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Preliminary analysis of the effectiveness of the Spatz-3® balloon in a sample of female patients in Ciudad Juarez, Mexico

Análisis preliminar de la efectividad del balón Spatz-3® en una muestra de pacientes femeninos en Ciudad Juárez, México

Óscar I Ortiz-Ruvalcaba,[*] Juan de Dios Díaz-Rosales,[‡] Gabriel Galván-Araiza,[*] Julio César Naranjo-Chávez,[*] Ana Luisa Márquez-Morales,[*] Dante Deras-Ramos,[‡] Raúl Luna-Lugo[‡]

Keywords:
gastric balloon, stomach, obesity, obesity management, women.

Palabras clave:
balón gástrico, estómago, obesidad, manejo de la obesidad, mujeres.

ABSTRACT

Introduction: obesity is a high-mortality pandemic. Its treatment is multidisciplinary and is based on lifestyle changes with limited benefit. Intragastric devices (IGD) are a treatment for weight loss, especially when the patient is unfit or denies surgery. **Objective:** to evaluate treatment results with the intragastric device Spatz-3® over 12 months. **Material and methods:** a longitudinal study was carried out to evaluate the efficacy of the intragastric device Spatz-3® in a private endoscopic center in northern Mexico; 27 female patients were analyzed between January 2019 and December 2021. **Results:** an average decrease in total weight of 14.2 kg (14.6% of total body weight and 37.6% of excess weight lost) was observed at 12 months. Despite lower effectiveness than that reported in surgical treatment, IGDs are more effective than conservative interventions based on changing the patient's lifestyle. **Conclusion:** the intragastric device Spatz-3® showed a considerable reduction in total weight, being also a method with a lower rate of complications and completely reversible.

RESUMEN

Introducción: *la obesidad es una pandemia de alta mortalidad. Su tratamiento es multidisciplinario y tiene como base el cambio del estilo de vida con un beneficio limitado, por lo que en la mayoría de los casos es necesario realizar otras intervenciones. El uso de dispositivos intragástricos colocados por endoscopia es un método en el tratamiento para la pérdida de peso, principalmente cuando el paciente no es apto o no acepta una intervención quirúrgica.* ***Objetivo:*** *evaluar los resultados del tratamiento con el dispositivo intragástrico Spatz-3® en un periodo de cuatro a 12 meses.* ***Material y métodos:*** *se analizaron los resultados de un estudio longitudinal para evaluar la eficacia del dispositivo intragástrico Spatz-3® en un centro endoscópico privado en el norte de México. Se analizaron 27 pacientes del género femenino en un periodo comprendido entre enero de 2019 y diciembre de 2021, a quienes se les colocó el dispositivo Spatz-3®.* ***Resultados:*** *se observó una disminución del peso total en promedio de 14.2 kg (14.6% del peso total corporal y 37.6% del exceso de peso perdido) a los 12 meses. Aunque estos resultados están por debajo de lo reportado por otros estudios con tratamiento quirúrgico (manga gástrica, bypass gástrico), el dispositivo intragástrico tiene una efectividad más alta comparada con las intervenciones conservadoras basadas en el cambio del estilo de vida del paciente.* ***Conclusión:*** *el dispositivo intragástrico Spatz-3® mostró una reducción considerable del peso total, siendo además un método con menor tasa de complicaciones y completamente reversible.*

[*] OrmaMed – *International Surgical Services*. Ciudad Juarez, Chihuahua.
[‡] Medicine Program, Universidad Autónoma de Ciudad Juarez. Ciudad Juarez, Chihuahua.

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INTRODUCTION

Obesity is the disease that generates the most deaths worldwide (up to 12.3% in 2016). Its mortality is related to its comorbidities, mainly: diabetes, hypertension, and dyslipidemia.1 In Mexico, it is considered a public health problem; regardless of socioeconomic level or region, the prevalence of obesity continues to increase. Currently, in Mexico, the prevalence of overweight is 39.1%, obesity 36.1%, and abdominal adiposity 81.6%.[1]

Morbid obesity is a condition that requires structured attention and specific capacity. Unfortunately, these conditions are not available in most of Mexico.[1] The management of obesity includes conservative measures such as lifestyle modification (diet and exercise). This measure needs more patient adherence and is of limited and reversible efficacy. The discrete success of the initial measures against obesity forces us to look for other alternatives, where bariatric surgery procedures are one of the preferred measures for the treatment of obesity; however, only 1% of obese patients (with criteria for bariatric surgery) will have access to these procedures.[2] Therefore, non-surgical interventional procedures are alternatives for the treatment, and their popularity is increasing due to the safety they project and their proven effectiveness.[3]

Balloon intragastric devices (IGDs) are considered a safe alternative with a better success rate than conservative measures. This fast-acting, minimally invasive IGDs are restriction therapies that limit food intake, induce early satiety, increase gastric emptying time, and reduce caloric intake (with subsequent weight loss).[4] IGDs have also been documented to decrease ghrelin secretion, aiding in managing comorbidities such as diabetes, dyslipidemia, and non-alcoholic fatty liver disease (NAFLD).[5]

Balloon IGDs have been continuously redesigned to increase weight loss, improve patient tolerance, and decrease complications. The ideal balloon IGD should have specific characteristics: it should be made of soft and durable material, has a low ulcerogenic potential, has a radiopaque marking for tracking and identification, and be size adjustability and of simple removal.[3] There are several devices of this type, such as Orbera®, Obalon®, ReShape®, Elipse®, and Spatz-3®, among others. They are made of silicone and are filled with air or liquid (stained with methylene blue) with volumes ranging from 500 to 900 ml. The time this therapy can last inside the stomach ranges from six to 12 months.[2]

Bariatric procedures, regardless of the technique performed, are considered of good quality if they meet the following objectives: reduce pathological weight, maintain it over time, improve or cure comorbidities that reduce the life span of the obese patient, improve quality of life, and induce a minimum number of sequelae.[6] this study aimed to measure the effect of the DIG Spatz-3® (Medical Great, Neck NY.) in a sample of women in a private endoscopic medical center in northern Mexico.

MATERIAL AND METHODS

A longitudinal and analytical study was conducted on a sample of female patients undergoing therapy with the DIG Spatz-3® in a private bariatric unit in Ciudad Juarez, Chihuahua (OrmaMed-International Surgical Services) from January 2019 to December 2021.

The selection criteria were female gender, over 18 years of age, compliance with balloon adjustment at four months, and balloon removal at 12 months of treatment. Exclusion criteria were patients who did not authorize control lab tests, active or recent gastric ulcer, previous gastric surgery, esophageal or gastric varicose veins, hiatal hernia > 5 cm, and the use of anticoagulants. Elimination criteria: patients who underwent adjustments or balloon removal in another unit.

The following variables were evaluated: age, ideal weight, height, current weight, body mass index (BMI), total excess body weight, excess body weight lost (BWL), percentage of BWL (%BWL), body weight lost, fasting glucose, triglycerides, high-density lipoproteins (HDL), aspartate aminotransferase (AST), alanine aminotransferase (ALT), and glycated hemoglobin (HbA1c).

The ideal weight was calculated using the formula: ideal weight = ideal BMI × height.[2]

In the case of women, the ideal BMI is 21.5 kg/m^2. The formula was used to calculate excess body weight: excess body weight = actual weight - ideal weight. The formula used for the calculation of %EPP was %BWL = (BWL × 100)/excess weight.

For the placement procedure of the IGD Spatz-3®, the informed consent form was signed. Under sedation, the gastric cavity was evaluated with Fujinon EPX-4400® endoscopy equipment in the left lateral decubitus position. Then, the balloon DIG Spatz-3® was introduced, verifying that it was in place in the gastric cavity. Then an initial volume of 500 cm^3 (saline solution stained with methylene blue) was instilled, and after a few hours of observation, the patient was discharged and monitored by telephone. Subsequently, after four months of treatment, an appointment was made to adjust the balloon (until 900 ml of saline solution stained with methylene blue was completed). At the end of 12 months of treatment, the patient was again seen, the variables were remeasured, and the balloon was removed.

IBM SPSS® version 24 (Chicago, IL) software was used; averages as a measure of central tendency and standard deviation (SD) as a measure of dispersion were calculated. Averages were compared using Student's t-test for variables with normal behavior in related samples and the Wilcoxon test for variables with non-normal behavior in related samples. It was considered statistically significant when the p-value result was < 0.05. The Kolmogorov-Smirnov test was used to define the behavior of each quantitative variable.

RESULTS

Twenty-seven female patients were included with an average age of 45.4 ± 10.6 years, height of 1.63 ± 4 cm, and BMI of 36.5 ± 2.7 kg/m^2. An ideal weight of 57.4 ± 2.9 kg and an average excess weight of 40.1 ± 7.1 kg were calculated. *Table 1* shows the differences in the variables at balloon placement, during the adjustment (four months), and at device removal at 12 months. *Figure 1* shows the average evolution of the patients concerning initial weight, weight at adjustment, and weight at the end of therapy, and shows the initial excess weight (in kg), excess weight at adjustment, and excess weight at the end of therapy.

Table 2 shows how the variables were modified at four months of treatment compared to the pre-treatment state. A decrease in total body weight on average of 8.9 ± 5.7 kg ($p \leq 0.001$) was observed, representing a loss of 9.1% of the patient's % of total body weight lost, a decrease in %BWL of 23.1% ± 14.6%,

Table 1: Changes in variables during Spatz-3® balloon treatment.

Variable	Baseline	SD	Adjustment	SD	Removal	SD
Weight (kg)	97.5	7.9	88.6	8.3	83.3	11.9
BMI (kg/m^2)	36.5	2.7	33.2	3.4	31.2	4.4
Weight excess (kg)	40.1	7.1	31.2	8.5	25.9	11.7
Glucose (mg/dl)	98.0	21.4	90.3	22.9	99.7	41.7
Triglycerides (mg/dl)	148.6	54.3	125.6	67.9	139.0	84.9
HDL (mg/dl)	65.8	46.8	48.4	9.5	52.1	12.5
AST (U/l)	27.7	8.2	29.8	13.8	22.8	6.7
ALT (U/l)	30.8	10.2	26.7	10.5	23.6	9.9
HbA1c (%)	6.4	1.3	6.5	1.2	6.3	1.8

SD = standard deviation. BMI = body mass index. HDL = high-density lipoproteins. AST = aspartate aminotransferase. ALT = alanine aminotransferase. HbA1c = glycated hemoglobin,
Source: electronic file OrmaMed.

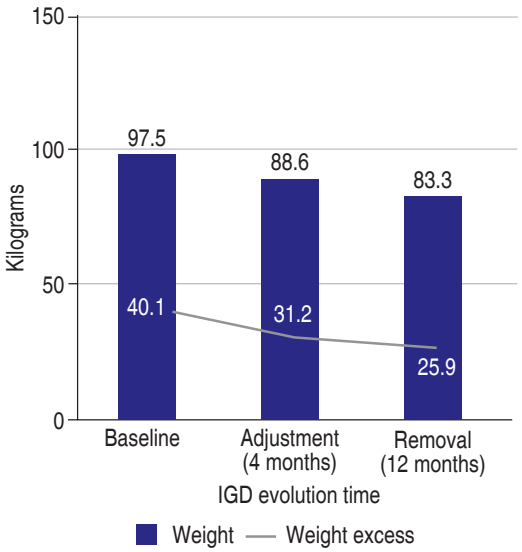

Figure 1: *Graphic representation of total and excess weight loss during therapy at baseline, four months, and 12 months with the intragastric device (IGD).*

and a decrease in BMI of 3.3 kg/m^2 ($p \leq 0.001$). Glucose and triglyceride levels were also significantly reduced at four months of treatment. However, HDL levels, liver enzymes, and HbA1c showed no significant changes.

Table 3 describes the patients at the end of DIG therapy (12 months). On average, a decrease in total weight of 14.2 ± 8.5 kg ($p < 0.001$) was observed, representing 14.6% total weight loss and accounting for 37.6% ± 26.2% of %BWL. BMI had a statistically significant decrease of 5.3 kg/m^2 ($p < 0.001$). AST and ALT levels also decreased statistically significantly, while glucose, triglycerides, HDL, and HbA1c showed no significant reductions.

DISCUSSION

Obesity is a complex disease to treat, and we must remember that medical treatment (conservative, endoscopic, or surgical) will have a high failure rate if it is considered the only therapy. It is of utmost importance that a multidisciplinary team strictly follows up with the patient to foresee the anxiety mechanisms that will provoke new habits that limit weight loss and condition the failure of even the most radical bariatric therapies.

Although %BWL does not translate into a proportional patient weight loss, it has been documented. Klingler reports that patients undergoing an IGD placement (from four to 12 months) usually have an average of %BWL of 6 to 15%.[7] In this sense, the %BWL better represents that weight loss, and in general, the American Society of Gastrointestinal Endoscopy (ASGE) recommends that IGDs have an average %BWL of 25% at six months.[8] With these numbers and recommendations, we can analyze the results.

Although international studies show that IGDs effectively reduce up to 58% of %BWL at six months,[2] our results reveal the likely reality in most centers where IGDs are frequently used. Our analysis shows that during treatment with the IGD Spatz-3®, an average weight loss of 14.2 kg is achieved at 12 months of treatment, which is 14.6% of total body weight and 37.6% of %BWL, according to Klingler's publication and ASGE.[7] In our sample of patients, this weight loss represents a reduction in average BMI from grade II obesity to grade I obesity (36.5 versus 31.2 kg/m^2, $p < 0.001$).

In a study performed with the Orbera® balloon, the average weight loss at six months was 14.7 kg,[2] compared to our lower results at four months (8.9 kg), while after adjustment, the threshold of 14 kg was reached at 12 months of treatment. However, the 14.7 kg lost at six months (with Orbera®) represented 32.1% of %WBL versus 14.2 kg at 12 months (in our study), which represented 37.6% of %WBL. This difference was 5.5% in favor of the 12-month therapy. Another study performed with the ReShape® device showed a %BWL of 15.4%,[2] slightly higher than the 14.6% total body weight loss obtained in our study. In another study conducted in Mexico, the average weight loss was 10.7 kg after an eight-month therapy with an IGD,[8] a slightly lower average than our group's.

In more extensive samples of patients (1,523 patients), the efficacy of different DIGs has been evaluated, where a %BWL of 17.9% and a %EPP of 4.4% were observed.[9] These results reveal lower averages than those shown in our study (%EPP 37.6% and %EPP 14.6%, respectively). The higher averages in our study may be because the sample was small

compared to the more than 1,500 patients evaluated. When the study sample is larger, the statistical power stabilizes. However, our study is preliminary, and we will continue documenting it until we obtain more stable and reliable results.

In another study conducted by Nucci in Italy with the Spatz-3® balloon, the average weight loss in 138 patients at 12 months was 24.8 kg,[10] of which was almost double that shown in our analysis (14.2 kg at 12 months). In other studies, with the Spatz-3® balloon, it was observed that the %BWL at 12 months ranged from 45.8 to 56.7%.[3] These excellent results reveal how great the benefit can be at the individual level. In our study, one patient had a %BWL of 67%. As such, this result cannot be inferred, but it demonstrates that some patients will respond better.

Although fasting glucose levels were significantly reduced at four months, this result could not be corroborated at 12 months of treatment with the IGD Spatz-3® balloon. There was no significant reduction in glycated hemoglobin levels, so we could not show improvement in the metabolic profile of the patients at the end of treatment. However, we must remember that this preliminary study should consolidate the results once we have an adequate sample.

Few complications are reported concerning IGDs, such as early removal of the IGD due to intolerance or pain (4 to 7%), nausea and vomiting (30 to 50%), and balloon rupture (4.1 to 15.8%).[3] Serious complications (0.84%) are rare; most resolve with endoscopic treatment. Surgery has been required in 0.07% of patients, with no apparent related mortality.[11] Major complications include bleeding, ulceration, gastric perforation,[12] esophageal perforation due to tearing,[11] and gastric outlet obstruction syndrome.[13] In general, complications during medium-term therapy are based on loss of patient follow-up (both by the service provider and the patient's carelessness). In our study, post-placement pain was observed in 10% of patients (which did not warrant removal), nausea and vomiting in 60% of patients (managed with antiemetic drugs), and esophagitis in up to 40% of patients (probably related to poor adherence to proton pump inhibitor therapy).

These results for %EPP show actual numbers from a bariatric center in northern Mexico. These results are less satisfactory than those presented in other research papers; however, these numbers provide ethical information obtained in a specific population and do not evoke false results.

Table 2: Evolution of patients at four months after Spatz-3® balloon adjustment.

Variable	Baseline	SD	Adjustment	SD	Difference	p
Weight (kg)	97.5	7.9	88.6	8.3	8.9	< 0.001
BMI (kg/m^2)	36.5	2.7	33.2	3.4	3.3	< 0.001
Weight excess (kg)	40.1	7.1	31.2	8.5	8.9	< 0.001
Glucose (mg/dl)	98.0	21.4	90.3	22.9	7.7	0.002
Triglycerides (mg/dl)	148.6	54.3	125.6	67.9	23.0	0.002
HDL (mg/dl)	65.8	46.8	48.4	9.5	17.4	0.070
AST (U/l)	27.7	8.2	29.8	13.8	-2.1	0.180
ALT (U/l)	30.8	10.2	26.7	10.5	4.1	0.080
HbA1c (%)	6.4	1.3	6.5	1.2	-0.1	0.300

SD = standard deviation. BMI = body mass index. HDL = high-density lipoproteins. AST = aspartate aminotransferase. ALT = alanine aminotransferase. HbA1c = glycated hemoglobin.
Source: electronic file OrmaMed.

Table 3: Final result at the end of the 12-month treatment with the Spatz-3® balloon.

Variable	Baseline	SD	Removal	SD	Difference	p
Weight (kg)	97.5	7.9	83.3	11.9	14.2	< 0.001
BMI (kg/m^2)	36.5	2.7	31.2	4.4	5.3	< 0.001
Weight excess (kg)	40.1	7.1	25.9	11.7	14.2	< 0.001
Glucose (mg/dl)	98.0	21.4	99.7	41.7	-1.7	0.300
Triglycerides (mg/dl)	148.6	54.3	139.0	84.9	9.6	0.200
HDL (mg/dl)	65.8	46.8	52.1	12.5	13.7	0.700
AST (U/l)	27.7	8.2	22.8	6.7	4.9	0.009
ALT (U/l)	30.8	10.2	23.6	9.9	7.2	0.002
HbA1c (%)	6.4	1.3	6.3	1.8	0.1	0.200

SD = standard deviation. BMI = body mass index. HDL = high-density lipoproteins. AST = aspartate aminotransferase. ALT = alanine aminotransferase. HbA1c = glycated hemoglobin.
Source: electronic file OrmaMed.

We are aware of the limitations of the use of BMI as an indicator of obesity or risk of associated comorbidities since it is not very accurate for assessing adiposity at the individual level and for specifying its location;[14] nevertheless, it continues to be a valid marker, albeit with a subjective tinge. Waist circumference is an index that allows us to evaluate visceral fat and better characterize this area.[15] Unfortunately, we did not have this variable at the time of the study, but it will be included in future reports.

Predictors of treatment success with DIGs go hand in hand with weight reduction, classifying it as %TPP and %EPP; however, these two measures focus on different areas of study. The %TPP in a 5-15% range reduces weight-related morbidity.[6] In comparison, the %EPP determines the success or failure of the therapy and classifies it as < 20% unsatisfactory result, from 20 to 50% as a good result, and > 50% as an excellent result.[16,17] In our study, the decrease in %TPP was 14.6% and a %EPP of 37.6%. Within the classifications mentioned above, the results obtained in this study are defined as successful, as they comply with the established ranges.[6]

The importance of the success of these two criteria varies depending on the objective of the study, taking into account the surgical point of view in case the use of DIG therapy is a predecessor of some other surgical intervention, the range of success based on %EPP is mainly used, while those patients who reject some other intervention and the therapeutic objective is to improve the prognosis of life and reduce morbidity and mortality, the decrease in total weight is considered as an expected predictive value.[18]

CONCLUSIONS

Significant weight reduction using the DIG Spatz-3® is documented in this preliminary study. Although the reduction is not dramatic as in surgical bariatric procedures, the DIG Spatz-3® represents a safe and reversible option for patients who are bridging prior to a surgical procedure, patients who do not desire a surgical procedure, or patients with obesity who wish to decrease their weight and BMI without undergoing the risks and morbidity and mortality that other definitive procedures may have.

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Correspondence:
Óscar I Ortiz-Ruvalcaba
E-mail: droscarortiz@gmail.com