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Laparoscopic Large Hiatal Hernia Repair With RefluxStop: Outcomes of Six Months Follow-up in Thirty Patients

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Objective: The antireflux surgical technique with the RefluxStop device is one of the latest approaches to treating patients with gastroesophageal reflux disease (GERD). The aim of this study was to assess the safety and feasibility of laparoscopic hiatal hernia (HH) repair with the RefluxStop device in patients with GERD and concurrent large HH ($\geq$4 cm).

Patients and Methods: A retrospective chart review was performed for the first 30 patients with a large HH who consented and underwent HH surgery with the RefluxStop device. The operative technique and outcomes were evaluated to assess safety and feasibility, HH recurrence, dysphagia, and patient satisfaction.

Results: Between May 2020 and April 2022, 30 patients underwent laparoscopic HH repair with the RefluxStop device. All patients had typical symptoms of GERD, such as heartburn and regurgitation, and 15 patients (50%) had preoperative dysphagia. Median HH size was 5 cm (interquartile range, 4 to 5). Median operating time was 56 minutes (interquartile range, 52 to 63), with no intra and postoperative complications related to the device. One patient required laparotomy due to adhesions and associated bleeding when accessing the abdomen. All patients had postoperative imaging (video fluoroscopy) on postoperative day 1 and at 3 months, confirming the correct location of the RefluxStop device. One patient (3.3%) needed postoperative balloon dilatation due to severe dysphagia. Reflux symptoms (heartburn and acid regurgitation) resolved significantly in all patients ($P < 0.001$) at 6 months. One episode of recurrence of HH (3.3%) occurred during the follow-up period of 6 months.

Conclusion: This study demonstrates the short-term safety and feasibility of laparoscopic HH repair with the RefluxStop device in patients with large HH, with a low rate of postoperative dysphagia and subsequent improvement or resolution of reflux symptoms in all patients.

Key Words: RefluxStop, antireflux surgery, hiatal hernia, Barrett esophagus, gastroesophageal reflux disease, recurrence, dysphagia

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Hiatal hernia (HH) is a condition that involves herniation of abdominal contents into the mediastinum through the diaphragmatic hiatus and is characterized by an enlarged esophageal hiatus.[1,2] HH is classified anatomically into 4 types, based on the position of the gastroesophageal junction with the diaphragm. The prevalence of HH varies between 15% and 20% in western countries.[3–5] HHs are more common in Western Europe and North America and are rare in rural Africa.[6,7] As HH is linked to obesity,[8] its incidence is expected to rise in the coming decades due to the current global obesity epidemic. HH imposes a considerable financial burden on patients and payers, and results in high health care resource utilization. There is, therefore, a great interest in studies assessing the feasibility, safety, and cost of new treatment options for patients suffering from gastroesophageal reflux disease (GERD) related to the presence of an HH.

Current recommendations for the management of most of the HHs in patients with GERD who are under 60 years of age, and otherwise healthy, involve laparoscopic HH repair with antireflux surgery,[9–12] which aims to reconstruct the local anatomic and functional deficiencies of the gastroesophageal junction. Laparoscopic antireflux surgery (LARS), irrespective of the type of fundoplication performed, has been reported to be more efficient than proton pump inhibitors[13–16] and superior to the open operative approach,[2,17,18] in terms of subjective, as well as objective, efficacy. However, the challenge with LARS is that it is underused due to potential associated long-term side effects, such as dysphagia, inability to belch or vomit, and bloating.[19,20] There exists a lack of clarity on the differences among the antireflux treatment approaches, thus leaving patients and clinicians in the dilemma to either tolerate a lifetime of drug dependence with sometimes incomplete symptom relief or undergo a surgical procedure with potential complications, side effects, and risk of recurrence.

To address these challenges in LARS, a novel surgical technique with an implantable device, called RefluxStop, was used in adjunct to laparoscopic HH repair. The RefluxStop device is reported to be safe and tolerable. It has a minimal effect on the gastric anatomy and increases the physiological barrier to reflux.[21] The aim of this study was to assess the 6-month outcomes after laparoscopic HH repair in adjunction with the implantation of the RefluxStop device in patients with GERD and concurrent large HH ($\geq$4 cm).

PATIENTS AND METHODS

Study Design and Patient Population

This study was a retrospective chart review of the first 30 patients who presented with typical symptoms of GERD,

large HH ($\geq$4 cm), and underwent LARS with the RefluxStop device (Implantica), by a single surgeon (J.Z.) in a private hospital setting (Hirslanden Clinic Beau-Site, Bern, Switzerland). LARS using the RefluxStop device was advised rather than other antireflux procedures if patients had features of ineffective esophageal motility (IEM), preoperative dysphagia, or troublesome preoperative symptoms, such as bloating and flatulence, which would have likely worsened with the use of techniques, such as Nissen or Toupet fundoplication, or magnetic sphincter augmentation. Information on the procedure and the available published data were provided to the patients ahead of obtaining consent at the Swiss1Chirurgie private practices (Bern, Solothurn, Wallis). Ethical approval for this study was obtained from the Local Ethics Board of Canton Bern, Switzerland (Ethics Approval No. 2018-01827).

Patients aged 18 years or older with documented GERD and who were diagnosed with a large HH, defined as an axial hernia length of 4 cm or more irrespective of the type of HH, and who underwent laparoscopic HH repair with the RefluxStop device were included in this study. The diagnosis of HH was made preoperatively by gastroscopy, high-resolution esophageal manometry, or video-esophagram. In case of a discrepancy in the measurement among the different techniques, a higher value was taken. Patients included in this study had to have typical reflux symptoms, such as heartburn and/or regurgitation, which were not adequately relieved with standard medical therapy, meaning the use of proton pump inhibitors once or twice daily. Patients younger than 18 years of age, with HH > 10 cm, long-segment Barrett esophagus, or a history of previous esophageal or gastric surgery were excluded. Foreign patients were also excluded from this study due to the inability to achieve adequate follow-up. As the focus of the study was to assess the feasibility and safety of the use of the RefluxStop device in GERD treatment, a control group was not included.

Presurgical Assessment

Preoperative work-up comprised an upper endoscopy with biopsies of the distal esophagus, a standardized history and physical examination, and a standardized questionnaire for reflux disease [GERD–health-related quality of life (HRQL) score, 0 to 75 points] including an additional quality-of-life question (Question: How satisfied are you with your current quality of life-related to GERD?; possible responses: "satisfied," "neutral," or "dissatisfied"). Esophageal motility was evaluated by video-esophagram under fluoroscopy in a standardized manner, with swallows of contrast-enhanced liquid medium in an upright and supine position according to the protocol. If the esophageal motility was questionable, a further study with high-resolution manometry was performed at a specialized reflux center in selected patients. Patients with a large HH with typical symptoms like heartburn and regurgitation, night-time aspiration, Barrett esophagus, or reflux esophagitis grade C or D according to the Los Angeles classification, were not further assessed with pH studies. All other patients underwent either a 24-hour pH-impedance study or a 48-hour pH study with the Bravo capsule to confirm the presence and assess the severity of reflux disease.

Surgical Technique

Features of the RefluxStop Device

The RefluxStop device is an implantable, single-use, nonactive sterile device, consisting of 5 small parts, which are held together by an absorbable suture before its implantation. The device is fabricated out of medical-grade silicone and weighs ~9 g. The device is positioned in the abdominal cavity through a special trocar with the help of a specifically designed deployment tool (Implantica).

Surgical Insertion and Placement of the RefluxStop Device

The operating technique with the RefluxStop device is similar to other laparoscopic antireflux procedures. After the installation of the pneumoperitoneum in the left upper quadrant, the typical LARS trocar positioning is used. With an Optiview trocar, the camera is introduced about 5 to 7 cm above the umbilicus, paramedian to the left. A 10 mm trocar is placed in the left upper quadrant, a 5 mm trocar in the right upper quadrant, and another 5 mm trocar in the left flank. An epigastric port is made for the Nathanson liver retractor, used to elevate the left lobe of the liver.

After opening the pars flaccida with the harmonic scalpel, the right crus are identified and the esophagus is visualized. The anterior aspect of the esophagus is dissected with caution to preserve the anterior vagus nerve, and the top of the left crus is identified. Then the short gastrics are taken down and the complete left crus is visualized and freed up from adhesions. An easy-flow drainage tube of 18 cm in length is placed around the distal esophagus for retraction. Mediastinal dissection of the distal esophagus is performed while preserving the vagal nerves, with a reduction of the HH and resection of the hernia sac. With sufficient dissection, an intra-abdominal length of at least 4.5 cm should be achieved only with gentle traction on the esophagus, providing a maximum 1.5 cm downward movement of the angle of His. An HH closure is performed with 2 to 3 figure-of-eight sutures using Gore sutures (W.L. Gore and Associates, Inc.) without compressing the esophagus. No bougie is used for sizing the hiatal closure. As no tension is applied to the esophagus, the hiatal closure does not cause narrowing of the esophageal lumen. This avoids postoperative dysphagia and secures a good hiatal closure. In case of an excessive fat pad at the angle of His, further resection of the fat pad is performed.

The angle of His is then recreated using 2 rows of sutures with V-Loc nonresorbable, 3-0 (Medtronic Inc.), creating an esophagogastric plication. The first row of sutures is placed between the esophagus and the fundus, starting at the angle of His and ~4 cm of the distal esophagus and the fundus caudocranially. The slight tension on the esophagus during this plication creates a downward movement of the angle of His (a maximum of 1.5 cm), allowing dissection higher up. Then a single Gore suture is placed to secure the fundus at the top of the plication at the esophagus. The second row of sutures is placed 1 to 1.5 cm anteriorly to the first suture row, without creating folds or kinks.

After switching the 5 mm port in the left flank with the 22 mm reusable port provided with the device, the RefluxStop device is then introduced with the deployment tool. The RefluxStop implant is then gently placed next to the suture line and parallel to the esophagus, at the top of the fundus, into a fundic pocket, without tension. The RefluxStop device is secured in position at the top of the fundus next to the esophagogastric suture line with a suture row from cranial to caudal and a second suture row from caudal to cranial, with no narrowing or kinking of the esophagus. (Fig. 1). The deployment tool, as well as the easy-flow drain, are then removed.

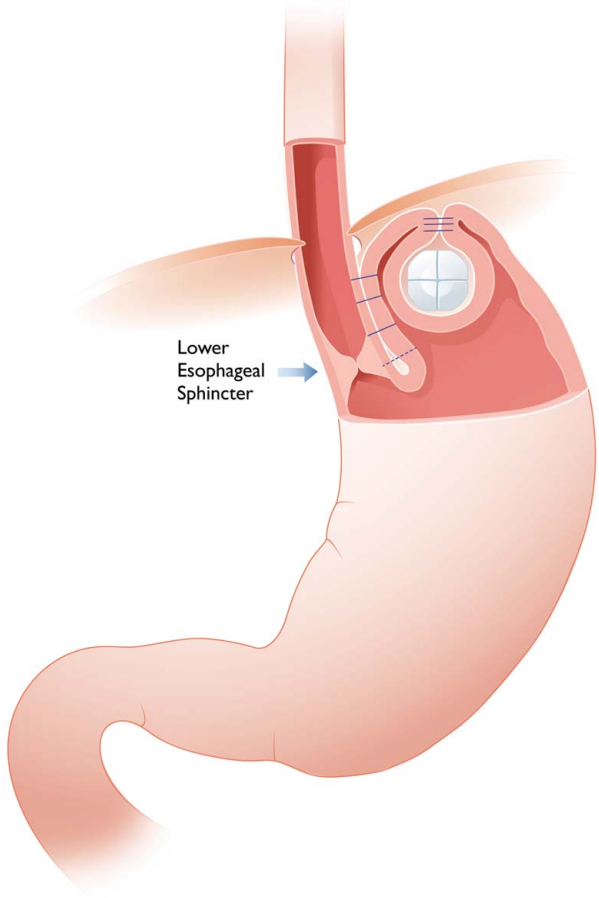

FIGURE 1. Schematic drawing with the position of the RefluxStop device. RefluxStop instruction for use, reproduced with permission of Implantica (Zug, Switzerland).

The main principle of this technique is the formation of an esophagogastric plication with a 90 to 110-degree wrap instead of a 360-degree or 270-degree wrap. This aids in the closure or recreation of the angle of His, which is often wide open due to an HH. The RefluxStop device is sutured into the fundus in a fundic pocket close to the wrap to stabilize the fundus. This keeps the lower esophageal sphincter (LES) in a stable position in the abdomen and prevents reherniation.

Postoperative Assessment

Follow-up of the patients at postoperative day 1 included a video-esophagram. All patients had a second video-esophagram at 3 months postsurgery. The 3-month follow-up, along with the questionnaire, was highly effective in recording reflux control, as well as the absence of HH recurrence. Office visits with history and physical examination were mandatory at 4 weeks, 3 months, and 6 months after the procedure. The same standardized reflux questionnaire (GERD-HRQL score, 0 to 75 points), including an additional quality-of-life question, was filled out by patients at the 6-month visit. Improvement in GERD symptoms was based on the decrease in GERD-HRQL questionnaire scores. Reported results were defined as excellent if the GERD-HRQL scores were between 0 and 5, good if the scores were between 6 and 10, fair if the scores were between 11 and 15, and poor if the scores were > 15 or if the patient required reoperation.

Study Outcomes

The primary outcome was the occurrence of complications related to the RefluxStop device. The secondary outcomes comprised duration of hospital stay, perioperative complications recorded up to 90 days after surgery and defined according to the Clavien-Dindo classification,[22] resolution of symptoms (heartburn and regurgitation), and postoperative dysphagia assessed by the GERD-HRQL score, quality of life, and radiologically confirmed HH recurrence, defined as any part of the stomach—visible rugal gastric folds—above the hiatal plane. Transient dysphagia was defined as any self-limiting dysphagia within the first 2 to 3 weeks postsurgery, usually caused by the diaphragmatic closure, swelling around the distal esophagus resulting in outflow obstruction, and consequently leading to temporary weakening of esophageal motility.

Statistical Analyses

All continuous variables were expressed as mean ± SD or median with interquartile range (IQR) as appropriate, and categorical variables as percentages and frequencies. The Mann-Whitney-Wilcoxon test was used to compare continuous variables and the χ^2 or Fisher exact tests (as required, respectively) for categorical variables. Statistical analyses were performed using GraphPad Prism version 9 (GraphPad Software) with a significance level of 0.05.

TABLE 1. Demographic, Baseline Clinical Characteristics, and Peri and Postoperative Courses in Patients Undergoing Surgery for Large HH (≥4 cm) With the RefluxStop Device

Parameters	N = 30
Demographics	
Gender (F)	14 (46.7)
Age (y), mean (SD)	61 (15)
BMI (kg/m^2), mean (SD)	26.8 (4.3)
ASA classification (1–6), median (IQR)	2 (2–3)
Reflux-related clinical parameters	
Axial length of hernia (cm), median (IQR)	5 (4–5)
IEM	24 (80)
Preoperative dysphagia	15 (50)
Perioperative characteristics	
Abdominal access	
Laparoscopic	29 (96.7)
Converted to open	1 (3.3)
Duration of operation (min), median (IQR)	56 (52–63)
Intraoperative complication	1 (3.3)
Duration of hospital stay (d), median (IQR)	4 (3–5)
Postoperative characteristics	
Complications within 90 d*	
Grade II	1 (3.3)
Grade IIIa	1 (3.3)
Dysphagia requiring dilatations	1 (3.3)
Recurrence of HH within 6 mo	1 (3.3)

Values are N (%) unless stated otherwise.

*Postoperative complications are graded according to the Clavien-Dindo classification.

ASA indicates American Society of Anaesthesiologists; BMI, Body Mass Index; HH, hiatal hernia; IEM, ineffective esophageal motility; IQR, interquartile range.

RESULTS

Baseline Characteristics and Demographic Details

The present study comprised 30 patients who underwent laparoscopic HH repair with the RefluxStop device. The demographic, baseline clinical, and operative and postoperative characteristics of study participants are summarized in Table 1. The axial length of HH varied between 4 cm and 8 cm among the study population. Fifteen patients (50%) had preoperative dysphagia. Among them, 14 patients (93.3%) had IEM, whereas in the group with no preoperative dysphagia, there were 10 patients (66.7%) with IEM ($P = 0.169$). The mean length of HH was 5 ± 1.2 cm and was the same in both patient groups ($P = 0.271$). Complete follow-up (100%) was achieved in all 30 patients at 6 months. All 30 patients provided responses to the standardized questionnaire (GERD-HRQL score) preoperatively, whereas 29 patients provided responses at the 6-month visit.

Perioperative and Postoperative Course

The RefluxStop procedure was feasible in all patients. In the majority of the patients (96.7%), surgery was performed laparoscopically; in one patient who had a previous open surgery, the procedure was converted from laparoscopic to an open procedure due to adhesions and subsequent bleeding while establishing laparoscopic access to the abdomen. After conversion, the intended procedure was performed safely as described in the methods section. The median operating time for the RefluxStop procedure was 56 minutes (IQR, 52 to 63). All patients had postoperative imaging (video fluoroscopy) on postoperative day 1 (Fig. 2). Adequate reduction of the HH and correct location of the RefluxStop device were confirmed in all patients. The median hospital stay was 4 days (IQR, 3 to 5). All patients tolerated a blended soft diet starting on day 1 for 7 days, followed by a soft diet for 3 to 4 weeks.

Two patients (6.7%) had postoperative complications within 90 days of the surgery. At 4 weeks postsurgery, one patient reported persistent fatigue due to pericardial effusion. Another patient required endoscopic dilations due to persistent dysphagia to both solids and liquids, 12 weeks after the operation. No life-threatening complications or complications requiring surgical intervention were recorded during the 3 months after implantation.

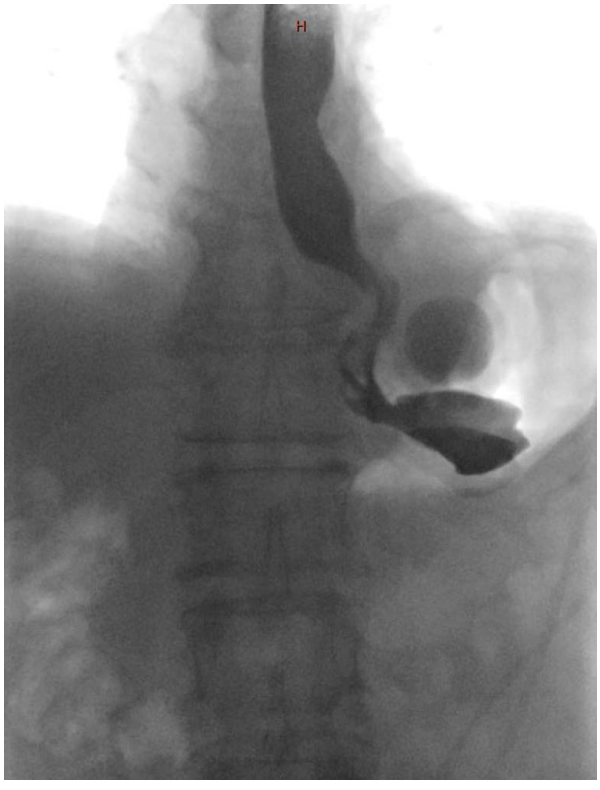

FIGURE 2. Radiographic image of normal fluoroscopy on postoperative day 1 depicting the position of the RefluxStop device in the video-esophagram.

Primary Endpoint Results

No device-related complications were encountered at the time of surgery, during the 6-month clinical follow-up, or upon video-esophagram at day 1 and 3-month follow-up. Device-related reoperations were not reported for any of the patients during the study.

Clinical Outcomes at Six Months

All patients had partial or complete resolution of reflux symptoms. Significant improvements in terms of resolution of heartburn and regurgitation were observed, based on GERD-HRQL questionnaire scores (Fig. 3). The mean GERD-HRQL score preoperatively was 37.6 ± 15.5, which significantly reduced to 3.1 ± 5.4 at 6 months ($P < 0.001$) postsurgery. Subscores (0 to 30 points) for heartburn (16.5 ± 8.1 preoperative vs 1.1 ± 2.3 at 6 mo) and regurgitation (16.5 ± 7.2 preoperative vs 0.9 ± 2.0 at 6 mo) also showed a significant improvement in all patients ($P < 0.001$).

Based on the GERD-HRQL scores of 29 patients who provided responses to the GERD-HRQL questionnaire 6 months postsurgery, results were excellent in 26 patients (89.7%), fair in 1 patient (3.5%), and poor in 2 patients (6.9%). The two patients with poor results had scores of 17 and 23 points at the 6-month visit, respectively, indicating that, nonetheless, there was an improvement in symptoms in both cases. The considerable improvement in symptoms after surgery was also mirrored by the patients' responses to

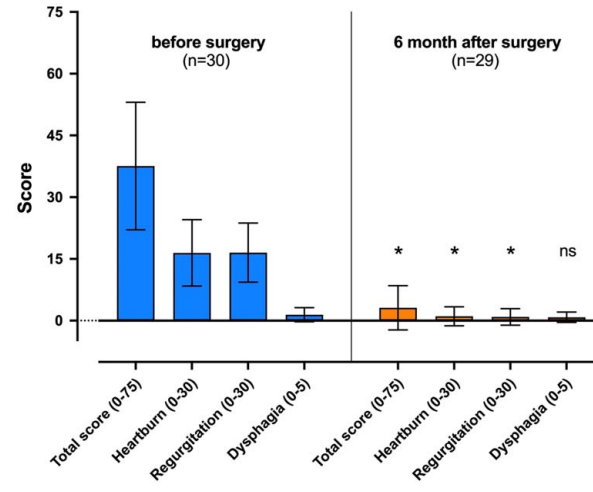

FIGURE 3. Gastroesophageal reflux disease (GERD) health-related quality of life scores before and 6 months after surgery, with detailed analysis for heartburn, regurgitation, and dysphagia. Scores are presented as mean (box) and SD (whiskers). The level of significance was set at 0.05. "*" represents statistically significant. ns indicates nonsignificant.

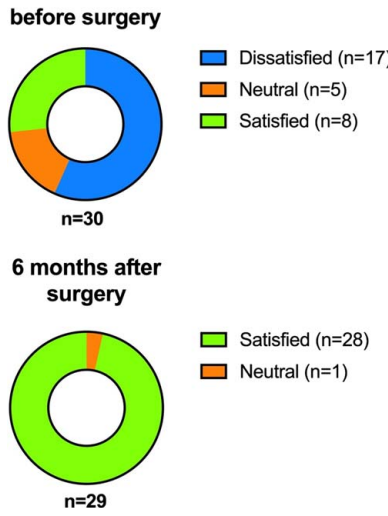

FIGURE 4. Quality of life related to GERD before and 6 months after surgery.

the additional quality-of-life question. Before surgery, 23 patients (76.7%) described an impaired quality of life attributed to GERD; at 6 months postsurgery, 28 (of 29) patients (96.6%) reported satisfaction (Fig. 4). The preexisting dysphagia seen in 15 patients was significantly improved postsurgery, with a mean score of 2.7 ± 1.5 at baseline versus 0.6 ± 0.9 after 6 months ($P < 0.001$). Among the 15 patients who did not report swallowing problems at baseline, a new onset of dysphagia was recorded in 5 cases. Four patients were treated successfully without any intervention, with an adaptation of the recommended diet in the 12 weeks after surgery. However, one patient required repeated endoscopic dilatations due to severe dysphagia.

Recurrence of Hiatal Hernia

In all patients, video-esophagram at 3 months postsurgery confirmed the correct location of the RefluxStop device and there were no recurrences of HH. One episode of HH recurrence (3.3%) was recorded at 5 months postsurgery in a patient with a preexisting large HH measuring 8 cm. The episode of HH recurrence was perceived to be a consequence of severe vomiting from food poisoning. The upper third of the stomach including the RefluxStop device had slipped through a ruptured hiatus in this patient. An emergency laparoscopic procedure was performed outside the institution to reposition the fundus and the RefluxStop device, and the hiatus was sutured with pledgeted polytetrafluoroethylene sutures.

DISCUSSION

This is the first study evaluating laparoscopic HH repair with the RefluxStop device in patients with large HHs (between 4 cm and 8 cm). This technique not only involves the new implant but also represents an entirely new concept of surgical antireflux treatment. Despite a high rate of patients with preoperative dysphagia and preoperative IEM, the results at 6 months revealed that patients experienced a low rate of postoperative dysphagia. To assess the recurrence of HH and GERD, patients in this study underwent a routine video-esophagram at day 1 and at 3 months after surgery, and completed a validated GERD-HRQL score questionnaire, to look for symptoms of reflux recurrence.[23]

According to the "Instructions for Use" for the RefluxStop device, the initial indication is patients with GERD with HHs of up to 3 cm in length. Therefore, by providing preliminary data on 30 patients with larger HH, this study contributes to the literature on the use of the RefluxStop device. There was also limited evidence to substantiate the preferable type of fundoplication in patients with HHs more than 8 cm. Hence, depending upon the esophageal motility, a routine laparoscopic Nissen or Toupet fundoplication was performed in such patients.[24,25] Independent of the esophageal motility, evolution in laparoscopic HH repair techniques over the decades has gradually alleviated hernia recurrence.[26,27] Surgical guidelines were established 10 years ago by the SAGES Guidelines Committee, referencing the most important studies, reports, and principles to achieve a consistent and safe repair.[28] Sizing of the hiatal surface area was not widely adopted, and, therefore there, are only limited studies where measuring the surface of the hiatal opening has been reported.[29] Currently, there is no consensus on measuring the HH, and measurements can be taken during endoscopy, video-esophagram, as well as manometry studies. Consensus on the use of mesh, depending on the hernia size, is presently lacking. There is also a paucity of standard approaches for hiatal closure among the various antireflux surgery techniques, leading to inadequate evidence on the actual recurrence rates of HH and GERD symptoms. Since the first Nissen fundoplication surgery, it has been understood that acid reflux is caused by a weak LES. The premise of the RefluxStop procedure, however, is that it is the intrathoracic position of the LES, rather than LES weakness per se, that allows reflux to occur. Previous studies have observed a reduction of HH recurrence with the use of alternative approaches involving mesh placement and fixation for HH repair.[30,31]

Interestingly, the RefluxStop surgical technique includes all three components for the control of reflux, as described by the American Foregut Society in their recent publication.[32] Till 2018, the majority of reflux procedures adopted the principle of encircling the distal esophagus fully or partially, to create a neo-valve below the hiatal closure. However, the RefluxStop procedure employs a different approach that involves positioning the LES well below the diaphragm, in addition to hiatal closure, without full or partial encircling of the LES.

Unlike the magnetic sphincter augmentation using the LINX® Reflux Management System or the long-abandoned Angelchik procedure, the RefluxStop device is not circumferentially placed. The RefluxStop procedure not only restores the position of the LES but also maintains it in the long term, preventing its movement towards the diaphragm and chest. This is accomplished by reinforcing the fundus, using the RefluxStop device, placed outside the stomach, near the top of the fundus. This reinforcement of the top part of the stomach dynamically interacts with the diaphragm, ensuring that a large distance between the LES and the esophageal hiatus is always maintained, thereby avoiding the recurrence of acid reflux.

The RefluxStop device neither gets compressed nor inflated or filled, as a gastric band does, which frequently results in local pressure and ischemia leading to tissue damage and occasional perforation of the gastric band. As this is a preliminary description of the new technique with the RefluxStop device, a comparison to other wrap

techniques has not been performed. Some of the previous reports on various wrap techniques have reported herniation of the wraps, such as telescope-herniation, despite additional suturing. Also, with the soft condition of a full or partial wrap, posterior slippage of the wrap is possible due to a small recurrence of the hiatal surface area opening, allowing recurrence of the HH and reflux symptoms, often leading to dysphagia and nausea, or recurrent vomiting.[25]

Making predictions about the recurrence of HH is challenging within the scope of this present study and its limited follow-up period. The RefluxStop device dynamically interacts with the diaphragm to prevent re-herniation. The only way a reherniation could occur is if the hiatus opening becomes enlarged due to failure of the hiatal repair. Therefore, reherniation with the RefluxStop device is likely to be less common than with current fundoplication techniques. Small herniations may be left in place, as they are asymptomatic in most cases,[33] but it is recommended to reoperate on patients in whom the RefluxStop device is above the diaphragm, repositioning the device and the gastric fundus back into the abdominal cavity.

Although half of the study population in this study had preoperative dysphagia, the postoperative transient dysphagia was within acceptable limits, and endoscopic balloon dilation for severe persistent dysphagia was only deemed necessary for one patient. Since the RefluxStop technique involves the formation of a 90 to 110-degree plication, the esophagus can dilate freely to let the food bolus pass through. However, dysphagia can still occur due to the HH repair, or a technical failure during suturing the plication. Adding too much tension on the 2 vertical running sutures while forming the esophagogastric plication could potentially shorten the distal esophagus, or create kinking or narrowing, and, therefore, cause an amotile or weak 3 cm area of the distal esophagus.

The RefluxStop device is suspended in the stomach cavity in a tear-drop–shaped pouch, with a line of sutures and a double wall of stomach on top. However, there is a possibility of device migration through the stomach wall, especially if the pouch is sutured too tightly and affects the blood supply in the stomach wall. The RefluxStop device has been designed as a combination of 5 separate components. If the device were to migrate, it would end up in the gastric lumen due to the tear-drop shape formed by the encapsulated device protruding into the stomach cavity. The individual components are small and would easily pass through the pylorus and the intestinal tract, thereby avoiding the need for reoperation. Furthermore, the device is radio-opaque, allowing x-ray images to visualize any migration or erosion.

Mediastinal dissection of the distal esophagus is crucial, and an abdominal length of 4.5 cm is necessary to create the correct plication and device positioning. Therefore, treatment with the RefluxStop device may not be suitable in patients with larger hernias, or with a foreshortened esophagus, where Collis gastroplasty is necessary.[34]

Limitations of the study include the absence of a comparison group, and selection bias as patients were more likely to undergo a RefluxStop procedure if they had ineffective or weak esophageal motility (related to our own treatment algorithm including other LARS procedures offered to patients without IEM), and a short follow-up period (6 mo) to assess recurrence of HH. Previous studies have published preliminary results at 6 months, and as this is a new technique, it was seen as reasonable to present the data on the first 30 patients.

CONCLUSIONS

This study shows the safety and feasibility of laparoscopic HH repair with the RefluxStop device in patients with large HHs ranging from 4 to 8 cm, with all patients experiencing complete resolution or improvement of reflux symptoms and GERD-HRQL scores, and only one symptomatic recurrence of HH within 6 months. Further mid-term and long-term clinical studies with larger patient populations, with a focus on sustainability and complications over time, particularly erosion and migration, are required to enrich the evidence base on this novel technique for the treatment of patients with GERD.

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