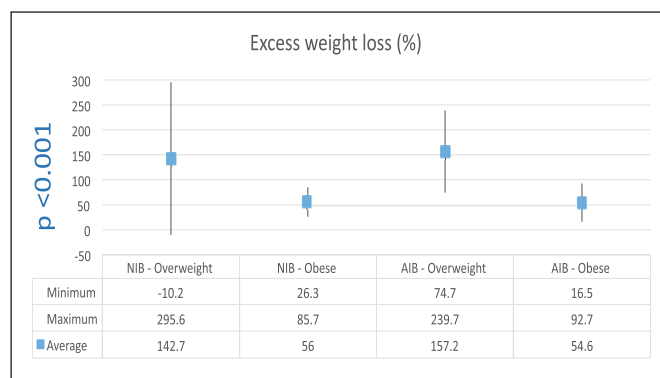


FIGURE 6. Relationship of balloon type to excess weight loss and classification as overweight or obese.

NIB: non-adjustable intragastric balloon; AIB: adjustable intragastric balloon; * P values: $P < 0.001$ comparing obese patients with NIB. $P < 0.001$ comparing obese patients with AIB. $P < 0.001$ comparing NIB with AIB. $P < 0.001$ comparing NIB with AIB. Source: elaborated by the authors, 2019.

Analyzing the sample group, there was a difference between the %TBWL of overweight patients (13.2 ± 5.8) and obese patients (15.7 ± 8), ($P = 0.009$). A similar difference ($P < 0.001$) was found between overweight and obese patients in the case of %EWL. The %EWL for all overweight patients was 145.9 ± 140 , higher than that for all obese patients, which was 55.6 ± 32.3 .

TABLE 5 offers a description of the demographic characteristics and the multidisciplinary follow up according to %TBWL and divided into groups above and below the 50th percentile. According to initial BMI, about 76 (37.3%) patients with class III obesity achieved total body weight losses above the 50th percentile, and 77 (36.7%) overweight patients achieved weight losses of up to the 50th percentile.

Patients with more than four consultations with nutritionists achieved notably higher %EWL values ($> 18\%$, $P < 0.001$).

TABLE 5. The relations between %TBWL of both balloon models with the qualitative and demographic variables.

Demographic variables	%TBWL			P
	≤18%	>18%	Total	
Initial BMI*				<0.001
25–29.9	77 (36.7%)	26 (12.7%)	103 (24.9%)	
30–34.9	58 (27.6%)	46 (22.5%)	104 (25.1%)	
35–39.9	48 (22.9%)	56 (27.5%)	104 (25.1%)	
≥ 40	27 (12.9%)	76 (37.3%)	103 (24.9%)	
Consultations with nutritionist				<0.001
≤4	134 (63.8%)	80 (39.2%)	214 (51.7%)	
>4	76 (36.2%)	124 (60.8%)	200 (48.3%)	
Consultations with psychologist				0.140
≤3	115 (54.8%)	96 (47.1%)	103 (24.9%)	
>3	95 (45.2%)	108 (52.8%)	107 (25.8%)	

TBWL: total body weight loss. *Values divided into: up to percentile 50 (from -10–18) and above percentile 50 (from 18.01–68). Source: elaborated by the authors, 2019.

DISCUSSION

The mean age of patients using NIBs was 40 and of those using AIBs, 39.7 – numbers higher than those registered in a similar study conducted by Genco et al.⁽¹⁷⁾. The gender variable showed a pattern similar to other studies^(17,23). Females represented 79.9% of the NIB users and 72.4% of the AIB users. Females achieved greater TBWL percentages (15.5%) and EWL percentages (70.6%) compared to the male patients (15.1% and 48% respectively).

The greater demand for endoscopic treatment from women than men can be attributed to patients' aesthetic motivations rather than to increased co-morbidities associated with obesity, but further studies are needed to investigate behavioral aspects in detail⁽²⁴⁾. However, considering only dietary adherence, they have better eating standards and selectivity regarding food and, consequently, a better overall pattern of adherence to the dietary regimen^(25,26).

The incidence of early balloon removal was 11.7%. Removal due to intolerance was more prevalent among the patients using NIBs (7.4%); the literature estimates an incidence of 2%–7%^(13,17,27-29). The lower incidence of premature removal caused by intolerance registered for patients with adjustable balloons (1.7%) is likely due to the fact that this type of balloon can be adjusted to lessen any gastrointestinal symptoms that arise. However, there was a higher incidence of balloon removal (1.27%) because of patient regret registered amongst users of the AIB than to those with NIBs (0.21%). A possible explanation, in the authors' view, is the longer duration of the therapy with the AIB; patients who choose it are usually expecting a much easier course and so their adherence to treatment is weakened. Nevertheless, this study was not focused on analyzing early removal.

In spite of the longer time spent with the AIB in place, patients using the NIB achieved %EWL values significantly higher than those using AIBs. Within the group of AIB users there was no statistically significant difference between those who made adjustments and those who did not, in terms of excess weight loss. Although, 85.9% of those who underwent adjustment achieved an EWL of 25% or over, whereas 73% of those who did not undergo adjustment reached this %EWL. Those results may be due to the non-standardization of the readjustment volumes, resulting in subtherapeutic adjustment levels, especially in cases of patient intolerance of the

balloon and/or other subjective complaints. In this study, the choice of intragastric balloon model was voluntary and, considering the aforementioned non-standardization of adjustment volumes, non-randomization made it impossible to make a precise estimation as to which IGB offered the best rate of response to treatment. To obtain results with fewer biases, it is necessary to conduct studies dividing patients in groups for intragastric balloon implantation and, for the AIBs, to define the parameters of the endoscopic readjustments. Some authors suggested that after three months of treatment, the volumes should be reset to a higher level, given that 80% of weight loss occurs during that interval, after which there is a heightened level of gastric compliance and a diminished effect of early satiety^(19,30). However, there is much divergence of opinion in the literature concerning readjustment^(18,31).

Regarding initial BMI, the average values in this study were somewhat lower than another similar study⁽¹⁷⁾ for the NIB group (41.6±6.5) and the AIB group (40.9±4.8), but those figures were within the range of averages reported by Tate's systematic review (33±2.7 to 50.4±7.8)⁽¹⁵⁾. The disparities may be due to patient samples from differing locations and the specific referral centers. Some of the studies in the systematic review concerned the implantation of intragastric balloons only in super-obese individuals with a focus on a posterior bariatric procedure, thereby introducing bias in the initial BMI variable. The population involved in the present study was effectively heterogeneous in terms of the clinical variables, namely age, gender, initial BMI and excess weight.

Regarding the percentage of total body weight loss in patients using IGBs, there was a statistically significant positive correlation between the initial BMI and weight loss, whereby the obese patients achieved greater weight losses than the overweight patients, but there were no statistically significant differences found when comparing the results achieved by the two different types of balloon. As to %EWL, it was found to be inversely proportional to the BMI. That is likely because individuals with a low BMI have less excess weight and, in the case of the sample in this study, such patients had BMIs lower than that which was used as the reference (24.99 kg/m²) to calculate the ideal weight. This explains the range of %EWL in both IGBs were greater because some patients experienced weight gain and others excessive weight loss, according to the BMI used has reference (24.99 kg/m²). Thus, there is a need for additional randomized studies to enable a better analysis of the clinical and demographic variables.

Analysis of the effect of balloon type used in patients with different BMIs showed that, in overweight patients, the AIB delivered a higher %EWL and, among the patients diagnosed as obese, the non-adjustable model achieved the highest percentages, suggesting that the indication of the model to be used should be based on the patient's BMI. In a similar study, Fernandes et al. compared the use of the non-adjustable model alone in overweight and obese patients, showing that %EWL was greater in the overweight patients and %TBWL was greater in the obese patients⁽³²⁾. Ribeiro da Silva et al. obtained similar results; patients with higher BMIs registered the greatest weight losses⁽³³⁾.

Regarding the demand for interdisciplinary follow up, there was no difference between patients with NIBs and those with AIBs. However, this study did identify that the follow up with a nutritionist had a considerable impact on achieving greater weight loss. Studies such as those undertaken by Mazure et al. also demonstrated a similar effect from nutritional follow up, in that the average excess weight loss percentage was 42.75% in those with NIBs implanted⁽³⁴⁾. The

CONCLUSION

present study showed that patients who attended four consultations or more with a nutritionist obtained a higher weight loss percentage. Indeed, the patients' commitment to interdisciplinary endoscopic treatment appeared to be more important in achieving positive clinical results than initial BMI or the type of balloon used, showing that these variables, even though they are non-standardized, may be associated with better patient compliance to dietary and behavioral recommendations. Recently, that relationship was demonstrated in an article published by Genco et al., reporting on a randomized sample of patients using NIBs but divided into two different dietetic groups. Patients on a low-calorie, high-protein diet achieved 11% more excess weight loss than the other group⁽³⁵⁾.

Based on the present study and the very few other similar studies, it is not possible to determine which is the best type of intragastric balloon according to initial BMI values and which have obtained the best clinical results with the greatest percentage losses of excess weight and total weight. Considering this is a retrospective study, the population concerned is highly stratified, and the decision as to which type of endoscopic treatment to undergo was made by the patients themselves.

Nevertheless, in spite of the selection bias, this study corroborates the literature with significant associations between %EWL/%TBWL and initial BMI, female gender, type of balloon, interdisciplinary accompaniment, and percentage losses of excess weight and total weight. There is, however, a need for more studies in bigger centers with case randomization and greater control over patients, stratifying them in accordance with BMI and balloon type in order to arrive at firmer conclusions.

Women attained higher weight loss rates than men irrespective of the kind of intragastric balloon used. The greatest weight loss was observed among overweight patients who made use of adjustable intragastric balloons and obese patients using non-adjustable ones. There is an association between the use of non-adjustable balloons and higher rates of excess weight loss. Nutritional accompaniment had a strong positive impact on weight loss. To obtain better conclusions comparing the two types of balloons, randomized, prospective studies are necessary with control based on sham endoscopy.

Authors' contribution

Schwaab ML: data collection, execution of research, text writing, statistical analysis. Usuy Jr EN: text writing. Albuquerque MM: execution of research, text writing. Moreira DM: statistical analysis. Derossi VO: data collection. Usuy RT: text writing.

Orcid

Máira L Schwaab: 0000-0002-1019-6292.

Eduardo N Usuy Jr: 0000-0002-6233-057X.

Maurício M de Albuquerque: 0000-0001-9959-3843.

Daniel Medeiros Moreira: 0000-0003-0605-8003.

Victor O Derossi: 0000-0002-9023-5983.

Renata T Usuy: 0000-0002-4426-9904.

Schwaab ML, Usuy Jr EN, Albuquerque MM, Moreira DM, Derossi VO, Usuy RT. Avaliação de perda de peso após o uso de balão intragástrico não ajustável e ajustável. *Arq Gastroenterol.* 2020;57(1):13-8.

RESUMO – Contexto – O uso do balão intragástrico (BIG) é indicado para pacientes cujo IMC contraindica a cirurgia bariátrica ou que necessitam perder peso antes da cirurgia. É um procedimento minimamente invasivo e atualmente existem dois modelos principais de BIG – o balão intragástrico não ajustável (BINA), implantado por seis meses, e o balão intragástrico ajustável (BIA), por até 12 meses. **Objetivo** – Analisar os fatores associados aos resultados clínicos comparando o uso de balão intragástrico não ajustável com o uso de balão intragástrico ajustável. **Métodos** – Estudo transversal em 470 pacientes, com sobrepeso ou obesidade, submetidos ao tratamento entre outubro 2011 e julho de 2018. A associação entre as porcentagens da perda de excesso de peso (%PEP) e da perda do peso total (%PPT) com as variáveis demográficas e clínicas foram calculados com o teste qui-quadrado ($P < 0,05$). Foi utilizado o teste *t* de Student para amostras independentes para comparar variáveis quantitativas, com IC 95%. O cálculo do excesso de peso foi estimado em peso ideal correspondente a um IMC de 24.99 kg/m². **Resultados** – Um total de 414 pacientes realizaram o tratamento até o final, com %PPT média de 15,4±7 no BINA e 15,5±9,6 no BIA. Os com sobrepeso apresentaram maiores %PEP no BIA (157,2±82,5) e os obesos maiores %PEP no BINA (56±29,7), com $P < 0,001$. Mulheres (65,6±62,2) apresentaram maiores %PEP do que homens (48±27,1), com $P < 0,001$. Os indivíduos que atenderam a >4 consultas com nutricionista obtiveram %PPT >18% (60,8%), com $P < 0,001$. **Conclusão** – Obesos e mulheres tiveram maiores perdas ponderais. Maior perda de peso foi identificada em pacientes com sobrepeso que utilizaram BIA e em obesos os quais utilizaram BINA. O BINA esteve associado com maiores taxas de %PEP. O acompanhamento nutricional impactou positivamente na %PPT.

DESCRITORES – Obesidade. Balão gástrico. Perda de peso.

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