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Multicenter study on the safety of bariatric endoscopy

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ABSTRACT

Introduction: Bariatric endoscopy includes a series of specific techniques focused on the management of obese patients. As a quality criterion, safety as expressed by a minimal incidence of serious complications is required in addition to efficacy.

Methods: A descriptive, retrospective, multicenter review of the experience recorded at seven hospitals included in the Grupo Español de Endoscopia Bariátrica (GETTEMO) in order to document the incidence, cause, and resolution (including legal consequences) of serious complications reported for each bariatric technique, and according to endoscopist expertise.

Results: In all, 6,771 bariatric endoscopic procedures were collected, wherein 57 serious complications (0.84%) were identified. *Balloons:* Orbera®-Medsil®, 5/5,589; Spatz2® (older model): 44/225; Heliosphere®: 1/70; Obalon®: 0/107. *Sutures:* POSE®, 5/679; sleeve gastroplasty with Apollo® system: 0/55. *Prostheses:* Endobarrier®: 2/46. All complications were resolved with medical/endoscopic management except for five cases (0.07%) that required surgery. A single lawsuit occurred (esophageal perforation with Spatz2® balloon), which had a favorable outcome. There was no mortality, and apparently no differences were found according to endoscopist expertise level.

Conclusions: In our multicenter experience, bariatric endoscopy may be considered as a safe procedure (0.84% of serious complications in all). However, some devices may induce a higher proportion of complications, such as 19.55% for Spatz2® balloons (already replaced) or 4.34% for Endobarrier® (at the upper limit of accepted safety), although our experience with the latter is limited. All complications were resolved with conservative medical management, and only exceptionally required surgery (0.07%). No technique-related mortality was seen, and only one lawsuit occurred. Further evolutionary studies are required on the novel endoscopic techniques presently emerging to authenticate our results.

Key words: Endoscopy. Bariatric. Obesity. Safety. Complications.

Conflict of interest: Dr. Espinet-Coll and Dr. López-Nava Breviere are Apollo Endosurgery consultants, but they declare no scientific neither economic conflicts of interest in the present study.

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INTRODUCTION

The treatment of obesity and its associated metabolic diseases requires a multidisciplinary assessment, with adequate nutrition education, lifestyle modification, and physical exercise as key measures. For morbid obesity and super-obesity, bariatric surgery remains the most effective therapy option in the long term (1). However, despite its effectiveness, it is estimated that less than 1-2% of obese patients potentially eligible for bariatric surgery eventually undergo these procedures (2). This is primarily due to the high cost associated with this surgery, its associated morbidity (15-20% of major complications) and potential mortality (very limited in the last few years), and persistent social "fear" (3,4).

On these grounds, for a selected target population (grade I and II obesity or morbid obesity, that reject surgery or before surgery) bariatric endoscopy has emerged, including a number of specific techniques that attempt to replicate the anatomical changes resulting from bariatric surgery via a transoral, endoluminal route. Initially, these techniques have seemingly shown fairly promising efficacy results (5-12), with better outcomes when compared to diet alone (13). Furthermore, *a priori* they are more cost-effective and less invasive than surgery, hence a lower complication rate and higher safety should be expected.

In this paper we describe the multicenter experience of the Grupo Español de Trabajo para el Tratamiento Endoscópico del Metabolismo y la Obesidad (GETTEMO), a member group of the Sociedad Española de Endoscopia Digestiva (SEED) and Sociedad Española de Patología Digestiva (SEPD), regarding the safety of the various bariatric endoscopy techniques currently performed in our country (different balloon types and gastric suture systems, and malabsorptive endoluminal duodenal-jejunal bypass)

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in the largest series, with a greater variety of endoscopic therapies reported thus far. We document the incidence, cause, and resolution of the serious complications recorded, as well as their legal consequences, if any.

PATIENTS AND METHODS

Following the setup of the GETTEMO in November 2013, all 15 centers initially involved were invited to take part in the present study. They were sent a questionnaire to retrospectively record all bariatric endoscopies performed in each of them, as well as the type of therapy administered.

Differentiation was required between fluid-filled, 6-month extant balloons (Orbera®, Medsil®), 12-month re-adjustable balloons (second generation Spatz2®), successive balloons (Obalon®), and air-filled balloons (Heliosphere Bag®) as used as primary therapy or bridge therapy to bariatric surgery; gastric suture systems (POSE®, endoscopic sleeve gastroplasty using the Apollo® system); and malabsorptive endoluminal duodenal-jejunal liner (Endobarrier®).

As *inclusion criteria* for each therapy the following was required. *Serious complications* observed, such as gastrointestinal (GI) tract injuries (ulcer, bleeding, migration with bowel occlusion, mucosal laceration, necrosis, perforation), infectious-inflammatory lesions (pancreatitis, abscesses, empyema, cholecystitis, bronchoaspiration), and traumatic device breakage, as well as mortality, should be reported. Furthermore, they were asked to document the therapy applied in each case, whether medical, endoscopic or surgical. *Mild incidents or complications* were dismissed for the study: cases with transient symptoms not affecting overall treatment outcomes (nausea, reflux, constipation, lab changes with no clinical impact, etc.), early device removal cases for only clinical or psychological reasons (that is, with no mucosal injury or other justifying abnormalities during endoscopic assessment), and balloon breakdown or deflation without gastrointestinal compromise.

Serious complications were divided up according to the endoscopic technique and endoscopist experience (all had documented expertise): 10-30 years in general endoscopy and 2-12 years in bariatric endoscopy. Furthermore, all centers involved offered multidisciplinary patient follow-up for at least one year.

For each serious complication, the presence of documented legal consequences with judicial opinion and final court resolution were requested.

Seven endoscopists from a number of Spanish bariatric endoscopy units responded, and a total of 6,771 bariatric endoscopic procedures were collected, most of them with different intragastric balloons and a significant number of suture systems and initial experiences with endoluminal duodenal-jejunal bypasses (Table I). Results correspond to treatments performed through September 2014, and were the subject of an oral communication at the SEED conference in November 2014.

The study's retrospective nature represents a limitation. However, patient loss due to follow-up was minimal, since all sites involved have a permanent emergency department ready to document and solve any potential complications. Also, the study includes and documents all complications reported, even when resolved in centers other than those where primary endoscopic therapy was administered.

RESULTS

Among the 6,771 bariatric procedures reported, 57 (0.84%) serious complications were identified; all were resolved with conservative medical management or on occasions with endoscopic management except for five (0.07%), which required surgery (Table I). No deaths occurred. Casuistry was as follows:

– *Orbera®/Medsil® balloon:* 5,589 procedures including only five serious complications (0.09%): one bronchoaspiration with respiratory distress during balloon removal endoscopy because of gastric food remnants and the absence of orotracheal intubation (OTI) during sedation, which was resolved after in-hospital antibiotic therapy; three cases of deflat-

Table I. Major complications of endoscopic treatment for obesity

Procedure	*No. complications / no. cases (%)*	*Medical-endoscopic treatment*	*Surgical treatment*
Orbera®/Medsil®	5 / 5,589 (0.09%)	1 bronchoaspiration 3 migrations	1 perforation
Spatz2®	44 / 225 (19.55%)	34 ulcers 7 migrations 1 pancreatitis	1 perforation 1 intestinal occlusion
Heliosphere Bag®	1 / 70 (1.43%)	1 balloon breakage	
Obalon®	0 / 107 (0%)		
POSE®	5 / 679 (0.74%)	2 UGIB 1 subphrenic abscess 1 empyema	1 splenectomy
Sleeve gastroplasty (Apollo®)	0 / 55 (0%)		
Endobarrier®	2 / 46 (4.34%)	1 UGIB	1 cholecystitis
Total	*57 / 6,771 (0.84%)*	*52 (0.77%)*	*5 (0.07%)*

ed balloon migration within the standard six months after implantation, without urine discoloration, and with balloons spontaneously expelled after a follow-up period; and one serious gastric perforation detected after balloon removal, which required surgery and suturing.

- *Second-generation Spatz® balloon (Spatz2®):* amongst 225 implanted balloons, 44 serious complications were identified (19.55%): 34 ulcers, seven migrations, and one acute pancreatitis, all of them resolved with endoscopic balloon removal and medical therapy. Two surgeries were required: one elective procedure for migration and bowel occlusion and one emergent procedure for esophageal perforation during balloon removal (thoracotomy and linear tear repair).
- *Heliosphere Bag®:* several balloon deflation cases occurred, but there was only one serious complication among the 70 procedures performed (1.43%), which was a balloon that burst and broke during endoscopic removal, requiring multiple endoscopies for total extraction with no surgery.
- *Obalon®:* 107 procedures with only five deflations without migration, which required early endoscopic removal with no serious complications or need for surgery.
- *POSE®:* five serious complications among 679 procedures (0.74%). There were two moderate UGIB events detected at 5 h and 24 h after the procedure, which required endoscopic therapy (sclerosis with epinephrine), and the second patient also requiring a RBC concentrate transfusion. There were also two patients with sustained abdominal pain who were found to have a subphrenic abscess and empyema plus pleural effusion, both solved with antibiotic therapy. There was also one splenic bleeding event from gastroesplenic ligament traction and tear, which required prophylactic splenectomy for re-bleeding. In two exceptional, atypical cases the procedure could not be carried out because of the inability to pass the incisionless operating platform (IOP) beyond the pharyngo-esophageal junction.
- *Sleeve gastroplasty (Apollo® endosleeve):* no serious complication emerged from the 55 procedures thus far performed.
- *Endobarrier®:* two serious complications among 46 procedures (4.34%). There was one case of severe bleeding that required device removal and urgent sclerotherapy, and one case of alithiasic acute cholecystitis secondary to gall bladder impaction by a device anchor, which required emergency surgery with laparoscopic cholecystectomy and endoscopic device removal.

With regards to endoscopist expertise, it seems that more experience in bariatric endoscopy corresponds to more varied endoscopic treatments, but the differences are small in proportion to serious complications. These are only associated with endoscopists using the Spatz2® balloon (now fallen into disuse) (Table II).

For all these complications only one lawsuit occurred, a civil case related to an esophageal perforation during a Spatz2® removal that required surgical repair. This represents 0.014% of all bariatric endoscopies and 1.75% of serious complications. In the final resolution and sentence the endoscopist was absolved of liability.

DISCUSSION

Endoscopic treatment for obesity was initiated in the 1980s with the Garren-Edwards Gastric Bubble, which had to be abandoned for safety issues and multiple complications (14). In 1987 an international multidisciplinary meeting of experts was held in Tarpon Springs (Florida, USA) (15), and ideal recommendations were established to improve both the efficacy and safety of bariatric balloons. Subsequently, various types were made available, and the late 1990s saw the arrival of the Bioenterics® balloon, which became the most widely used device to this day.

The Fobi-Baltasar criteria for ideal bariatric surgery (16-18), as adapted to endoscopy according to the *Documento Español de Consenso en Endoscopia Bariátrica* (19), should guide these procedures. In this regard, we define bariatric endoscopy as a safe technique when entailing a number of serious complications < 5% (ideally < 1%), as in our series (0.84%), that may be mostly medically or endoscopically resolved, with surgery being required in < 0.1% of cases (0.07% in our series) and mortality approaching 0%. Furthermore, various systems are available to assess the quality of bariatric surgery/endoscopy, including the Bariatric Analysis and Reporting Outcome System (BAROS) (20), which includes complications (major, minor, reintervention) as a crucial criterion in the final assessment of bariatric quality (Table III).

Sites including bariatric endoscopy must have specific multidisciplinary units with adequate infrastructure, and both human and structural resources (19). Both oral and written informed consent should be specifically granted for each technique and individual patient. To obtain the low number of serious complications thus far reported, endoscopists need be specifically trained in each bariatric technique, and adequately follow extant protocols including prior complete assessment (also endoscopy, to rule out any foreseeable complications and contraindications), endoscopic review on procedure completion, and stringent individualized multidisciplinary follow-up. A round-the-clock emergency department is also required with the presence of an expert endoscopist and a surgeon able to effectively resolve any potential complications (21).

Side effects and complications should be recorded, including their severity and resolution, to facilitate continuous improvement in the quality of these techniques.

Table II. Major complications according to endoscopist experience and endoscopic technique

Endoscopic experience (years)	*Endoscopic treatments*	*Major complications*	*Surgical resolution*
GeneraL: 12 Bariatric: 7	IB: 120	0	0
	POSE®: 42	0	0
	Apollo®: 3	0	0
	Endob: 36	1	1
	Total: 201	*1 (0.49%)*	*1 (0.49%)*
General: 22 Bariatric: 10	IB: 1,800	1	0
	Spatz2®: 120	14	1
	POSE®: 220	2	0
	Apollo®: 2	0	0
	Total: 2,142	*17 (0.79%)*	*1 (0.046%)*
General: 19 Bariatric: 12	IB: 2,700	3	0
	Spatz2®: 100	30	1
	HB: 50	1	0
	Obalon®: 100	0	0
	POSE®: 350	2	1
	Apollo®: 50	0	0
	Endob: 10	1	0
	Total: 3,360	*37 (1.10%)*	*2 (0.059%)*
General: 30 Bariatric: 10	IB: 604	1	1
	Obalon®: 2	0	0
	Total: 606	*1 (0.16%)*	*1 (0.16%)*
General: 17 Bariatric: 9	IB: 210	0	0
	Spatz2®: 5	0	0
	POSE®: 43	1	0
	Total: 258	*1 (0.38%)*	*0 (0%)*
General: 20 Bariatric: 5	IB: 150	0	0
	HB: 20	0	0
	POSE®: 12	0	0
	Total: 182	*0 (0%)*	*0 (0%)*
General: 10 Bariatric: 2	IB: 5	0	0
	Obalon®: 5	0	0
	POSE®: 12	0	0
	Total: 22	*0 (0%)*	*0 (0%)*

IB: Orbera® or Medsil®-type intragastric balloon; HB: Heliosphere Bag®; Apollo®: Endosleeve or tubular "sleeve" gastroplasty using the OverStitch-Apollo® system; Endob: Endobarrier®.

The *Orbera® intragastric balloon* (initially Bioenterics®, now marketed by Apollo Endosurgery, Austin, Texas, USA) has a highly variable overall complication rate (2.8 to 40%) according to the various series reported, with most being resolved with medical treatment or early balloon removal (1-2.5%). Overall, the technique may be considered to be simple and safe, with very few serious complications (5,12), which are potentially more common in supermorbid patients when used as a bridge therapy to surgery. Because of their systems and filling similarities, we have included *Medsil® balloons* (CSC Medsil, Mytischi Moscos, Russia) in this same category.

Major serious complications during endoscopic procedures include iatrogenic mucosal laceration, bleeding, and perforation (usually instrument-related lesions). In our series, there was a case of early device removal because of intolerance with persistent abdominal pain, which prompted an X-ray study that suggested antral perforation. It was resolved with surgery and simple suturing, and the intraoperative assessment reported two mucosal lacerations, likely from decubitus and wall ischemia, with no apparent relation to the endoscopic instrumentation. The most widely feared anesthetic complication during removal is bronchoaspiration, mainly of gastric contents, as occurred in one of our subjects. To reduce the risk for this complication a fluid diet is recommended in the 24 hours prior to the procedure, and that removal be carried out with deep sedation and OTI.

Balloon breakage-deflation may be identified early by colored urine (0-4%), which should prompt early endoscopic removal of the device (7.5%). If delayed, migration to the bowel may occur (1.4%). In such cases close clinical, laboratory, and radiographic monitoring is advised,

Table III. BAROS score as adapted to bariatric endoscopy

1. *Weight loss, percentage of excess (% EWL): (baseline weight-current weight)/(baseline weight-ideal weight) x100:*
(-1): Weight gain
(0): Loss of 0-24%
(+1): Loss of 25-49%
(+2): Loss of 50-74%
(+3): Loss > 75%
2. *Comorbidity:*
(-1): Aggravated
(0): Unchanged
(+1): Improved (unresolved)
(+2): Improvement: one major resolved, others improved
(+3): Improvement: all major resolved, others improved
3. *Quality of life questionnaire: (much worse, worse, same, better, much better):*
Self-esteem (score -1, -0.5, 0, +0.5, +1)
Physical (score -0.5, -0.25, 0, +0.25, +0.5)
Social (score -0.5, -0.25, 0, +0.25, +0.5)
Labor (score -0.5, -0.25, 0, +0.25, +0.5)
Sexual (score -0.5, -0.25, 0, +0.25, +0.5)
4. *Complications:*
(-0.2): For each minor complication
(-1): For each major complication
(-1): For endoscopic or surgical reintervention
Final assessment (sum of all four items)
– *No comorbidities:*
Failure: 0 or less
Fair: 0-1.5
Good: 1.5-3
Very good: 3-4.5
Excellent: 4.5-6
– *Comorbidities:*
Failure: < 1
Fair: 1-3
Good: 3-5
Very good: 5-7
Excellent: 7-9

since spontaneous evacuation is common (as in three of our subjects); however, small intestinal obstruction may also develop (0-4%), which would require surgery.

Other mild, atypical complications in our series that led to early device removal included isolated vomiting-hypokalemia, psychological/clinical intolerance without mucosal lesions upon endoscopy, and spontaneous balloon breakage without migration (both Orbera® and Medsil®).

In order to try and minimize these drawbacks, and to enhance efficacy and safety, new balloon concepts, designs and types are emerging of late (5-7,22). These include swallow balloons (*Obalon®,* Therapeutics Inc., Carlsbad, CA, USA) (23), designed to save up one or two endoscopic procedures. These are air-filled balloons, hence they might have a higher rate of deflations, thus requiring early endoscopic removal (as was the case with five of 107 balloons in our series). Occasionally they may migrate distally, but they are usually excreted with feces because of their smaller size, with a lower risk for obstruction. Air-filled *Heliosphere® bags* (Helioscopie Medical Implants, France) theoretically reduce motility changes and gastric discomfort given their lighter weight and polyurethane rather than silicone composition. Overall, they have a slightly higher incidence of deflation and migration with more difficulties upon removal (24), as occurred in one of our subjects when the device burst and broke into pieces during explantation, with several endoscopic procedures being required to completely remove all fragments.

Finally, adjustable *Spatz®* balloons (Spatz GFAR, Inc., NY, USA), which last for one year, allow volume reductions for intolerance and volume increases for failing weight loss. The second-generation (Spatz2®) models used in our series consisted of a silicone balloon with an emerging catheter that branches off perpendicularly into two ends. A shorter one is for filling and adjustment. The second, longer end has a metallic axis with a curved stabilizing band, its shape allegedly designed to prevent migration.

In our series we recorded two surgical resolutions. The first one was an elective surgical procedure for duodenal occlusion secondary to migration and anchor impaction in the duodenum with deep ulceration. The second operation was an emergency surgical procedure for a 2.5 cm-long esophageal tear caused by the metallic axis during balloon removal. A joint endoscopist-surgeon intraoperative assessment dismissed the use of stents or clips given the perforation's size and morphology, treatment ensued with antibiotic therapy and thoracotomy with esophageal perforation repair. This case led to the only civil lawsuit in the series. This represents 0.014% of our bariatric endoscopies and 1.75% of serious complications. The final resolution and sentence (judge ruling) favored the endoscopist, who was acquitted on malpractice, as he had provided the patient with adequate, complete oral and written information on this potential risk, and had responded with appropriate action to the complication arisen.

Three reports between 2011 and 2014 (5,25,26) found an exceedingly high rate of serious complications (10-39%), including the need for emergency surgery (1-4%). Interestingly, it was this catheter impaction issue that gave rise to most complications, which led to device review and withdrawal. In our view, further safety studies and controlled clinical trials should be carried out before marketing is granted for medical devices with a high rate of potential complications.

This metallic axis has been removed from the current Spatz3® balloon, hence adequate efficacy with none of the aforementioned axis-derived complications is now envisaged.

Suture systems (POSE®, Apollo® gastroplasty) are technically more time-consuming and complex, hence it is recommended that they be implemented under general anesthe-

sia, OTI, and CO_2 insufflation. A pre-procedural antibiotic prophylaxis regimen is advisable because of the transmural nature of sutures, a crucial aspect to make each plication durable. Also, they require observation and/or hospital admission for early control. Some centers confirm the absence of complications using lab tests and/or upper GI series.

The *POSE® method* (Usgi medical, Inc., San Clemente, CA, USA) has proven safe in the few series so far reported (27-29). While suturing as such usually conditions some bleeding, clinically significant hemorrhage is uncommon. In our series we report two moderate upper gastrointestinal bleeding (UGIB) events identified at 5 hours and 24 hours after the procedure, which were effectively managed with endoscopy (epinephrine sclerosis); bleeding was more severe in the second patient, who required red blood cells (RBC) concentrates transfusion, with no rebleeding after 48 hours. We also had two cases of sustained abdominal pain at five and seven days post-procedure; an abdominal computed tomography (CT) scan showed a subphrenic abscess and empyema plus pleural effusion, which were both resolved with conservative management using IV antibiotics. The most atypical serious complication was splenic bleeding from gastrosplenic ligament traction and tear. The patient presented with hypotension and dizziness to a hospital different to where endoscopy was performed, which had no experience in the management of patients undergoing POSE®. While we believe that management could have been conservative, the patient underwent prophylactic splenectomy for rebleeding with a favorable outcome.

Vertical "sleeve" gastroplasty using the Over-Stitch-Apollo® system (endosleeve) (Apollo Endosurgery, Inc., Austin, Texas, USA) seems a safe technique. In the first series reported, using the older model, three isolated complications were encountered (perigastric collection, lung embolism, pneumothorax), which were solved with medical treatment (30). No other complications have been reported in the other series reported so far (31-35), nor regarding the initial experience of 55 cases in our series.

In the endoscopic duodenal-jejunal bypass that the *Endobarrier®* system (GI Dynamics, Inc., Watertown, Massachusetts, USA) represents, primary issues do not seem to stem from the endoscopic device implantation or removal procedure, but arise when in place, and occurred mostly with the device's first generation. With the improvements that the second generation is fitted with (mainly regarding size and anchor rigidity), overall serious complications have considerably decreased, the most common ones including migration (4.9%), bleeding (3.8%), and device inner obstruction (3.4%). Isolated cases of liver abscess, cholangitis, cholecystitis, and esophageal perforation (0.1%) have been reported (12), hence the system has been temporarily withheld from commercialization in some countries. Despite this, overall it is considered as a safe, reliable technique (36,37), with safety still remaining within the upper limit of acceptability (< 5%). In our series we report two major complications: UGIB associated with duodenal bulb mucosal tear by anchors, which was resolved by endoscopic removal of the involved device and local sclerosis with epinephrine; and device anchor impaction into the gall bladder wall, which resulted in acute cholecystitis and required endoscopic removal and laparoscopic cholecystectomy (38). Less traumatic anchoring systems are being designed to avert the risk for this kind of complications.

To conclude, we may consider that current bariatric endoscopy, in all its assessed variants, is seemingly safe, particularly when performed by experienced endoscopists according to a protocol including appropriate prior assessment and stringent follow-up. Reported serious complications are scarce (0.84%), mostly occurring with obsolete or later modified devices/balloons. When present, most are resolved with medical or endoscopic treatment, surgery is rarely required (0.07%), and no mortality is associated. Legal claims and civil suits are also uncommon.

Bariatric endoscopy is a constantly evolving field. Other novel techniques (new balloon designs and suture systems, substance injections, magnets, aspiration methods, duodenal mucosal resurfacing, endoscopic repair for bariatric surgery, etc.) are emerging, which will require further studies to confirm, among other parameters, their high safety indices before being fully incorporated by the daily endoscopic practice.

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