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Original Article

Sleeve gastrectomy with duodenoileal bipartition using linear magnets: feasibility and safety at 1-year follow-up

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ABSTRACT

Background: Single-anastomosis metabolic/bariatric surgery procedures may lessen the incidence of anastomotic complications. This study aimed to evaluate the feasibility and safety of performing side-to-side duodenoileal (DI) bipartition using magnetic compression anastomosis (MCA). In addition, preliminary efficacy, quality of life (QoL), and distribution of food through the DI bipartition were evaluated.

Methods: Patients with a body mass index (BMI) of ≥35.0 to 50.0 kg/m^2 underwent side-to-side DI bipartition with the magnet anastomosis system (MS) with sleeve gastrectomy (SG). By endoscopic positioning, a distal magnet (250 cm proximal to the ileocecal valve) and a proximal magnet (first part of the duodenum) were aligned with laparoscopic assistance to inaugurate MCA. An isotopic study assessed transit through the bipartition.

Results: Between March 14, 2022 to June 1, 2022, 10 patients (BMI of 44.2 ± 1.3 kg/m^2) underwent side-to-side MS DI. In 9 of 10 patients, an SG was performed concurrently. The median operative time was 161.0 minutes (IQR, 108.0-236.0), and the median hospital stay was 3 days (IQR, 2-40). Paired magnets were expelled at a median of 43 days (IQR, 21-87). There was no device-related serious advanced event within 1 year. All anastomoses were patent with satisfactory diameters after magnet expulsion and at 1 year. Respective BMI, BMI reduction, and total weight loss were 28.9 ± 1.8 kg/m^2, 15.2 ± 1.8 kg/m^2, and 34.2% ± 4.1%, respectively. Of note, 70.0% of patients reported that they were very satisfied. The isotopic study found a median of 19.0% of the meal transited through the ileal loop.

Conclusion: Side-to-side MCA DI bipartition with SG in adults with class II to III obesity was feasible, safe, and efficient with good QoL at 1-year follow-up. Moreover, 19% of ingested food passed directly into the ileum.

Introduction

Surgery is the only treatment for class III obesity that has proven effective over the long term [1,2]. The American Society for Metabolic and Bariatric Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) have endorsed the safety and efficacy of 7 metabolic/bariatric surgery (MBS) procedures, including Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and duodenal switch (DS); moreover, there is no consensus that 1 intervention is best for every patient.

Procedural complexity, complications, and insufficient weight loss or weight regain require ongoing technical improvements and inspire the development of new interventions to avert these challenges. One such minimally invasive surgery strategy is the reduction of the number of gastrointestinal (GI) anastomoses, as applied in single-anastomosis duodenoileal (DI) bypass with SG (SADI-S) and single-anastomosis sleeve ileal bypass (SASI) [3,4]. Each procedure involves the creation of an SG, an end-to-side bipartition between the duodenum and ileum in SADI-S, and a side-to-side bipartition between the stomach and ileum in SASI.

Both single-anastomosis operations offer good weight loss and reduction of associated medical conditions relative to RYGB and SG [5-9]. In SASI, the portion of food that transits rapidly from the

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stomach to the distal ileum promotes immediate satiety hormone secretion (ie, GLP-1 and PYY-36), preserving the neuroendocrine effects of a DS [10] while minimizing its hypoabsorptive activity; moreover, possible complications include reflux esophagitis, dumping syndrome, ulcer, stenosis of the gastroileal anastomosis, and risk of the entire transit passing through the terminal ileum with no passage through the duodenum [8,11]. SADI-S is associated with fewer nutritional concerns than SASI; moreover, suturing or stapling the anastomosis can be technically challenging [12]. We considered that a modified SADI-S procedure, a side-to-side DI bipartition, might offer an effective approach with even greater safety. Furthermore, forming the bipartition using a magnetic compression anastomosis (MCA) technique would obviate materials retained in the body (eg, sutures, staples, clips, or glue), lessening the potential instigation of leaks, bleeding, infection, and stricture [13-15]. In the event of insufficient weight loss, this procedure can likely also be revised to a full SADI-S or DS.

A novel minimally invasive GI MCA technology using 2 linear magnets has shown short-term safety and feasibility in preclinical testing [16] and safety and preliminary efficacy in a first-in-human (FIH) MBS study [17]. The interim outcomes of a multisite (Georgia, Belgium, Spain, and Canada) evaluation of the safety and efficacy of using linear magnets to perform side-to-side DI bipartition with or after SG were recently reported [18,19]. The current study presents the feasibility, safety, and preliminary efficacy outcomes at 1-year follow-up of a single-site (Belgian) series of incisionless and sutureless/stapleless side-to-side magnetic DI bipartitions with or after SG. In addition, the distribution of food through the DI bipartition and the quality of life (QoL) at 1-year follow-up were evaluated.

Materials and methods

Study design and protocol

The study was designed as a prospective, observational, single-center analysis of the investigational Magnet Anastomosis System (MS; GT Metabolic Solutions) in patients with class II to III obesity who underwent side-to-side magnetic DI concurrent with an SG or who had undergone previous SG with unsatisfactory weight loss or weight regain. The protocol was registered before the study was conducted at ClinicalTrials.gov (https://classic.clinicaltrials.gov/ct2/show/NCT05322122).

Ethical conduct

The study protocol incorporated regulatory guidelines established for investigational devices and was approved by the ethical committee of the Centre Hospitalier Universitaire Saint-Pierre and the competent Belgian authority, the Federal Agency for Medicines and Health Products. An independent data safety monitoring board approved the study on January 14, 2022. All procedures were performed following the Declaration of Helsinki and Medical Devices Regulation 2017/745 standards to ensure the safety and well-being of patients.

Patient inclusion and exclusion

Patients identified through existing records were introduced to the goals of the study and the expected benefits and risks of the procedure. Written informed consent was obtained from each patient after a discussion with the surgeon.

For study inclusion, patients were required to be adults aged 18 to 65 years old having obesity with either a body mass index (BMI) of ≥40.0 to ≤50.0 kg/m^2 or a BMI of ≥30.0 to ≤40.0 kg/m^2 with at least 1 or both of the following: type 2 diabetes mellitus (T2D) or weight regain after an SG. In addition, the study inclusion required that patients agree to refrain for 1 year from additional MBS or reconstructive surgery that could affect body weight; females agreed to prevent pregnancy with contraception use for 1 year. Over-the-counter or prescription nonsteroidal anti-inflammatory drugs and weight-loss medication were not permitted 14 days before the procedure or during the study.

Study exclusions were uncontrolled T2D; type 1 diabetes mellitus; dyslipidemia; previous non-MBS intestinal, colonic, or duodenal surgery; previous trauma, abnormal anatomy, or genetic expressions, which prevented or contraindicated the study procedure; refractory gastroesophageal reflux disease; *Helicobacter pylori* positive and/or active ulcer disease; large hiatal hernia; inflammatory bowel or colonic diverticulitis; any anomaly precluding laparoscopic or orogastric access by gastroscope and catheters; an implantable pacemaker or defibrillator; untreated or poorly controlled psychiatric illness or substance abuse history; pregnancy; breastfeeding; a surgical or interventional procedure 30 days before or after the procedure; stroke/transient ischemic attack within 6 months of the study; chronic anticoagulation therapy (except aspirin); active infection; terminal disease; or a preoperative positive COVID-19 test.

Procedure

Under general anesthesia, with the surgeon positioned between the patient's legs, 5 trocars were placed (right paramedian, umbilical, left paramedian, left lateral, and epigastric). A marker was placed laparoscopically in the ileum 250 cm from the cecum. The ligament of Treitz was exposed, and a retrievable metal bowel clamp (Aesculap AG) was placed 10 to 15 cm distal to the ligament. The first (distal) MS linear BC42 neodymium magnet was delivered orogastrically by flexible endoscopy (pediatric 190 colonoscope; Olympus America) to the first jejunal segment, released, and grasped by a magnetic positioning device. The clamp was removed, and the positioning device was used to direct the magnet laparoscopically through the jejunal lumen to the position marked in the ileum. The second (proximal) magnet was delivered endoscopically to the postpyloric duodenal magnet fusion site. The distal ileal magnet was brought antecolic and side to side with the duodenum and released to align with the proximal magnet. The endoscope and positioning device were withdrawn, and Petersen's space was closed (Figs. 1-4).

If the patient's BMI was ≥40.0 kg/m^2, an SG was added to the procedure using an Endostapler (Ethicon Inc). The stomach was marked with the coagulating hook approximately 6 cm above the pylorus. The short gastric vessels were taken down along the greater curvature of the stomach with the Harmonic scalpel (Ethicon Inc). A 38F orogastric bougie was placed, and the stomach was transected along the bougie using a linear stapler with a 60-mm blue cartridge (Ethicon Inc). The staple line was reinforced with a running suture (Polydioxanone/PDS 2.0; Ethicon Inc). No leak test was performed.

Postoperative care

Before discharge, patients' hemodynamic condition, blood chemistry, and fluoroscopic results were closely monitored. Patients met with a nutritionist to learn the postprocedure diet and were asked to attend 6 follow-up visits (days 30, 60, 90, 180, 270, and 360). The arrangement of office visits for any procedural concerns was encouraged.

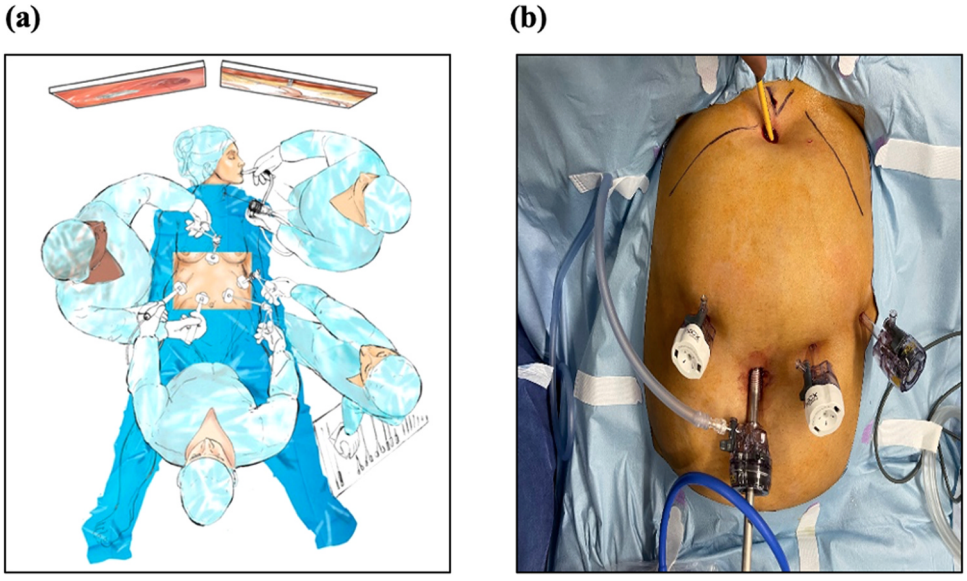

Figure 1. A, Patient and surgeon positions. B, Positioning of 5 trocars: right paramedian, umbilical, left paramedian, left lateral, and epigastric.

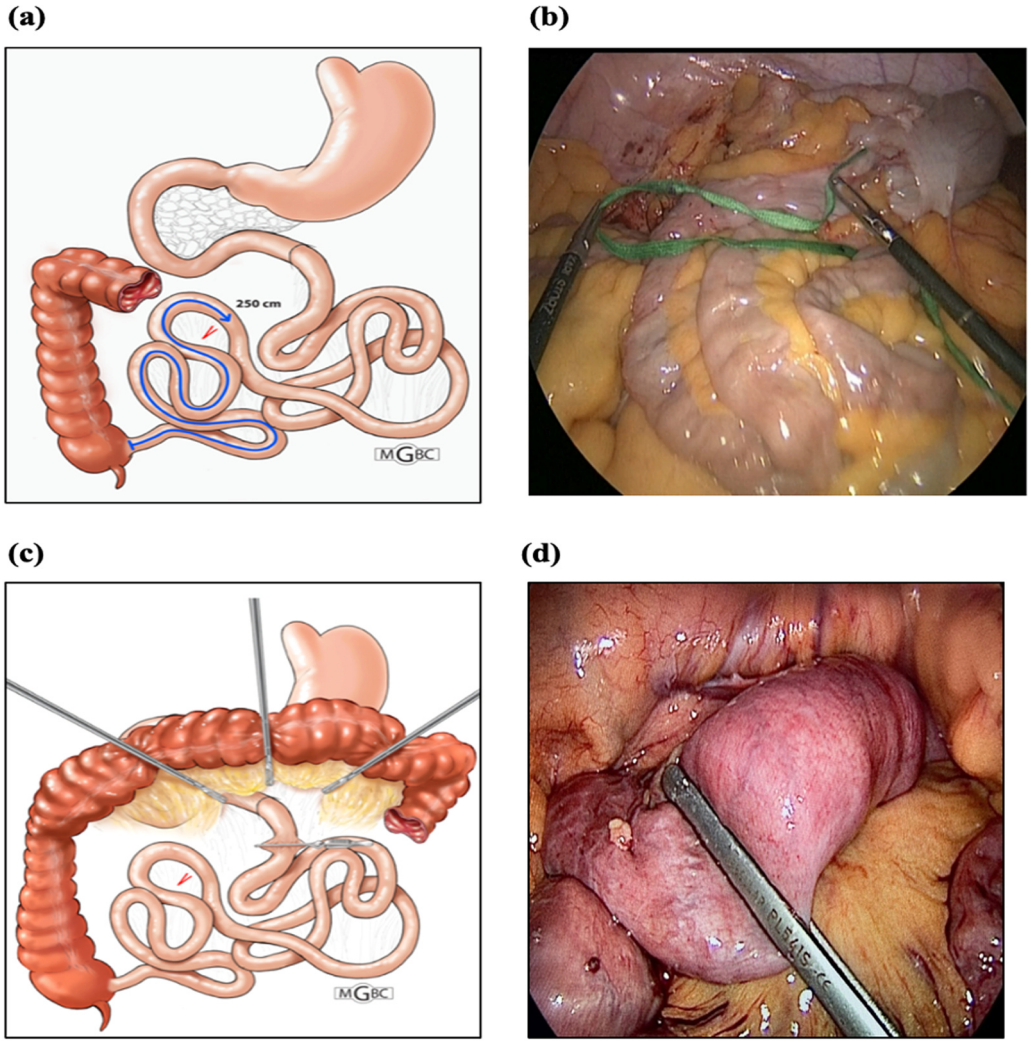

Figure 2. A and B, Bowel marker placed in the ileum 250 cm from the cecum. C, Exposure of the ligament of Treitz. D, Placement of a retrievable metal bowel clamp 10 to 15 cm distal to the ligament of Treitz.

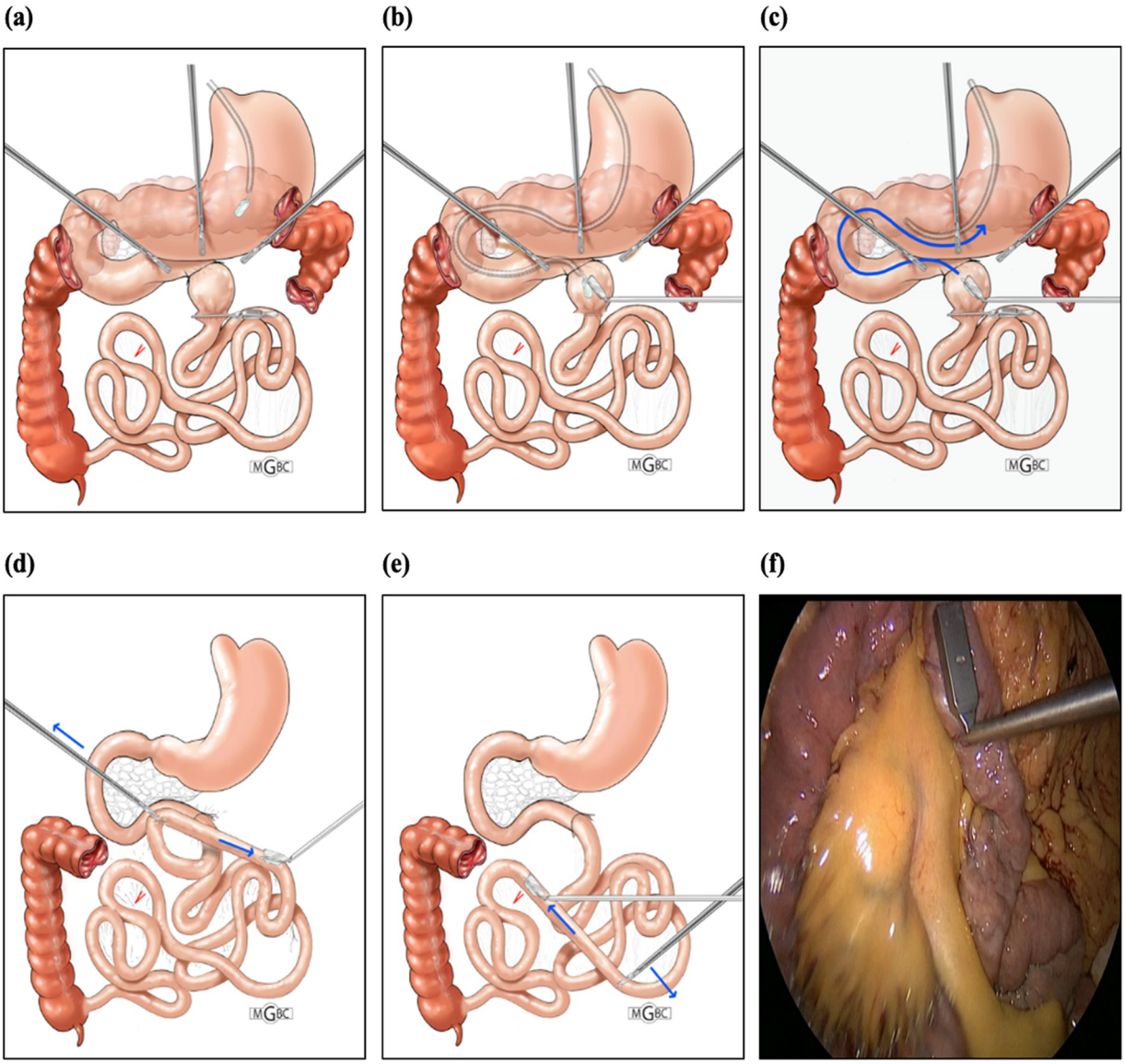

Figure 3. A, First (distal) magnet introduced orogastrically by flexible endoscopy to the fourth part of the duodenum. B, Magnet released and grasped by the positioning device. C, Clamp is removed, and the endoscope is retracted to the level of the stomach. D, The positioning device used to direct the distal magnet through the jejunal lumen laparoscopically. E and F, Magnet placed at the marked ileal position.

Endpoints

The primary feasibility and safety endpoints were (i) surgical feasibility of performing a side-to-side MS DI anastomosis, including correct alignment of the 2 linear magnets in apposition across the duodenal and ileal bowel, (ii) natural expulsion of the fused magnets without adverse events (AEs) or severe AEs (SAEs) requiring surgical reintervention, and (iii) creation of a patent anastomosis confirmed by endoscopy after magnet expulsion and at 1 year and also by fluoroscopy at 6 months.

The secondary endpoints were (i) incidence of acute and chronic AEs (evaluated using the Clavien-Dindo classification [CDC] [20]), (ii) preliminary efficacy (ie, weight loss evolution; T2D change based on glycosylated hemoglobin [HbA1c] and glucose outcomes), (iii) QoL after 1 year, and (iv) results of a radioactive isotope post-DI emptying study assessing the distribution of food through the DI bipartition.

Data collection

Patients' anthropometric and clinical characteristics and perioperative data, including procedure time, length of hospital stay, and early AEs, were collected. Long-term data recorded were patency of the anastomosis, magnet expulsion time, late AEs, and weight outcomes: absolute weight (kg), total weight loss (TWL) calculated as (baseline weight − follow-up weight) / (baseline weight) × 100, excess weight loss (EWL) calculated as (baseline weight − follow-up weight) / (baseline weight − ideal body weight) × 100, and BMI reduction calculated as initial BMI − follow-up BMI.

Endoscopy was performed at the preoperative screening, after magnet expulsion, and at 1-year follow-up to observe the evolution of reflux esophagitis (using the Los Angeles [LA] grading system [21]). The number of patients with proton-pump inhibitor (PPI) at 6 and 12 months was recorded.

QoL

All patients completed a GastroIntestinal Quality of Life Index (GIQLI) questionnaire [22] at their preoperative visit and follow-up visit at 1 year. The GIQLI is a 36-item GI-specific validated instrument designed to assess health-related QoL in clinical practice and clinical trials. The GIQLI is composed of 5 subscales: core GI symptoms (9 items), emotional

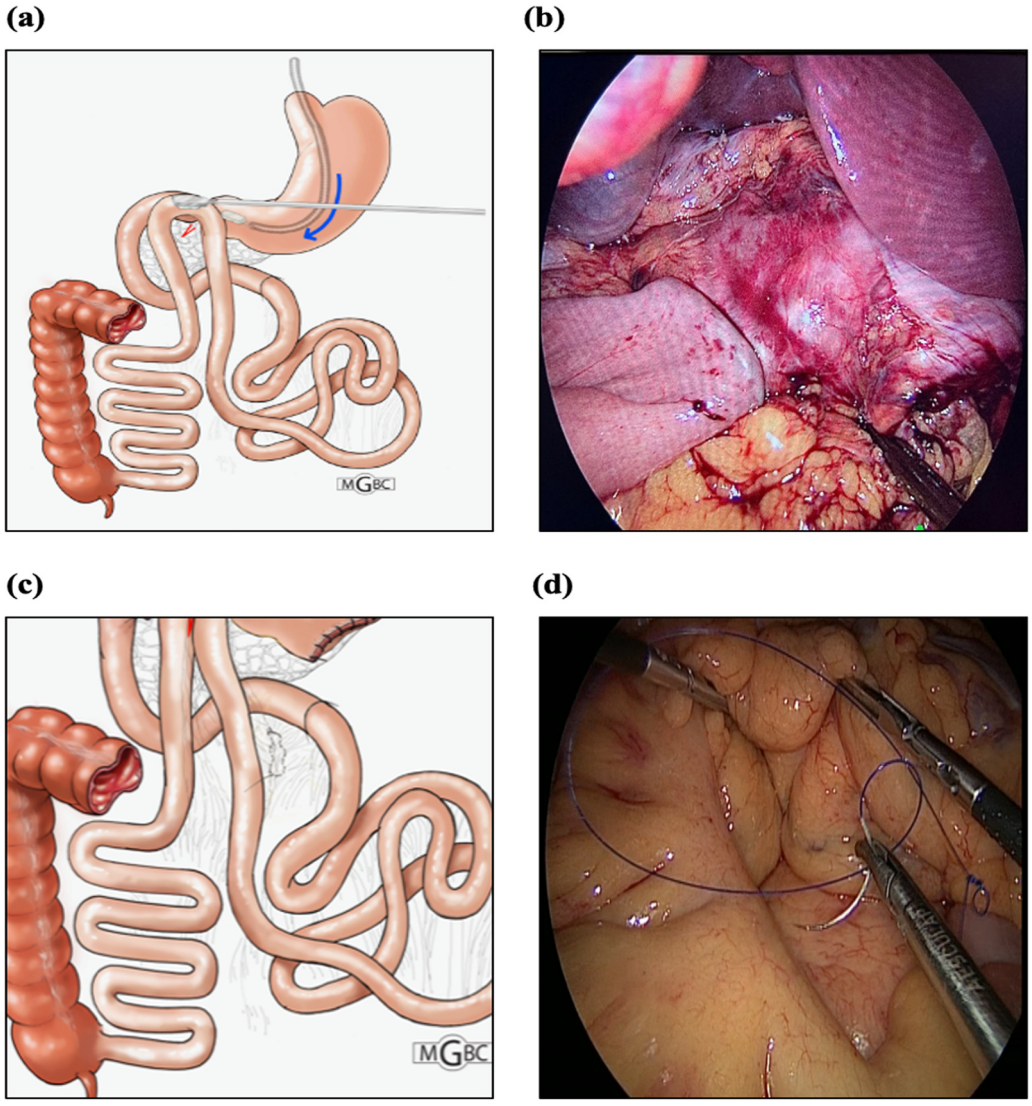

Figure 4. A and B, Endoscopic delivery of the second (proximal) magnet to the postpyloric duodenal fusion site and the ileal (distal) magnet laparoscopically elevated anterior and laterolateral to the fusion site and released to align with the proximal magnet. C and D, Closure of Petersen's space.

functioning (6 items), physical functioning (7 items), social functioning (4 items), and medical treatment effects (10 items). All 36 items are rated on a Likert scale from 0 to 4 points (0, least desirable; 4, most desirable option). Summed, the subscale scores yield a composite score ranging from 0 (worst health status possible) to 144 (best health status possible). Healthy normal individuals have a mean composite GIQLI score of 125. The minimal clinically important difference (MCID) in composite GIQLI scores has been established at 5 points and implemented in meta-analyses of bariatric surgery results [23]. In addition to the GIQLI, patients responded to a surgical procedure satisfaction question at 1-year follow-up using a Likert item scale ranging from 1 (very dissatisfied) to 5 (very satisfied).

Isotopic study

A modified isotopic study using a full-fat yogurt labeled with technetium colloid (Tc99m) was conducted within days of magnet expulsion to analyze the amount of the radioactive meal transit through the DI bipartition. Scintigraphic acquisition started immediately, and images were recorded continuously at a rate of 2 images per second for 30 minutes. The sum of all the images taken by the gamma camera results in 1 image on which a region of interest was drawn around the ileal loop and another around the natural pathway. The measurement of the radioactivity present in the 2 regions of interest over time produced a digestive transit curve. By the method of the area under the curve, the activities of a region were compared with the others and expressed as percentages.

Statistical analysis

The analyses were performed using the SPSS statistical package (version 20.0; IBM). Qualitative variables were reported as frequencies and percentages. Quantitative variables were generally reported using means and SEM; 95% CIs, medians, and ranges were provided for select variables. The group mean changes in weight, metabolic parameters, and QoL outcomes were assessed using the paired-samples *t* test or the Wilcoxon signed-rank test, as appropriate. The clinical significance of individual patient changes in GIQLI composite scores was assessed using the MCID method. Significance was set at a *P* value of $< .05$.

Results

Patients

Between March 14, 2022, and June 1, 2022, 9 of 10 patients enrolled in the study underwent side-to-side magnetic DI with added

Table 1
Patient characteristics and perioperative outcomes

Characteristics	N = 10
Preoperative	
Age (y), mean ± SEM (range)	37.5 ± 2.6 (28.0-52.0)
Females, n (%)	8 (80.0)
Ethnicity	
White	5 (50.0)
Latino	2 (20.0)
Maghrebian	1 (10.0)
Not offered	2 (20.0)
Height (cm), mean ± SEM (range)	165.3 ± 3.0 (153.0-185.0)
Weight (kg), mean ± SEM (range)	121.7 ± 6.9 (90.0-155.0)
Ideal weight (kg), mean ± SEM (range)	68.5 ± 2.6 (58.5-85.6)
Excess weight (kg), mean ± SEM (range)	53.2 ± 4.7 (31.5-69.6)
BMI (kg/m^2), mean ± SEM (range)	44.2 ± 1.3 (37.4-50.9)
Type 2 diabetes mellitus, n (%)	1 (10.0)
Hypertension, n (%)	1 (10.0)
Sleep apnea, n (%)	3 (30.0)
HbA1c (%), mean ± SEM	5.6 ± 0.2 (4.9-6.1) (n = 4)
Glucose level (mg/dL), mean ± SEM (range)	92.4 ± 3.2 (81.0-100.0) (n = 7)
Previous SG ≥ 12 months, n (%)	1 (10.0)
Perioperative	
Operative time, min	
Median (IQR)	161.0 (108.0-236.0)
Mean ± SEM	167.3 ± 14.9
Hospital stay, d	
Median (IQR)	3.0 (2.0-40.0)
Mean ± SEM	6.3 ± 3.7
Expulsion of magnets, d	
Median (IQR)	43.0 (21.0-87.0)
Mean ± SEM	49.1 ± 7.9

BMI, body mass index; HbA1c, glycosylated hemoglobin; SG, sleeve gastrectomy.

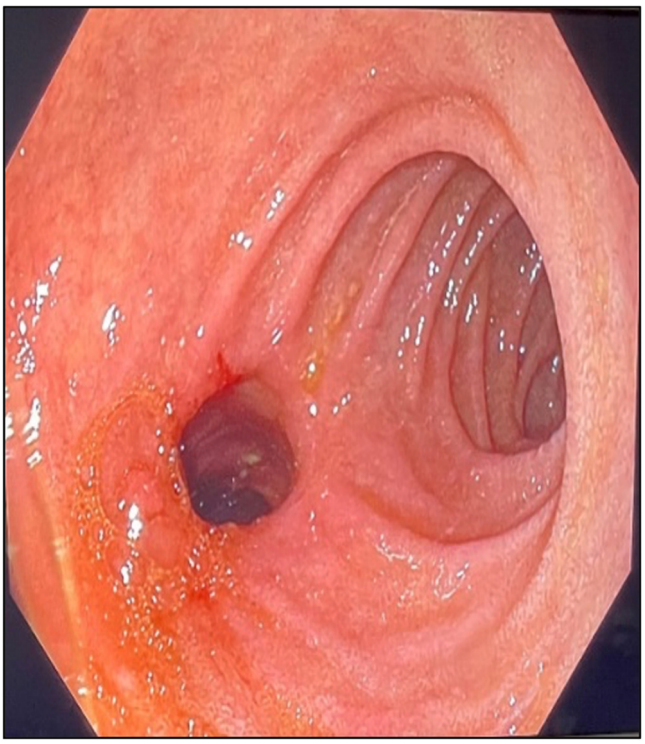

Figure 5. Endoscopic view of patent duodenoileal anastomosis with healthy mucosal tissue.

SG. Of note, 1 patient had undergone a previous SG because of weight regain. The average age of patients was 37.5 years (range, 28.0-52.0), and 8 of 10 patients (80.0%) were female (Table 1). The mean baseline weight was 121.7 ± 6.9 kg (range, 90.0-155.0) with a BMI of 44.2 ± 1.3 kg/m^2 (range, 37.4-50.9). Associated medical conditions included diagnosed T2D (n = 1), hypertension (n = 1), and sleep apnea (n = 3). The group mean HbA1c was 5.6% ± 0.2%; the mean glucose was 92.4 ± 3.2 mg/dL. Of note, 1 patient who received a concurrent DI + SG entered the study with a T2D diagnosis (baseline HbA1c of 6.0%; glucose not recorded).

Feasibility

The median operative time was 161.0 minutes (IQR, 108.0-236.0) (Table 1). The average operative times were 189.0 minutes for the first 5 patients and 145.6 minutes for the last 5 patients, constituting an approximate 45-minute mean reduction in operative time with advancing experience. The median hospital stay was 3.0 days (IQR, 2.0-40.0). The median expulsion time of the paired magnets was 43.0 days (IQR, 21.0-87.0). At endoscopy after passage of the paired magnets, 10 of 10 patients, and at 1-year follow-up, 9 of 10 patients (1 patient not available), DI anastomoses were patent and ample in size, permitting the introduction of the 9.5-mm gastroscope for examination (Fig. 5).

Safety

Placement and expulsion of the MS device did not lead to digestive perforation or any device-related AEs or SAEs. Regarding 30-day procedure-related complications, 2 patients had procedure-related serosal tears (CDC grade III, considered SAEs) because of intraoperative use of nonmagnetic forceps in the duodenum. These did not result in excessive bleeding and were resolved with 2 extra mucosal stitches without further consequences. At 1 year, 1 patient with no preoperative esophagitis developed LA grade B esophagitis, and the LA grade A reflux esophagitis of 2 patients increased to LA grades B (n = 1) and C (n = 1). Moreover, 3 patients were treated with PPI medication at 1-year follow-up, including 2 patients with esophagitis and 1 patient without esophagitis (Table 2).

There was no anastomotic leakage in the study. Of note, 1 severe SG-related leak at the angle of His resulted in narrowing and a fistula (CDC grade IV). A laparoscopic reoperation with washing-draining and endoscopic treatment (double prosthesis pigtail drains) was necessary. The leak was resolved within 4 months. This patient was somewhat dissatisfied with having undergone the procedure.

In addition, 3 patients experienced dehydration caused by nausea and vomiting (CDC grades I and II, 1 classified as an SAE). They required hospitalizations (2, 4, and 13 days) to be rehydrated and receive antinausea medication, and their episodes were resolved within 4 months; by 6 months and through 1-year follow-up, each patient was very satisfied to have undergone the intervention. Initially, following a novel procedure, some deviation from standard outcomes is expected as we learn how to take the best care of these patients.

A late SAE was experienced by a patient on postoperative day 125: the diagnosis of a partial bowel obstruction on an internal hernia at a partially repaired Petersen's space (CDC grade IIIb, classified as an SAE) required laparoscopic closure. Treatment was effective, and the patient returned home on the second postoperative day.

Efficacy: weight loss

The evolution of individual patient body weight and group mean BMI from baseline to 1 year is presented in Fig. 6; moreover,

Table 2
Esophagitis, PPI, satisfaction index, and GQLI results at 1-year follow-up

Patients	Esophagitis		PPI medication		Satisfaction index		GIQLI		
	Screening	Month 12	Screening	Month 12	Score	Clinical outcome	Screening	Month 12	Delta
05-01-01	A	B	–	+	5	–	113	109	−4
05-01-02	0	0	–	+	4	Bile reflux	101	90	−11
05-01-03	A	C	–	+	5	–	102	101	−1
05-01-04	0	–	–	–	5	–	93	131	38
05-01-05	0	0	–	–	5	–	103	99	−4
05-01-06	0	0	–	–	1	No weight loss	79	106	27
05-01-07	0	0	–	–	5	–	101	109	8
05-01-08	0	0	–	–	2	Fistula	127	94	−33
05-01-09	0	B	–	–	5	–	83	77	−6
05-01-10	0	0	–	–	5	–	115	123	8
Mean ± SD					4.2 ± 0.5	–	101.7 ± 4.6 *P* = .73	103.9 ± 4.9	2.2 ± 6.3

GIQLI, Gastrointestinal Quality of Life Index; PPI, proton pump inhibitor.
P value was based on paired-samples *t* test.
Oesophagitis – Los Angeles Classification of Esophagitis: grade A, ≥1 mucosal break no longer than 5 mm that does not extend between the tops of 2 mucosal folds. Grade B, ≥1 mucosal break more than 5 mm long that does not extend between the tops of 2 mucosal folds. Grade C, ≥1 mucosal break continuous between the tops of 2 or more mucosal folds but which involves < 75% of the circumference. Grade D, ≥1 mucosal break that involves ≥75% of the esophageal circumference.
PPI – on a PPI (+); off a PPI (−).
Satisfaction index: 1, very dissatisfied; 2, somewhat dissatisfied; 3, not satisfied or dissatisfied; 4, somewhat satisfied; 5, very satisfied.
GIQLI – 5 subscales: core gastrointestinal symptoms (9 items), emotional functioning (6 items), physical functioning (7 items), social functioning (4 items), and medical treatment effects (10 items). Items rated on a Likert scale (0, least desirable; 4, most desirable option). Summed, subscale scores yield a composite score ranging from 0 (worst health status possible) to 144 (best health status possible). Healthy normal individuals have a mean composite GIQLI score of 125.

corresponding progressive increases in mean TWL and EWL are shown for patients with complete study data (n = 8). All 10 patients had complete weight data at 6-month and 1-year follow-up (group results presented in Table 3). The mean absolute weight fell from 121.7 ± 6.9 kg at baseline to 79.2 ± 5.6 kg at 1 year, an overall mean change of 42.5 kg ($P < .001$). The group mean BMI was reduced from 44.2 ± 1.3 kg/m^2 to 28.9 ± 1.8 kg/m^2, an overall change of 15.2 kg/m^2 ($P < .001$). The respective mean TWL and EWL at 1 year were 34.2% ± 4.1% and 80.1% ± 10.3%, respectively; the respective medians were 37.0% and 89.9%.

Although metabolic parameters trended downward, no statistically significant mean change was detected in HbA1c and glucose levels in this group of patients without diabetes mellitus (Table 3). The single patient with T2D was taking 3 T2D medications at the start of the study. At approximately 2 weeks after the procedure, his metformin was discontinued. The patient's empagliflozin and gliclazide medications were continued through 1-year follow-up; the patient HbA1c fell from 6.0% to 5.0%.

Efficacy: QoL

Of note, 8 of 10 patients (80.0%) reported being generally satisfied with the procedure at 1-year follow-up, and 7 patients reported being "very satisfied." The overall mean satisfaction index was 4.2 ± 0.5. The patient with a sleeve fistula was dissatisfied because the weight loss was too quick, and the patient without the associated sleeve was very dissatisfied because of the absence of weight loss.

The group mean composite GIQLI score improved from 101.7 ± 4.6 at baseline to 103.9 ± 4.9 at 12 months; the mean change of 2.2 ± 6.3 points did not reach statistical significance ($P = .73$). At the individual patient level, 4 of 10 patients (40.0%) reported no clinically significant change in QoL as assessed by MCID for the GIQLI at 1-year follow-up. Among these 4 patients, 3 had esophagitis, 2 of whom continue to take PPIs. Another 2 of 10 patients (20.0%) reported significant QoL decline because of bile reflux for 1 patient and because of sleeve fistula for the other patient. Moreover, 4 of 10 patients (40.0%) reported significant clinical improvement in health-related QoL 1 year after the procedure (Table 2).

Efficacy: isotopic study

The results of the post-DI Tc99 emptying study assessing the distribution of food through the DI bipartition demonstrated the passage of the isotopic-marked yogurt through the ileal loop in 9 of 10 patients. A median of 19.0% (mean of 17.8%) of the radioactive meal passed through the ileal loop (Fig. 7).

Discussion

After a study of feasibility on 5 patients in Georgia, we started a series of 10 patients in Brussels. This is the fourth clinical examination of the feasibility, safety, and preliminary efficacy of side-to-side DI bipartition creation using the MS. The current results confirm those of the previous FIH and multisite studies [17-19]. In all patients (100.0%), satisfactory endoscopic positioning and alignment of the MS linear magnets in a narrow segment of the postpyloric duodenum and in the ileum with laparoscopic support were achieved. The operative time needed to place the distal magnet lessened markedly over the study, with a mean procedure time reduction of approximately 45 minutes in the second group of 5 of 10 patients. Ongoing improvements in instrumentation and technique standardization will facilitate further time reduction.

The full cohort met the 2 other feasibility endpoints: natural magnet expulsion without surgical reintervention and gradual formation of patent anastomoses with healthy mucosal tissue without retention of foreign materials in the body. The minimum time between the procedure and magnet expulsion was 3 weeks (median of 6 weeks), allowing sufficient time for robust tissue healing at the anastomotic periphery. When evaluated endoscopically, the diameter of the anastomoses permitted easy passage of the 9.5-mm endoscope. In contrast to the acute formation of a bowel anastomosis in the operating room, using magnets to create an environment conducive to gradual anastomotic healing is likely to lower AE and SAE incidence rates, as the procedure is technically less difficult and requires no enterotomy, averting the risk of inflammation, infection, and dehiscence from retained foreign materials [14].

Regarding the safety of the current study of MS DI, there was no mortality and no device-related AE or SAE through 1-year follow-up. A meta-analysis of 10 randomized controlled trials that compared MBS anastomosis formation with sutures/staples vs nonmagnetic

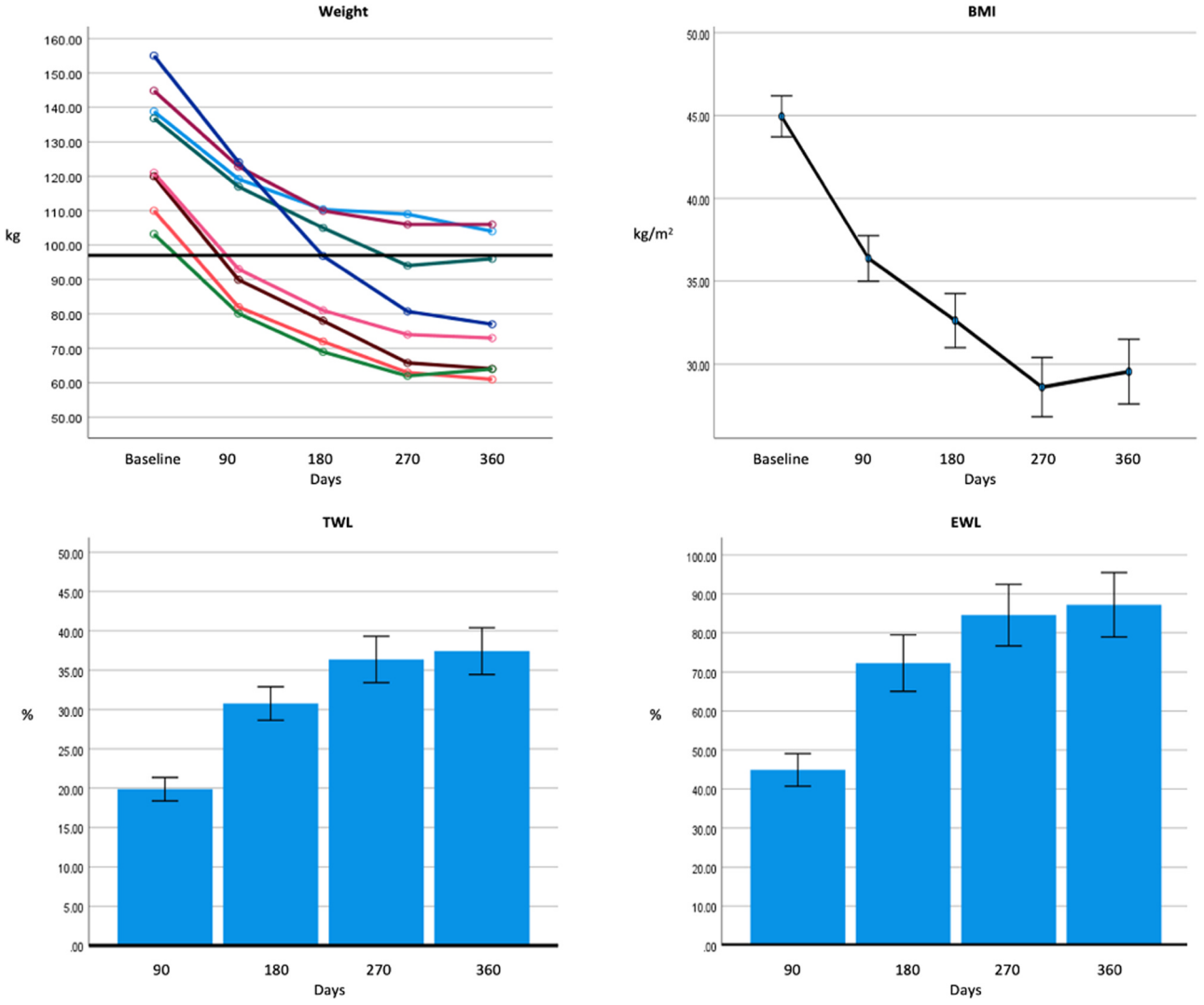

Figure 6. Evolution of weight from baseline to 1-year follow-up for patients with complete data (8 of 10) after side-to-side magnet anastomosis system duodenoileostomy with sleeve gastrectomy in absolute weight (kg), BMI (kg/m^2), %TWL, and %EWL. %EWL, excess weight loss; %TWL, total weight loss; BMI, body mass index.

Table 3
Evolution of weight and clinical parameters after side-to-side magnetic duodenoileostomy with sleeve gastrectomy

Variable	Baseline (n = 10)	6-mo follow-up (n = 10)			12-mo follow-up (n = 10)		
	Mean ± SEM Median (IQR)	Mean ± SEM Median (IQR)	Mean change ± SEM (95% CI)	*P* value	Mean ± SEM Median (IQR)	Mean change ± SEM (95% CI)	*P* value
Weight							
Absolute weight, kg	121.7 ± 6.9 120.5 (90.0-155.0)	87.3 ± 5.6 85.0 (62.0-110.4)	34.3 ± 4.5 (24.1-44.5)	< .001	79.2 ± 5.6 75.0 (61.0-106.0)	42.5 ± 5.8 (29.3-55.6)	< .001
BMI, kg/m^2	44.2 ± 1.3 45.3 (37.4-50.9)	31.8 ± 1.7 29.8 (23.9-39.0)	12.4 ± 1.5 (8.9-15.9)	< .001	28.9 ± 1.8 27.3 (22.5-36.3)	15.2 ± 1.8 (11.0-19.4)	< .001
TWL, %	–	27.8 ± 3.5 33.1 (1.1-37.6)	–	–	34.2 ± 4.1 37.0 (5.6-50.3)	–	–
EWL, %	–	65.4 ± 9.5 74.8 (3.2-108.7)	–	–	80.1 ± 10.3 89.9 (15.9-112.4)	–	–
Clinical							
HbA1c,[a] %	5.6 ± 0.2 5.8 (4.9-6.1)	–	–	–	5.4 ± 0.1 5.4 (5.1-5.6)	0.2 ± 0.1 –[b]	.109[c]
Glucose level,[d] mg/dL	92.4 ± 3.2 96.0 (81.0-100.0)	–	–	–	88.3 ± 4.6 85.5 (79.0-109.0)	4.1 ± 1.2 –[b]	.109[c]

BMI, body mass index; EWL, excess weight loss; HbA1C, glycosylated hemoglobin; TWL, total weight loss.
[a] HbA1c at baseline (n = 5) and 12 months (n = 3).
[b] Not applicable because of the small sample size.
[c] Nonparametric Wilcoxon signed-rank test.
[d] Glucose level at baseline (n = 7) and 12 months (n = 6).

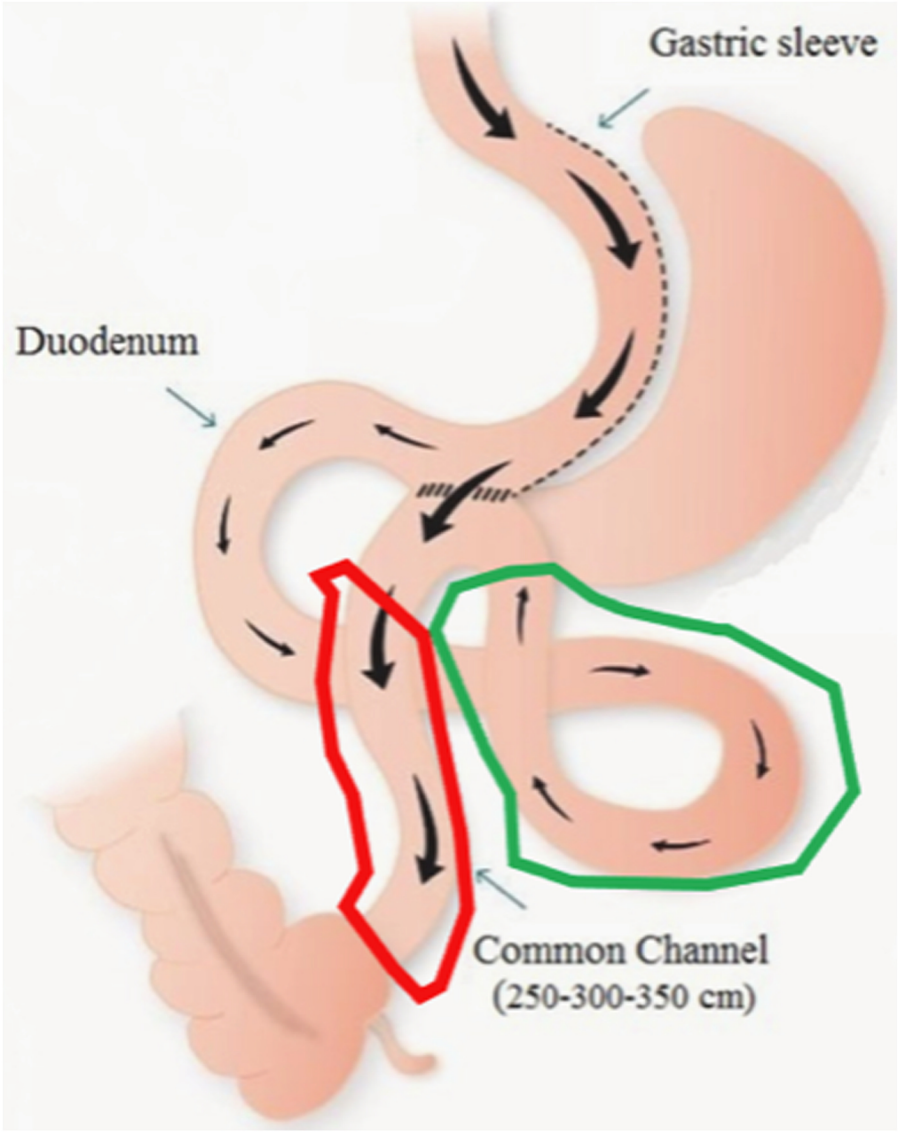

Figure 7. Regions of interest around the ileal loop (red circle) and around the natural gastrointestinal pathway (green circle) assessed by isotopic study.

compression devices found both approaches equivalent in anastomotic leakage rates [24]. However, to date, magnetic DI has only been studied in the current investigation of incisionless and sutureless linear magnet insertions and in a separate evaluation of patients with a median BMI of 38.8 kg/m^2 who underwent octagonal magnet insertion via enterotomy with suture closure [25,26]; both demonstrated feasibility without leak, bleeding, infection, or stricture.

Of note, 2 of the minimally invasive single-anastomosis procedures based on a first-step SG have been associated with high SAE rates compared with magnetic side-to-side DI + SG in this and the 3 previous early MS studies. SADI-S resulted in a 7.8% rate of early SAEs from leak, bleeding, abscess development, and stricture [5,27,28]. In a multicenter study of 58 matched pairs of patients who underwent SASI vs SG [9], AEs were comparable, suggesting that the addition of the SASI gastroileal anastomosis to an SG did not contribute further morbidity to the SG procedure. Similarly, in the current study, the 2 SAEs were both related to the SG portion of the procedure rather than to the DI anastomosis formation with linear magnets.

The preliminary effectiveness of side-to-side MS DI + SG at 1-year follow-up was confirmed by a mean TWL of 34.0%, EWL of 80.0%, and BMI reduction of 15.2 kg/m^2, which trends toward the intended outcomes of MBS (5, 28-30). For example, in 3 systematic reviews of SADI-S studies, the mean TWL ranged from 21.5% to 41.2% at 12 months [29-31], and the mean 12-month EWL ranged from 61.6% to 95.0% in the recent IFSO SADI-S systematic review (n = 1086)/position statement [5]. Weight loss because of the current side-to-side MS DI bipartition independently (without SG) could not be evaluated in this study because of the addition of the concurrent SG or after a previous SG.

The difference between the percentage of satisfied to very satisfied patients to have undergone the intervention (80%) and the nonsignificant improvement in the GICLI can be explained as follows: at least half of the questions in the GICLI are influenced by pathologic gastroesophageal reflux. Among the 6 patients in whom the GICLI score decreased, 4 patients were taking PPIs and/or had esophagitis, yet these 4 patients were very satisfied to have undergone the intervention at 1 year.

When we complete a bipartition, it is important to know the percentage of food in the separate loop. In the isotopic emptying study designed to estimate food flow through the bipartition into the ileal loop, 19.0% of ingested radioactive yogurt passed into the ileum. Further study of the MS DI procedure will aid in discerning whether this percentage approximates a proportion of food that will ensure

balanced nutrition compared with that of other single-anastomosis procedures.

Linear magnet DI bipartition may be the least invasive of the hypoabsorptive MBS procedures. As the approach is performed by endoscopy and laparoscopy, the intestine is never opened for manual suturing or stapling during the side-to-side anastomosis, and anastomosis development is sufficiently delayed so that the risk of leak is nearly nonexistent. Therefore, the postoperative period was particularly straightforward, except for the patient with a fistula at the angle of His. In case of metabolic issues or insufficient weight loss, the bipartition is likely reversible by linear stapling between the duodenum and ileum.

Limitations

The limitations of the study include the learning curve of performing the MS DI + SG technique, the small cohort, and the lack of a control group. In addition, combining an MS DI with an SG precluded the evaluation of independent MS DI outcomes.

Conclusion

The magnets were readily inserted, expelled naturally, created patent anastomoses, and left no potentially inflammatory material in the body. There was no anastomotic leakage in the study. Minimally invasive DI bipartition with a side-to-side magnetic anastomosis performed by linear magnets with an SG was feasible, safe, efficient, and associated with a good QoL at 1-year follow-up. Moreover, 19% of ingested food passed directly into the ileum.

Ethics approval

This study was conducted in compliance with the registered ClinicalTrials.gov protocol following the ethical standards of the hospital's institutional research committee, the 1964 Declaration of Helsinki and its later amendments, and the ISO14155 regulations, 21 CFR Parts 11, 50, 54, 56, and 812 Good Clinical Practices. Written informed consent was obtained with adequate understanding and consent of participating patients. The protocol was registered at ClinicalTrials.gov (identification number: NCT05322122) before conducting the study.

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Author contributions

G.B. Cadiere: protocol/project development, data analysis, data collection or management, and manuscript writing/editing; M. Poras: data analysis, data collection or management, and manuscript writing/editing; M.T. Marechal and L. Pau: data collection or management; R. Muteganya: data collection or management and isotopic examinator; M. van Gossum: data collection or management and gastroscopy examinator; B. Cadiere: data analysis and data collection or management; N. Van Sante: protocol/project development, data analysis, and data collection or management; M. Gagner: protocol/project development, data analysis, and manuscript writing/editing.

Declaration of competing interest

Guy-Bernard Cadière is a consultant for GT Metabolic Solutions and member of its scientific advisory board without remuneration. Nathalie Van Sante was an employee of GT Metabolic Solutions during the study and drafting of the manuscript. Michel Gagner is a consultant with GT Metabolic Solutions and Lexington Medical with stock options and a consultant for Medtronic. The other authors declare no competing interests.

Data availability

The datasets generated during the current study are available from the corresponding author upon reasonable request.

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