Mexican Experience in the Treatment of Obesity with Liquid-Filled Balloon

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Introduction

According to the National Health and Nutrition Survey of 2016, Mexico is facing a public health issue regarding obesity and overweight. The prevalence of both combined is 33.2% in children, 36.3% in teenagers, and 72.5% in adults (in 2016) [1–3].

The Garren–Edwards Bubble was the first endoscopic device used for the treatment of obesity, approved by the FDA in 1984, although it was removed from the market 4 years later due to the multiple complications associated with its use. Many devices have been developed since. Currently there are three FDA-approved devices in the United States for the treatment of obesity: Orbera® (Apollo Endosurgery, Inc., Austin, TX, USA), ReShape® Duo (ReShape Medical Inc., San Clemente, CA, USA), and Obalon® (Obalon Therapeutics Inc., Carlsbad, CA, USA), others being in the process of approval. A wider range of devices is found in Europe, such as Spatz® (Spatz Medical, Great Neck, NY, USA) and the Heliosphere BAG® (Helioscopie Medical Implants, Vienne, France) [4].

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Indications

In Mexico, the Health Department regulates the use of the intragastric balloon through guidelines that establish the following requirements: Patients must have a body mass index over 40 kg/m^2 (or 35 if comorbidities are associated), with a previous complete clinical and laboratory evaluation, and a multidisciplinary group that involves the psychology department, a clinical nutritionist, and the medical team appropriately certified for the insertion of the intragastric device. To meet these requirements, the Mexican College of Surgery for Obesity and Metabolic Diseases created, in collaboration with the pharmaceutical industry, the Clinical Guidelines of Psychology and Nutrition for the evaluation, management, and treatment of patients with intragastric balloon and gastric band. The same contraindications that are described in the international literature for the use of intragastric devices are ruled in Mexico, such as psychiatric disease, previous gastric surgery, intolerance to proton-pump inhibitors, hiatal hernia of 5 cm or greater, pregnancy, breastfeeding, among others [2, 3].

Nutritional Evaluation

In terms of nutrition, the preoperatory evaluation includes an anthropometric and biochemical evaluation with a complete medical history, emphasizing the alimentary aspects and lifestyle. The anthropometric assessment consists of taking measures of weight, size, body mass index, excess weight, fat excess weight, percentage of body fat, muscle mass, waist, abdominal and neck circumference, as well as a bioimpedance analysis. The biochemical evaluation, according to the Argentine consensus of nutrition in surgery of 2010, reviewed in 2014, consists of blood count with a count of platelets, blood sugar, kidney function tests, general urine test, and a lipid profile [5]. The assessment must be carefully done knowing the patient's condition and individualizing each case to determine if additional studies other than the usual are required. Dietary assessment evaluates the usual energy intake of the patient. Based on this, the reduction of energy intake is determined prior to any bariatric procedure. Since the patient tends to draw down to 50% of the caloric intake, it is important to know how their eating habits are. Having a balloon is different from person to person. Some find it a lot easier than others. The dietary guidelines include from day 1 to day 3 only liquids starting with simple water and if tolerated it is progressed to free fluids avoiding carbonated drinks, from day 4 to day 10 soft foods only, and beyond day 10 normal textured foods. The patient should have vitamin and mineral supplements for 6 months while they have the balloon [6].

Psychological Evaluation

The psychological intervention of the patient consists of three stages: the evaluation phase, the intervention phase, and the follow-up. In the evaluation phase, a structured interview is done, aimed at identifying the areas of opportunity that should be

worked on, such as the presence of psychopathologies or dysfunctional eating patterns, the quality of the support network, the expectations and degree of motivation, among others. Also, a battery of tests is applied, oriented to provide support for the identification of anxiety and depression, binge eating, and affectations in the quality of life. The second phase is characterized by a cognitive-behavioral intervention aimed at modifying the maladaptive behavior of the patient and developing new skills that allow weight loss. This intervention is carried out during the time that the patient has placed the intragastric balloon and can be administered monthly. Finally, once the balloon is removed, the patient is provided with a psychological follow-up aimed at maintaining the progress obtained from the treatment and, in some cases, continuing with the weight loss. This final phase may last about 6 months. The battery of tests must be provided at the end of the second and third phases as well to enhance the effectiveness of the treatment.

Results

In a prospective study held by the Obesity Clinic of the Dr. Manuel Gea González General Hospital, the use of intragastric balloon was compared with a hypocaloric diet as a treatment for obesity. Forty-seven obese patients were chosen, 20 of them were treated with a hypocaloric diet while 27 patients were treated with an intragastric balloon. In the hypocaloric diet group, the average initial body weight was 115.91 kg with an initial BMI of 41.05 kg/m^2 and the average final body weight was 101.9 kg, the final BMI of 39.09 kg/m^2, with a TBW loss of 13.85 kg and an EWL of 22.89%. In the intragastric balloon group, the average initial body weight was 107.44 kg with an initial BMI 39.67 kg/m^2 and the average final weight was 99.34 kg with the final BMI 36.64 kg/m^2, with a TBW loss of 8.11 kg and an EWL of 13.46%. Independent variables were compared using the t-student test without a significant difference found. In conclusion, the intragastric balloon was found as an effective therapy when compared to a supervised hypocaloric diet [7].

A second study in the same hospital included 22 patients, 16 of whom were female and 6 were male, with an average age of 41.6 years (21–63), an average weight of 113.9 kg (68–250), and a mean BMI of 41.4 kg/m^2 (30–89). Out of the 22 patients, 15 presented with associated comorbidities, the Orbera® balloon was used in 17 patients and the Spatz® balloon was used in 5. Seven patients presented some degree of discomfort after the procedure, nausea being the most prevalent symptom ($n = 4$), followed by vomit ($n = 3$), diarrhea ($n = 2$), and abdominal pain and bloating in one patient. A higher %EWL was seen in the group of patients with Spatz® balloon compared with Orbera® group. A %EWL during the first 6 months of follow-up was of 34.9%, although a regain of 40% of weight was seen 6 months after retrieval [8].

Another retrospective study included 53 patients that did not meet the criteria for bariatric surgery and had BMI under 35 kg/m^2. The average age was 33 years (17–63), 14 male and 39 female patients were included, with an initial average weight of 86.1 kg (62.1–121.4), the filling volume in average was of 612 ml (400–500), the

time of follow-up at 1, 3, 6, 9, and > 9 months showed an excess body weight loss of 21.9%, 34.1%, 34.5%, 30.5%, and 43.5% respectively [9].

The Orbera® company was first registered in Mexico with the name BIB and then changed to its actual name in 2014. Data provided by this company reveals that 18,000 devices have been applied to patients in our country. There are 215 registered physicians to install the Orbera® balloon in Mexico. The minimum body mass index authorized by COFEPRIS for the use of the Orbera balloon is of 27 kg/m^2.

Regarding the Spatz® balloon, the COFEPRIS authorized its use in February 2015. Since then, more than 16,000 devices have been applied in our country, and currently, more than 1600 devices are being installed every month. Mexico City, Monterrey, Tijuana, Ciudad Juarez, Nuevo Laredo, and Reynosa are the cities in which more Spatz® balloons are being installed both in the private and public sectors. The percentage of associated complications is of 0.7%, gastric ulcer is the most common one, and in the majority of cases, it is related to the lack of adherence to medical instructions.

Conclusions

There are two main indications for the use of an intragastric balloon in Mexico. The first one is a bridge therapy in patients with super obesity to improve their conditions before definitive surgical therapy. The second main indication is for patients that do not meet the criteria for surgery and have a body mass index between 27 and 35 kg/m^2; and in this group, the weight loss is efficiently controlled by a multidisciplinary group.

In Mexico, the insertion technique is dictated by guidelines established by the Health Department and the pharmaceutical industry based on national and international security standards.

The results observed until now with the use of an intragastric balloon in Mexican population are in accordance with the international literature; nevertheless, multicentric analysis and meta-analysis are needed to verify such findings. In conclusion, the best results depend greatly on the multidisciplinary approach given to patients that are candidates for the use of the intragastric balloon.

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