Chapter

# Bariatric Surgery—from the Non-surgical Approach to the Post-Surgery Individual Care: Role of Endoscopy in Bariatric Therapy

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## Abstract

Obesity is the underlying constant for the development of the most common modern diseases such as insulin resistance, high blood pressure, lipid metabolism disorders, non-alcoholic steatohepatitis (fatty liver), joint problems and various malignancies. The role of endoscopic diagnostic and therapy in obese patients is highlighted in this chapter. In this chapter all devices and methods used in flexible endoscopy for diagnostic and treatment in obese patients are introduced. Role of endoscopy is presented in three parts: in preoperative setting, in post-operative complication management and instead of surgery as endoscopic bariatric therapy. If possible presentation of the effectiveness is compiled with study data. Finally, the interaction between endoscopy and surgery in the treatment of obesity is complex, essential and promising. Endoscopy is indispensable in preoperative preparation, as a primary therapeutic approach, and also in the detection and treatment of acute complications and long-term complications of obesity surgery.

**Keywords:** endoscopic bariatric therapy, endoscopic complication management

## 1. Introduction

The annual number of obesity surgery and metabolic interventions increased worldwide significantly and the continued pressure to provide ambulatory surgery, endoluminal, and transgastric therapy has the potential to effect major changes in the way obesity is treated. Covering the "market demand" simply by further increasing the number of operations seems illusory if the prevalence of obesity is still rising. Endoluminal surgery is defined as surgery performed entirely within the lumen of the gastrointestinal tract using flexible endoscopy.

The interaction between endoscopy and surgery in the treatment of obesity is complex, essential and promising. Endoscopy is indispensable in preoperative preparation, as a primary therapeutic approach, and also in the detection and treatment of acute complications and long-term complications of obesity surgery.

The currently established and developing endoscopic procedures for bariatric therapy will be presented in this chapter. Division into pre-operative endoscopy,

endoscopic bariatric therapy (EBT) and post-surgical endoscopy for early and late complications was made.

## 2. Preoperative setting: diagnostic esophago-gastro-duodenoscopy

In "The clinical practice guidelines of the EAES on bariatric surgery: update 2020" the indication of a pre-operative EGD has been approved [1]. Clinically significant gastrointestinal (GI) symptoms should be evaluated before bariatric procedures with imaging studies, upper GI series, or endoscopy. All patients who where enrolled for a sleeve gastrectomy have to be examined with a gastroscopy for presence of hiatal hernia and esophageal reflux. Endoscopists have to look for signs of GERD. This diagnosis is a contraindication for a sleeve gastrectomy. Presence of hiatal hernia is also important from the surgical point of view, as it also needs to be repaired while bariatric surgery. In the diagnostic gastroscopy Helicobacter-pylorii diagnosis has to been established. Recent studies illustrate a relationship of Helicobacter pylori with the occurrence of marginal ulcers postoperatively especially following RYGB.

## 3. Endoscopic bariatric therapy

Primary endoscopic obesity therapy has now been given the proper name "bariatric endoscopy" or "endoscopic bariatric therapy". This illustrates the relevance of endoscopy for the treatment of obese patients. EBT currently includes six different mechanisms:

1. Space occupying

2. Endoscopic gastroplasty

3. Aspiration

4. Malabsorption

5. Endoscopic bypass

6. Others

In **Table 1** we present an overview of all endoscopic therapeutic concepts with available correlated EWL is presented.

For the completeness of the review, the swallow balloons Elipse™ and OBALLON™ are mentioned at this point. However, they do not require endoscopic control or filling and are therefore not considered further in this review.

EAES and IFSO guidelines recommend consultation on surgical or endoscopic bariatric therapy based on initial weight, previous eating habits, expected weight loss, patient-related risk stratification (pre-existing conditions, compliance) and local availability of surgical and/or endoscopic bariatric surgery experts EAES 2020 [1, 10]. The choice of bariatric intervention should be based on the consensus of a supervising, interdisciplinary board of experts, whose members are from the fields of surgery, nutritional medicine, endocrinology and psychology, and the fully informed patient.

| Mechanism | Product | Time | EWL |
|---|---|---|---|
| 1. Space occupying | 1.1 Spatz3 one-year-balloon | 12 months | 67.4% [2, 3] |
| | 1.2 ReShape™ Dual Balloon | 6 months | 29.9% [4] |
| | 1.3 ORBERA™ Intragastric Balloon | 6 months | 25.44% [5] |
| | 1.4 Transpyloric shuttle™ | 6 months | 30.9% [6] |
| | 1.5 Heliosphere bag | 6 months | 31.87% [7, 8] |
| 2. Endoscopic gastroplasty | 2.1 POSE™ | permanent | 49.4% [9] |
| | 2.2 ESG (Endoscopic Sleeve gastrectomy, Apollo OverStitch) | permanent | 61.84-68.3% [10–12] |
| | 2.3 RESTORe (EndoCinch) | permanent | 58.1% [13, 14] |
| | 2.4 TOGA (transorale gastroplasty) | permanent | 38.7% [15] |
| | 2.5 TERIS (trans-oral endoscopic restrictive implant system) | 6 months | 30.1% [16] |
| | 2.6 ACE-Stapler | permanent | 34.9% [13, 17] |
| | 2.7 Endomina System | permanent | 41% [13] |
| 3. Aspiration | Aspire Assist® | 6-24 months | 31.5% [18] |
| 4. Malabsorption | 4.1 EndoBarrier® (Duodeno-Jejunale liner) | 12 months | 35.3% [13, 19] |
| | 4.2 ValenTx™ (Gastro-Duodeno-Jejunale Liner) | 12 months | 39.7% [20] |
| | 4.3 DMR (endoscopic hydrothermal Duodenal Mucosal Resurfacing) | permanent | - |
| 5. Endoscopic Bypass | Incisionless Magnetic Anastamosis System (IMAS) | permanent | 40.2% [21] |
| 6. Others | 6.1 Full Sense | - | - |
| | 6.2 Satisphere | - | - |

**Table 1.**
*Mechanisms of endoscopic bariatric treatment, products and procedures are listed with mean EWL% after 12 months if available.*

In **Figure 1** following mechanisms and products are illustrated in a sketch:
A = Orbera Intragastric Balloon
B = ReShape Duo Intragastric Balloon
C = TransPyloric Shuttle
D = POSE™
E = ESG with Apollo OverStitch™
F = Endomina
G = Aspire Assist
H = EndoBarrier
I = Satisphere device

## 3.1 Space occupying

The common gastric balloons are well accepted. Besides the expected nausea and belching, possible gastric ulcerations and perforations should be discussed with the patients.

All endoscopic, bariatric mechanisms that have a timely limit should be combined with an intensive nutritional, medical and psychological therapy. Obesity is a chronic disease, so there is always the risk of a "yo-yo" effect after removal of the space occupying device in such procedures. This development must be discussed with the patient.

The time-limited procedures are particularly suitable with a step-by-step concept prior to bariatric surgery.

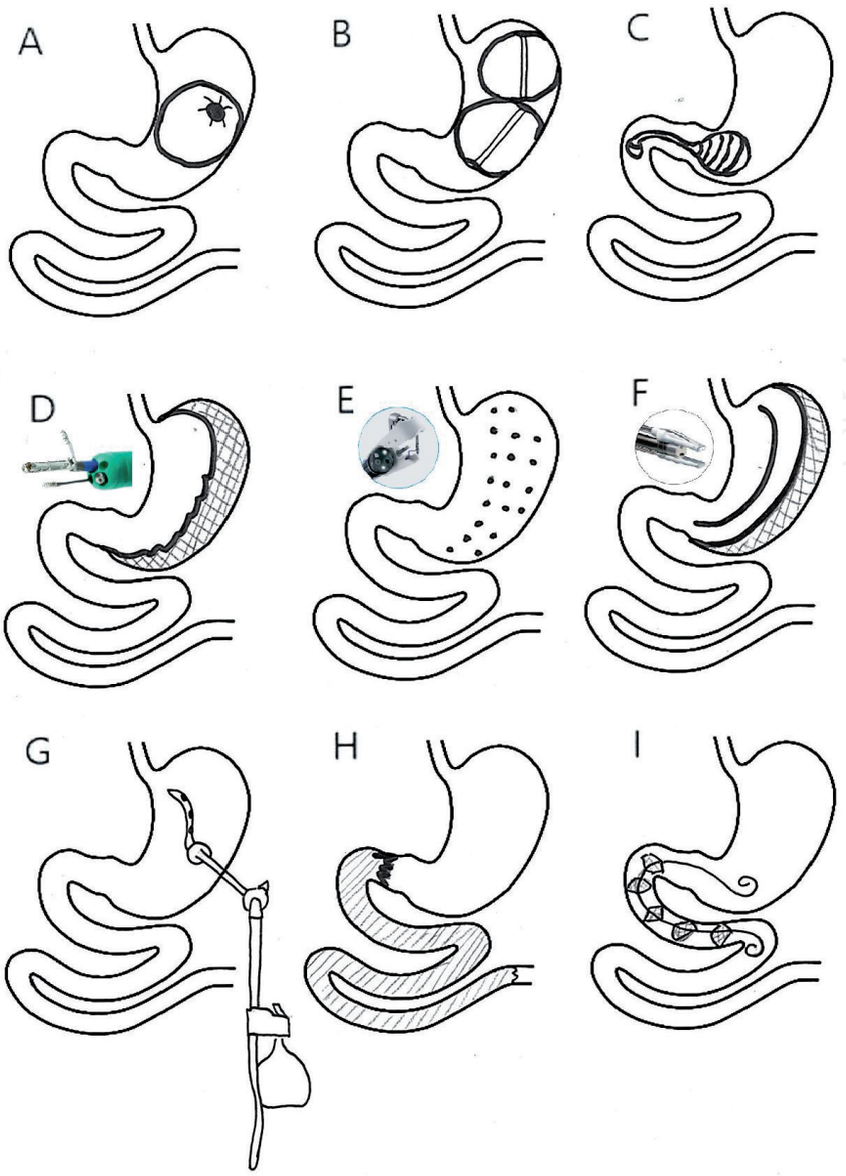


**Figure 1.**
*Relevant techniques and devices of EBT are sketchily presented. A) Orbera Intragastric balloon. B) Reshape duo Intragastric balloon. C) Transpyloric shuttle-device. D) POSE™ operating platform with fundal accomodation. E) Endoscopic gastric sleeve with the OverStitch™-device. F) Endomina-suturing-system. G) Aspire assist-device. H) Endobarrier duodeno-jejunal bypass liner. I) SatiSphere-device.*

### *3.1.1 Spatz3*

The Spatz3 (Spatz FGIA, Great Neck, NY, USA) intragastric balloon is the only space occupying system for using a time of 12 months. The balloon is placed endoscopically and filled with 400-750 ml saline and methylene blue.

Results: Usuy and Brooks reported 2018 about 165 patients with implanted Spatz3 balloons in two centers. Mean EWL after one year was 67.4% [3].

Complications: Complications were nausea (89–92%), vomiting (21–71%), and abdominal pain (22–24%). Five patients developed gastric ulcers, one gastric perforation occurred at week 17 after implantation.

## 3.2 ReShape duo intragastric balloon

The ReShape IGB (Reshape, San Clemente, CA, USA) device contains of two silicone balloons attached to each other by a flexible tube. It is inserted and retrieved endoscopically. Device is placed for 6 months. The ReShape Duo is filled

with 900 mL of saline solution (450 mL to each balloon). Each balloon has independent channels to prevent deflation of the other balloon if one leaks.

Results: In a seven-center study of Agnihotri and colleagues 202 patients were enrolled. EWL after 6 months was 29.9% [4]. In the REDUCE pivotal trial, including 326 patients, EWL was 25.1% in the Reshape arm compared to 11.3% in the sham arm [22].

Complications: Most common SAEs were nausea, vomiting, and abdominal pain that generally resolved after 1 week. The gastric ulceration rate was 0.9%.

### 3.3 Orbera

The Orbera (Apollo Endosurgery, Austin, TX, USA) is a single, spherical balloon composed of silicone previously known as the BioEnterics Intragastric Balloon (BIB; Allergan, Irvine, California, USA). The balloon filling volume ranges between 400 and 700 mL of saline.

Results: Courcoulas and colleagues [23] reported in a multicenter, randomized, comparative study about 137 patients with implanted Orbera balloon. Mean EWL after 9 months was 26.5%.

Complications: Early removal of the IGB occurred in 18.75% of patients. The most common adverse events were pain and nausea [23]. Reported SAEs with this balloon were rare, and consisted of migration in 1.4% of patients and gastric perforation in 0.1% [24].

### 3.4 TransPyloric shuttle

The TransPyloric Shuttle (BARONova Inc. Goleta, CA) consists of a spherical silicone bulb attached to a smaller silicone bulb by a flexible tether. Intermitted occlusion of the gastric antrum is reached by the larger bulb when the smaller bulb entering the duodenum with peristalsis.

Results: A randomized clinical trial showed a mean EWL of 30.9% at 12 months follow-up [6].

Complications: Premature balloon removal occurred in 22.7% (46/203) of the cases. SAEs were rare (2.8%) and included: esophageal rupture, device impaction, upper abdominal pain, gastric ulcer, vomiting, pneumothorax. Premature balloon removal occurred in 22.7% (46/203) of the cases.

### 3.5 Heliosphere bag

The Heliosphere BAG is filled with 950 mL of air rather than fluid. Balloons were implanted for six months.

Results: Lecumberri and colleagues reported about 82 patients with a EWL of 31.87% six months after insertion [8].

Complications: The Heliosphere BAG deflated and passed spontaneously in 2 cases (3%). De Castro et al. [25] described 2013 a comparative, prospective study of 91 patients: Orbera balloon (73 patients) with Heliosphere BAG (18 patients, mean BMI 45.2 kg/m$^2$). In this study balloon extraction was difficult in 8 cases, and a rigid esophagoscope as required in 4 cases; laparoscopic surgery was required to remove BAG in 1 case. BAG was significantly more likely to result in retrieval complications.

## 4. Endoscopic gastroplasty, endoscopic sleeve

Endoscopic gastroplasty or sleeve procedures are enjoying increasing popularity. The principle of all the procedures listed is a reduction of the stomach volume by

endoluminally placed sutures or clips. The procedures are performed transorally, so that no permanent scars result. By means of a suture/clip machine placed on the endoscope, the stomach is contracted from the intraluminal side and fixed accordingly, thus reducing its lumen. The change in the shape and function of the stomach primarily leads to delayed gastric emptying and thus increased saturation. Weight loss and reduction of the diabetic metabolic state are the result. These procedures have been evaluated for patients with obesity class 1 to 3 and are associated with excellent long-term results.

### 4.1 POSE™

Primary obesity surgery endoluminal (POSE) uses the incisionless operating platform (IOP; USGI Medical, San Clemente, CA, USA) to create full-thickness plications in the gastric fundus to reduce gastric volume. The Pose procedure targeted the gastric fundal accommodation. In 2020 López-Navada presented the POSE 2 procedure. Using the same devices, the POSE-2 procedure attempts to impair the gastric motility and restrict the gastric volume [26].

Results: Lopez-Navada et al. reported 2015 about 147 patients who underwent POSE procedure and were followed for one year [9]. Mean EWL was 44.9%. In a meta-analysis of Khan et al. with 7 included studies about POSE procedure Mean pooled EWL after 12 months was 44.91% [27].

Complications: Lopez-Navada reported that short-term adverse events included minor bleeding at the suture site, which was managed without incidence. Sullivan et al. [28], one of the included studies of the meta-analysis of Khan et al., reported that 45% of patients had post-procedure abdominal pain requiring pharmacotherapy, and 40% reported nausea and vomiting. For POSE 2 procedure no AEs were reported.

### 4.2 ESG (endoscopic sleeve gastrectomy) with the Apollo OverStitch™

The Apollo OverStitch™ (Apollo Endosurgery, Austin, TX) is an endoscopic suturing device that applies full-thickness sutures in a variety of patterns. The system attaches to a double-channel endoscope and utilizes a curved needle driver. The OverStitch Sx™ is available for using single working channel endoscopes.

Results: In the meta-analysis of Gys and colleagues from 2019 eight clinical trials (1721 patients, 2014–2019) were included with 6–24 months follow-up. Average pooled EWL at 12 months was 68.3% [12]. In the recent meta-analysis of Singh and colleagues pooled EWL after 12 months was 61.84% [11].

Complications: In the analysis of Gys et al. major adverse events were described in 18 patients: pneumothorax ($n$ = 2), perigastric collection ($n$ = 8), pulmonary embolism ($n$ = 2), intraluminal bleeding ($n$ = 5), and leakage ($n$ = 1). Singh et al. described a pooled incidence of serious adverse events of 2.26%.

### 4.3 RESTORe with the EndoCinch device

Endoluminal Vertical Gastroplasty (EVG) is performed using the EndoCinch suturing device (C.R. Bard, Inc., Murray Hill, NJ). Since 2004 this device is used to treat obesity. The RESTORe System (Bard/Davol, Warwick, RI) is an updated version of the EndoCinch device. It is capable of deeper tissue acquisition and suture reloading inside the patient. During this procedure, in addition to an anterior to posterior plication in EVG, the greater curvature is also incorporated to mimic LGP.

Results: In 2008, Fogel performed EVG in 64 patients using a continuous running suture along the lesser curvature. No serious adverse events were reported and weight loss at 1 year was 58.1% EWL [14].

Complications: No significant adverse events were seen. Twelve-month endoscopy revealed partial or complete release of plications in 13 of 18 patients.

### 4.4 TOGA (transorale Gastroplasie)

TOGA (Satiety Inc., Palo Alto, CA) is an endoscopic stapling device first introduced in 2008. TOGA creates a stapled sleeve and a restricted outlet. Similar to VBG, TOGA is associated with decreased ghrelin and increased GLP-1 levels.

Results: A sham-controlled trial including 67 patients showed 52.2% EWL (in patients with BMI < 40) and 41.3% EWL (in those with BMI ≥ 40) after one year [15].

Complications: Two cases of respiratory distress and an asymptomatic pneumoperitoneum from esophageal and gastric perforations that was treated conservatively however were reported.

### 4.5 TERIS (trans-oral endoscopic restrictive implant system)

TERIS (Barosense, Redwood City, CA) is an endoscopically implanted device introduced by Biertho and colleagues in 2009. A prosthetic diaphragm is placed at the gastric cardia to create a small reservoir with a 10-mm orifice. To anchor the device full thickness plications are used.

Results: In a study including 18 patients (mean BMI 42.1 kg/m$^2$) Verlaan et al. reported about a median EWL after six month of 30.1% [16].

Complications: Three SAEs occurred, one gastric perforation and two cases of pneumoperitoneum. Because of the poor durability of the system the company decided to discontinue the TERIS system and to further develop the successful parts of it, such as the articulating circular endoscopic (ACE) stapler.

### 4.6 ACE-stapler (articulating circular endoscopic stapler)

The ACE stapler (Boston Scientific Corporation, Natick, MA) is an endoscopic stapler. This device consist of a head capable of both 360-degree rotation and complete retroflexion. A 5-mm endoscope enables visualization; the device is 16 mm in diameter. This device use vacuum suction to mobilize gastric tissue; firing the stapler creates a full-thickness plication using a 10-mm plastic ring with 8 titanium staples. A defined number of plications is done in the fundus and antrum.

Results: Verlaan et al. [17] reported about 17 patients (BMI 40.2 kg/m$^2$) et al. reported in a prospective safety and feasibility study of gastric volume reduction. Median EWL was 34.9%.

Complications: The most common adverse event was abdominal pain (7 patients); sore throat, diarrhea, nausea, constipation, and vomiting were also reported. All were self-limited.

### 4.7 Endomina system

The Endomina suturing system (Endo Tools Therapeutics, SA-ETT, Gosselies, Belgium) is a triangulation platform to perform large plications with transmural sutures and serosa-to-serosa apposition to reduce the gastric volume.

Results: Two studies (62 patients) by Huberty et al. reported 29% EWL at 12 months [29, 30].

Complications: No major adverse events were reported.

## 5. Aspiration therapy

Nyström et al. [26] reported 2018 in a 4-year analysis on the results of the AspireAssist® system in 201 bariatric patients, including in particular class 2 and 3 obese patients. Using a modified PEG, patients can drain the food pulp and rinse with water 20 minutes after ingestion. This device could reduce the absorption of up to 30% ingested calories after a meal.

Results: EWL and TWL rates of 43.6% and 17.1%respectively were achieved after one year.

Complications: The complication rate corresponds to that of PEG (inflammation of the injection site, peritonitis, buried bumper).

## 6. Malabsorption

The procedures that lead to a barrier development of duodeno-jejunal or gastro-duodeno-jejunal contact are endoscopic, innovative interpretations of the mode of action of the surgically created gastric bypass. The implantation of a plastic liner into the lumen of these organs can result in good glycaemic control and, in addition, weight reduction. These procedures are named gastrointestinal bypass liners (EndoBarrier®, ValenTx™). They are particularly indicated for patients with poorly adjustable diabetes mellitus type II.

### 6.1 The EndoBarrier

The EndoBarrier consists of a single use endoscopic system including a liner, delivery system, and retrieval system. A 65 cm teflon covered sleeve is placed into the small bowel and can remain in situ for up to 3–12 months. Endoscopically implementation is done under general anesthesia. Placement of anchor and liner is controlled by endoscopy and fluoroscopic guidance. The anchors at the proximal end of the sleeve looks like a crown, consists of nitinol, which functions as a self-expandable stent. This allows fixation to the duodenal bulb distal to the pylorus, but proximal to the ampulla Vateri. The proximal and distal open liner ensures the passage of chyme from the stomach while bypassing the duodenum. Along the outside of the liner, pancreatic juices and bile will enter from the ampulla Vateri, thereby avoiding contact with gastric contents until these exit the sleeve in the jejunum. The EndoBarrier mimics the malabsorptive effects of the RYGB.

Results: Betzel and colleagues [19] reported 2020 about 44 patients treated with EndoBarrier-Devices. Twenty patients required early removal due to AEs(55%). During dwelling time, body weight decreased significantly (15.9 kg; TBWL 14.6%). HbA1c decreased non-significantly. In total, 68% of the patients experienced at least one AE. Patel et al. [31] 2018 reported about similar results in a multicenter, non-randomized clinical trial with 45 obese patients. Fourteen patients required early removal (24%). Significant reductions in weight, BMI and glycaemic control were observed during the device insertion period.

Complications: The ASGE Bariatric Endoscopy Task Force reported 2015 about an AE rate of 12.66% in 271 implantation [10]. Serious adverse events included migration (4.9%), GI bleeding (3.86%), sleeve obstruction (3.4%), liver abscess (0.126%), cholangitis (0.126%), acute cholecystitis (0.126%), and esophageal perforation(0.126%).

### 6.2 The ValenTx and its successor

The ValenTx-System is a gastro-duodenal-jejunal liner system which has to be inserted in an endoscopic/laparoscopic rendezvous technique. The system, a 120 cm long fluoropolymer liner with a proximal and a distal cuff, is primarily placed into the jejunum with a delivery catheter. The proximal cuff is anchored at the level of the Z-line of the GE junction and anchored with fullthickness sutures deployed in a circumferential manner. The successor of the ValenTx is a 120 cm long fluorpolymer sleeve which could implement without laparoscopy.

Results: Sandler et al. reported 2018 in sum about 32 obese patients (Mean BMI 42.3Kg/m$^2$) treated with the successor ValenTx for 12 months. Implantation and removal of the device according to the study concepts was possible in all patients. EWL after one year was 44.8% [20].

Complications: Implantation related AEs were mild (epigastric pain, heartburn or acid reflux, regurgitation, vomiting, dysphagia, and nausea). Longtime AEs were obstructions by knots or kinking. In one patient laparotomy for sleeve explantation was necessary.

### 6.3 The duodenal mucosal resurfacing (DMR)

DMR potentially mimics some of the mechanisms of action of bariatric surgery in a minimally invasive manner. The DMR procedure is performed using specially designed catheters which are advanced over a guidewire next to the endoscope. It is a single, minimally invasive endoscopic procedure that involves circumferential hydrothermal ablation of the duodenal mucosa resulting in subsequent regeneration of the mucosa. Before ablation, the mucosa is lifted with saline to protect the outer layers of the duodenum. The DMR procedure could be performed under either general anesthesia or deep sedation with propofol.

Results: Van Baar et al. reported 2020 about 37 of 46 patients underwent complete DMR (80%), 36 were finally analyzed; in remaining patients, mainly technical issues were observed [32]. Weight loss was observed in the first 4 weeks, overall was no significant weight loss registered but a significantly decrease of HbA1c and needed anti-diabetic medications. The principle of DMR also allows good glycemic control, but does not lead to significant weight loss [33].

Complications: In the study of Van Baar et al. [32] twenty-four patients had at least one AE (52%) related to DMR. Of these, 81% were mild. One SAE and no unanticipated AEs were reported.

## 7. Endoscopic bypass

In the context of NOTES development, endoscopically guided gastrojejunal bypass systems have already been developed and successfully performed in the pig model [34]. In the present publications magnets are used, which are applied via the working channel of the scope. These "intelligent" magnets are composed in square or hexagonal form intraluminally. Two such magnets, which act on each other with a force of 600-800 g, cause an anastomosis by reducing the blood supply of the enclosed tissue. This results in a gastro-jejunal [35] or jejuno-ileal [21] anastomosis.

The incisionless magnetic anastomotic system (IMAS; GI Windows, West Bridgewater, MA, USA) is a novel self-assembling magnetic device that allows for side-to-side anastomosis with enteral diversion.

Results: E. Machytka and colleagues [21] performed a prospective, single-arm pilot study, published in 2017. They evaluated the clinical outcomes, safety, and efficacy of IMAS placement and creation of a PJD in a total of 10 patients. At 12 months, patients had an EWL of 40.2%, and a decrease in HbA1c of 1.9% and a decrease in fasting glucose levels of 37% in diabetic patients.

Complications: No adverse events were reported.

## 8. Others

### 8.1 SatiSphere

The endoluminal mechanical device is a patent of Endosphere Inc. Columbus, OH, USA for implantation for 3 months. It is implanted endoscopically into the stomach and duodenum through an endoscope under general anesthesia and is composed of a nitinol backbone and spheres made of polyethylenterephtalat with two pigtails at each end. The stent form was made to stay in place by mimicking the anatomy of corresponding parts of the human intestine especially the duodenal C-shape down to the ligament of Treitz.

Results: Sauer et al. [36] reported about 26 treated patients. The study was prematurely terminated.

Complications: Migration of the endoluminal mechanical device was seen in 10/21 patients. Serious adverse events occurred in 10 out of 21 patients in the treatment group.

### 8.2 Full sense device

This device was introduced 2014 with an internet presentation. The Full Sense Device (Baker, Foote, Kemmeter, Walburn LLC, Grand Rapids, MI) is a temporary, reversible device that is deployed and removed endoscopically. It is a modified fully-covered stent with an esophageal component and a gastric disk component. To stretch the proximal stomach (cardia and fundus) stimulates the vagal nuclei and the vagus nervely. It is designed to induce satiety and fullness in the absence of food by applying pressure on the distal esophagus and gastric cardia.

Results: Only preliminary studies exist. Park and colleagues reported about FSD implantation in 12 pigs [37]. They used fully-covered, partially covered and uncovered stent devices. Luo and colleagues searched for the effects of this system in a rodent model [38].

Complications: There was a high migration rate (11/12) in the porcine model.

## 9. Endoscopic post-surgical complication management

Relevant early and longtime complications can occur after bariatric surgery. Because the majority of symptomatic patients are endoscopically evaluated, the gastroenterologists must be familiar with post-surgical anatomy and complications, and their endoscopic management.

### 9.1 Acute complications

#### *9.1.1 Bleeding*

Endoluminal hemorrhage after resective procedures in bariatric patients occur with an incidence of up to 5% [39]. Depending on the pathology, endoscopic

hemostasis can be achieved by clip (OTSC or TTSC), submucosal injection with fibrin glue or by endoscopic application of hematostyptics.

### *9.1.2 Anastomotic insufficiency or staple line leaks*

The insufficiency of an anastomosis or a staple line leak results in a leakage of enteral fluids into the abdomen. The visceral fat, which is present in pathological amounts, can result in occult peritonitis without typical pain symptoms this conditioned a delay of the detection of the insufficiency. Different endoscopic therapeutic procedures have been established in cases of clinical suspicion of an insufficiency or in cases of proven insufficiencies.

In the case of early detection of insufficiency, re-laparoscopy and, if necessary, overstitching may be appropriate. Often a combination of re-laparoscopy, lavage and drainage for sepsis control and endoscopic therapy is indicated. In hospitals with obesity centers and a 24-hour endoscopy rendezvous procedures with intraoperatively endoscopy could be established. Especially in cases of very small leaks, a reliable identification of the leak can be made [40].

The most frequently performed endoscopic therapy for leakages after bariatric surgery worldwide is the stent therapy [41]. A challenge is the stent fixation in bariatric patients. Stent dislocation is the most common complication of this type of therapy. Special bariatric stents have been developed. The leading brands ECBB HanaroStent® (MI-tech, Seoul, South Korea), MegaStent™ (Taewoong, Seoul, South Korea) and Gastro Seal™ (MI-tech, Seoul, South Korea) are stents 2013 [42]. In addition to the common hemo-clips, the endoscopic sewing machine (EndoStich®, Apollo endosurgery, USA) [43, 44] and a special OTSC (OTSC®Stentfix, Ovesco, Germany) can be used for stent fixation [43].

The endoscopic negative pressure therapy (ENPT) is based on an open-pored element (e.g. a sponge), which is either endoluminally inserted at the stage of the leakage or into the resulting insufficiency cavity (intracavitary). The open-pore element is fixed to a drainage with perforations, which is connected to a vacuum source. The negative pressure acts through the pores on the surrounding tissue and results in a continuous drainage of secretions, cell-detruitus and bacteria, the suction induces tissue proliferation [45]. Due to the good clinical results this therapy is used for numerous leakages of the gastrointestinal and urogenital tract [46, 47]. ENPT is also known under the synonyms E-VAC and EVT. For ENPT as primary endoscopic procedure for leakage, possibly in combination with laparoscopy, three studies are currently available with a cumulative success rate of 90.27% in a total of 31 patients [48–50]. In addition, there are numerous case reports and studies, some of which deal with the combined use of ENPT with stent procedures as first and second line therapy [51].

Closure of leakage after bariatric surgery can be successfully performed with OTSC® as first or second line therapy with good results up to closure rates of 86.3% [52, 53].

The drainage of secretions through an internal drainage by implantation of a double-pigtail-drainage to endoluminal can lead to a successful healing of the insufficiency in up to 78% according to the study results [41].

## 9.2 Long-time complications

### *9.2.1 Ulcera*

In patients after RYGB, gastrojejunal anastomosis ulceration occurs in up to 16% of cases. Typically, these ulcers occur within 1–6 months postoperatively.

Possible complications of these ulcerations are pain, bleeding and possibly perforations. Endoscopic diagnosis and bleeding therapy can be established as described in "bleeding".

Ulcerations can also occur after gastric banding operations due to the band. In this laparoscopic procedure, an adjustable silicone band is placed around the proximal corpus ventriculi, which causes a deliberate stenosis of the stomach by filling a port appropriately. Erosion of the gastric band can occur in almost 1/3 of the patients [41]. If necessary, the gastric band is then recovered endoscopically [54, 55].

*9.2.2 Stenosis*

With regard to stenosis after bariatric surgery, the following causes of stenosis should be divided:

- Primary anastomotic stenosis according to RYGB (3–28%) [41, 56],
- Primary stenosis in a sleeve stomach (0.1–3.9%) [57],
- Post-therapeutic stenosis after leakage therapy [41].

Stenosis after bariatric surgery is defined as lumen constriction to less than 10 mm. The therapy consists of an endoscopic controlled balloon dilatation. For the primary stenosis after sleeve gastrectomy (30 mm) achalasia balloons with very good clinical results are used stenosis sleeve.

*9.2.3 Weight regain caused by dilated sleeve or gastrojejunal anastomosis*

Weight regain after bariatric surgery is a multi-complex problem. While behavioral and genetic mechanisms a dilated gastrojejunal anastomosis (GJA) is a relevante factor of weight recidivism after Roux-en-Y gastric bypass surgery (RYGB).

### 9.3 TORe with OverStitch™

Endoscopic transoral outlet reduction (TORe) is a therapeutic option for management of weight regain after RYGB. By a full thickness endoscopic suturing device (Overstitch, Apollo Endosurgery, Austin, TX) the reduction of the GJA aperture is possible.

Results: Vargas and colleagues [58] reported in a meta-analysis about 330 patients who underwent TORe procedure. The pooled weight lost at 12 months was 8.4 kg.

Complications: Overall, 14% of patients experienced nausea, 18% had pain and 8% required a repeat EGD. No serious adverse events were reported.

## 10. OTSC-clip to reduce pouch-outlet and the new BARS device

The OTSC®-clip (Ovesco AG, Tübingen, Germany) is made of super-elastic shape memory alloy (Nitinol) which re-takes its former unbent shape after the clip is released and thus exerts a constant compression on the tissue between the jaws of the clip. In 2020 Ovesco created a new product to reduce pouch-outlet named BARS device (Bariatric Reduction System).

Results: Heylen and colleagues [59] reported about 94 patients who underwent reducing of a post-RYGB pouch-outlet. After one year mean BMI was 27.4 kg/m$^2$. Di Lorenzo published 2020 results of a clinical trial with BARS device in 6 patients [60]. Authors reported about safely performed procedures with a mean procedure time of 52 min and a mean weight loss of 6 kg at a 3-month FU.

Complications: No SAEs occurred. Some patients complained of a sore throat for 24 h after the intervention. In five patients with post-interventional dysphagia, a gastroscopy had to be performed. Two of patients required endoscopic dilatation.

### 10.1 StomaphyX device

The transoral StomaphyX device (EndoGastric Solutions) is a minimally invasive technique for revision after RYGB. Procedure seems to be safe and effective.

Results: 2014 Eid et al. [61] published a randomized clinical trial with 45 patients treated with StomaphyX and 25 patients in the sham group. The primary efficacy end point was reduction in pre-RYGB excess weight by 15% or more excess BMI. Patients undergoing StomaphyX treatment experienced significantly greater reduction in weight and BMI. Enrollment was closed prematurely because preliminary results indicated failure to achieve the primary efficacy end point in at least 50% of StomaphyX-treated patients.

Complications: There was one causally related adverse event with StomaphyX that required laparoscopic exploration and repair.

### 10.2 APC for pouch-outlet reducing

APC is a non-contact technique involving the application of an electrical current to tissues through ionized argon gas (argon plasma). It has also been successfully used in the treatment of the enlargement of the anastomosis after gastric bypass.

Results: Quadros and colleagues [62] published 2020 a randomized controlled trial with APC treatment and sham group. Authors reported about a significant weight decrease in the first months after APC.

Complications: No SAEs were reported.

#### *10.2.1 Choledocholithiasis*

The bariatric procedure can be lithogenic due to a hypersecretion of bile and the strong weight loss. A postoperative incidence of cholecystolithiasis in 50% has been described for RYGB. The current guidelines recommends primary cholecystectomy (CHE) in preoperative, symptomatic cholecytolithiasis and, if applicable, in preoperatively known gallstone disease [1]. Simultaneous CHE is not recommended in patients without gallstones. In case of a possibly resulting choledocholithiasis, RYGB is a challenge for the endoscopist. In these cases, laparoscopically assisted ERCP (LA ERCP) or double balloon enteroscopy for the establishment of ERCP (DB ERCP) has become established [41]. Furthermore, there is the possibility to place the duodenoscope laparoscopically assisted via a gastrostomy of the suspended stomach.

## 11. Conclusion

This overview about the role of endoscopic diagnostic and interventions in obese patients with requiremet of bariatric procedures is certainly not complete

and possibly some new and specialized techniques are not listed. Nevertheless we could show the immensely dimension of endoscopy in this field. Endoscopy is an essential part of diagnostics and therapy in the treatment of bariatric patients this applies to the pre- and postoperative phase. As bariatric endoscopy or endoscopic bariatric therapy, a large number of interventions have already been developed, which impress by their minimal invasiveness, low complication rates, manageable costs and good tolerability. Further revolutionary advances in the field of bariatric endoscopy can be expected in the medium term. Interventional endoscopy requires a high level of expertise and a learning curve. It can be expected an increasing number of primary bariatric endoscopic procedures will be performed and bariatric surgery will be relegated to the background due to peri-interventional complications and higher invasiveness.

## Abbreviations

| | |
|---|---|
| ACE | articulating circular endoscopic stapler |
| AE | adverse event |
| APC | argon-plasma-coagulation |
| BMI | body-mass-index |
| DB | double balloon |
| DMR | duodenal mucosal resurfacing |
| EAES | European Association for Endoscopic Surgery |
| EBT | endoscopic bariatric therapy |
| EGD | esophago-gastro-duodenoscopy |
| EGS | endoscopic gastric sleeve |
| ERCP | endoscopic retrograde cholangio-pancreaticography |
| ENPT | endoscopic negative-pressure therapy |
| EVAC | endoscopic vacuum-assisted closure therapy |
| EVT | endoscopic vacuum-therapy |
| EWL | excess weight loss |
| FU | follow-up |
| GERD | gastro-esophageal reflux disease |
| IFSO | International Federation for the Surgery of Obesity and Metabolic Disorders |
| IMAS | incisionless magnetic anastamosis system |
| IOP | incisionless operating platform |
| kg | kilogram |
| LA ERCP | laparoscopic assisted ERCP |
| LGS | laparoscopic gastric sleeve |
| m | meter |
| OTSC | over-the-scope-clip |
| PEG | percutaneous endoscopic gastrostomy |
| POSE | primary obesity surgery endoluminal |
| ROSE | restorative obesity surgery endoluminal |
| RYGB | Roux-Y-gastric bypass |
| SAE | severe adverse event |
| SLL | staple-line-leak |
| TORe | trans-oral outlet reduction endoscopic |
| TTSC | through-the-scope-clip |
| TWL | total weight loss |
| WHO | World Health Organization |

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