







# Pyloric distensibility measurement after gastric surgery: Which surgeries are associated with pylorospasm?

Charlotte Desprez<sup>1,2</sup>  | Chloé Melchior<sup>2,3</sup>  | Fabien Wuestenberghs<sup>1,2</sup>  |  
Emmanuel Huet<sup>2,4</sup> | Alberto Zalar<sup>3</sup> | Jérémie Jacques<sup>5</sup>  | Anne-Marie Leroi<sup>1,2,6</sup>  |  
Guillaume Gourcerol<sup>1,2,6</sup> 

<sup>1</sup>Physiology Department, Rouen University Hospital, Rouen, France

<sup>2</sup>Nutrition, Brain and Gut Laboratory, INSERM Unit 1073, Rouen University Hospital, Rouen, France

<sup>3</sup>Hepatogastroenterology Department, Rouen University Hospital, Rouen, France

<sup>4</sup>Digestive Surgery Department, Rouen University Hospital, Rouen, France

<sup>5</sup>Hepatogastroenterology Department, Limoges University Hospital, Limoges, France

<sup>6</sup>Clinical Investigation Center, INSERM 0204, Rouen University Hospital, Rouen, France

## Correspondence

Charlotte Desprez, Digestive Physiology Unit, Rouen University Hospital – 1 rue de Germont, 76031, Rouen, Cedex, France.  
Email: charlotte-desprez@orange.fr

## Abstract

**Background and study aims:** History of gastric surgery is found in 10% of patients with gastroparesis, and vagal lesion is often suspected to be the cause of pylorospasm. Recently, pyloric distensibility measurement using the EndoFLIP<sup>®</sup> system showed that pylorospasm was present in 30%-50% of gastroparetic patients. Our objective was to assess whether pylorospasm, diagnosed using EndoFLIP<sup>®</sup> system was observed in three different types of gastric surgeries: antireflux surgery, sleeve gastrectomy, and esophagectomy.

**Patients and Methods:** Pyloric distensibility and pressure were measured using the EndoFLIP<sup>®</sup> system in 43 patients from two centers (18 antireflux surgery, 16 sleeve gastrectomy, and nine esophagectomy) with dyspeptic symptoms after gastric surgery, and in 21 healthy volunteers. Altered pyloric distensibility was defined as distensibility below 10 mm<sup>2</sup>/mm Hg as previously reported.

**Results:** Compared to healthy volunteers (distensibility: 25.2 ± 2.4 mm<sup>2</sup>/mm Hg; pressure: 9.7 ± 4.4 mm Hg), pyloric distensibility was decreased in 61.1% of patients in the antireflux surgery group (14.5 ± 3.4 mm<sup>2</sup>/mm Hg; *P* < .01) and 75.0% of patients in the esophagectomy group (10.8 ± 2.1 mm<sup>2</sup>/mm Hg; *P* < .05), while pyloric pressure was only increased in the antireflux surgery group (18.9 ± 2.2 mm Hg; *P* < .01). Pyloric distensibility and pressure were similar in healthy volunteers and in sleeve gastrectomy (distensibility: 20.3 ± 3.8 mm<sup>2</sup>/mm Hg; pressure: 15.8 ± 1.6 mm Hg) groups, with decreased pyloric distensibility affecting 18.7% of sleeve gastrectomy patients. **Conclusion:** Antireflux surgery and esophagectomy were associated with pylorospasm although pylorospasm was not found in all patients. Sleeve gastrectomy was not associated with altered pyloric distensibility nor altered pyloric pressure.

## KEYWORDS

antireflux surgery, distensibility, gastroparesis, pylorus, sleeve gastrectomy, sphincter

## 1 | INTRODUCTION

Gastroparesis is defined as delayed gastric emptying and is often accompanied with dyspeptic symptoms, including gastric fullness, nausea, and vomiting. Postsurgical gastroparesis accounts for 7.2%<sup>1</sup> to 13%<sup>2</sup> of gastroparetic patients among studies, but the exact prevalence is difficult to assess in the absence of studies describing preoperative and postoperative gastric emptying measurements in large cohorts of patients. Lesion of the vagus nerves is suspected to be the main mechanism, although up to now there is no routine diagnostic tool to assess vagal lesion. Nevertheless, vagotomy is known to induce spasm of the pylorus,<sup>3</sup> and therefore, is associated with delayed gastric emptying.

Different types of esogastric surgery have been suspected to delay gastric emptying. Historically, postsurgical gastroparesis was frequently diagnosed among patients undergoing vagotomy in the case of peptic ulcer disease,<sup>4</sup> which has become exceptional over time by the use of proton pump inhibitors. Antireflux surgery, mostly Nissen fundoplication, was suspected to delay gastric emptying in 3.8% of operated patients in a large retrospective cohort of 3512 patients,<sup>5</sup> leading to reoperation in 2% of patients. Moreover, delayed gastric emptying has also been suspected to explain dyspeptic symptoms after bariatric surgery, including sleeve gastrectomy.<sup>2,6</sup> Last, we previously showed that laparoscopic esophagectomy, which involves the removal of the vagus nerves, is associated with pyloric dysfunction in the absence of pyloroplasty in patients reporting dyspeptic symptoms.<sup>7</sup> Of note, although gastric emptying is suspected to be delayed in the two latter situations with partial gastrectomy, gastric emptying tests are meaningless in the absence of normal values performed in asymptomatic patients.

Recently, sphincter distensibility measurements were enabled using EndoFLIP® technology (Endoluminal Functional Imaging Probe). Previous works performed in healthy volunteers and gastroparetic patients identified decreased pyloric distensibility in approximately one-third of gastroparetic patients.<sup>7</sup> Pyloric dysfunction was associated with symptom severity, quality of life, and gastric emptying.

Therefore, we took the opportunity to explore pyloric distensibility, as a surrogate of vagal lesion, in patients undergoing these three types of surgery, and compared them with previously reported normal values.

## 2 | PATIENTS AND METHODS

### 2.1 | Approval

Approval was obtained from the Ethics Committee of Upper Normandy (CPP2011-012) and CERNI (Comité d'Ethique de la Recherche Non-Interventionnelle, no E2019-07). The study was registered with clinicaltrials.gov (number NCT01519180). Written informed consent was obtained from all subjects.

### Key Points

- Patients with dyspeptic symptoms after gastric surgery and healthy volunteers underwent a pyloric distensibility measurement using the EndoFLIP system. Altered pyloric distensibility was defined as distensibility below 10 mm<sup>2</sup>/mm Hg as previously reported.
- Antireflux surgery and esophagectomy were associated with pylorospasm although pylorospasm was not found in all patients.
- Sleeve gastrectomy was not associated with altered pyloric distensibility nor altered pyloric pressure.

### 2.2 | Patients

Eighteen patients with a history of laparoscopic Nissen fundoplication were investigated. All patients reported dyspeptic symptoms starting after surgery associated with delayed gastric emptying using the octanoic breath test as described below. Sixteen patients reporting dyspeptic symptoms after laparoscopic sleeve gastrectomy for morbid obesity were also investigated. Nine patients who had undergone esophagectomy without pyloroplasty served as positive controls. All patients had an upper gastrointestinal endoscopy prior to investigations, and the presence of an organic disease was ruled out by multiple biopsies and anatomopathological examination in patients with significant lesion at inspection (eg, hiatal hernia <3 cm, mild gastritis, grade I esophagitis, etc.). *Helicobacter pylori* infection was ruled out either by serology or anatomopathologic examination. Moreover, no narrowing of the esophageal segment operated on was notified during the endoscopic evaluation, and patients were investigated off-prokinetic agents. Dyspeptic symptoms including vomiting, nausea, epigastric pain, bloating, fullness, and satiety were investigated. An assessment of each item was realized using a 5-point Likert scale which varies from 0 (absent) to 4 (most severe symptoms). Total symptomatic score (TSS) was defined as the aggregation of individual symptom scores.<sup>8,9</sup> A minimal TSS of eight for each patient was necessary for inclusion in the present study.

Twenty-one healthy volunteers (eight males), median age 40 ± 3.2 years (range 29–58), were recruited by local advertising. None of these subjects had any evidence of organic or functional gastrointestinal disorders, and none were on any medication known to affect gastrointestinal function. Data related to healthy volunteers have already been published in a previous report.<sup>7</sup>

### 2.3 | Quality of life

Quality of life and overall dyspeptic symptoms were evaluated using Gastrointestinal Quality of Life Index (GIQLI)<sup>10</sup> which was previously

validated in French.<sup>11</sup> The GIQLI score is specific for digestive diseases and varies from 0 (worst quality of life possible) to 144 (best quality of life).

## 2.4 | Pyloric distensibility

EndoFLIP<sup>®</sup> probe (Crospon Inc) was used to assess pyloric sphincter characteristics in all subjects after 12-hour fasting as previously reported.<sup>7</sup> After trans-nasal insertion of the catheter, correct positioning in the pylorus was controlled using either videofluoroscopy or endoscopy. Previous studies showed that both positioning techniques achieved similar values in patients.<sup>12,13</sup> The EndoFLIP<sup>®</sup> probe allowed real-time measurement of the cross-sectional areas (CSA) and the pressure of the pyloric sphincter using a bag inflated within the sphincter. Correct positioning was also ascertained continuously with the distinctive shape of the pylorus represented as a narrow segment with decreased CSA. After correct positioning, the bag was filled at set volumes of 10, 20, 30, 40, and 50 mL. For each set volume, pyloric pressure and pyloric distensibility were measured as previously described.<sup>7</sup> A cut-off of 10 mm<sup>2</sup>/mm Hg at 40 mL of inflation for normality of distensibility was determined in a previous study<sup>7,14</sup> in healthy volunteers. Using this threshold value of 10 mm<sup>2</sup>/mm Hg, pyloric distensibility was classified as normal (>10 mm<sup>2</sup>/mm Hg) or decreased (<10 mm<sup>2</sup>/mm Hg).

## 2.5 | <sup>13</sup>C-octanoic acid breath test

To ascertain the presence of gastroparesis, gastric emptying measurement was performed after 12-hour fasting as previously reported<sup>15</sup> in patients with history of laparoscopic antireflux surgery. Gastric emptying was not investigated in patients with sleeve gastrectomy or esophagectomy, as there are no normal values established in asymptomatic subjects with similar surgical modification of the gastric architecture.

## 2.6 | Statistics

Group analyses were carried out using Kruskal-Wallis test followed by Dunn's post-test for multiple comparisons. Correlation studies used the Spearman test. Intraindividual analysis was performed using Wilcoxon test or one-way ANOVA for repeated measures when two or more groups were compared, respectively. A  $P < 0.05$  was considered as significant. Results are expressed as the median [25th-75th percentile].

# 3 | RESULTS

## 3.1 | Patients

Patients' characteristics were similar between the four groups, except for age that was higher in the esophagectomy group [63 years;

60-73] in comparison with the healthy volunteer group [40 years; 29-58;  $P = .01$ ]. In addition, a lower BMI was observed in the antireflux surgery group [20.9 kg/m<sup>2</sup>; 19.1-23.9] versus the sleeve gastrectomy group [29.1 kg/m<sup>2</sup>; 26.2-36.5;  $P = .01$ ]. The delay between surgery and pyloric studies was significantly increased in patients with fundoplication in comparison to patients with sleeve gastrectomy ( $P < .05$ ; Table 1). Characteristics of patients are summarized in Table 1.

Data on GIQLI score were available for all healthy volunteers, but only for 10 patients with fundoplication, eight patients with sleeve gastrectomy, and five patients with esophagectomy. As expected, GIQLI score was lower in all surgical groups in comparison with healthy volunteers ( $P < .0001$ ). However, no difference was observed between the esophagectomy, postfundoplication, and sleeve gastrectomy groups (Table 1).

## 3.2 | Fasting pyloric distensibility and pressure at 40 mL of inflation

In comparison to the healthy volunteer group [24.8 mm<sup>2</sup>/mm Hg; 18.7-30.9], fasting pyloric distensibility at 40 mL of inflation was decreased in the antireflux surgery group [7.5 mm<sup>2</sup>/mm Hg; 4.5-18.3;  $P < .01$ ] and in the esophagectomy group [9.5 mm<sup>2</sup>/mm Hg; 6.0-15.8;  $P < .05$ ], while it remained unchanged in the sleeve gastrectomy group [18.3 mm<sup>2</sup>/mm Hg; 13.3-21.4;  $P = .42$ ]. Fasting pyloric pressure at 40 mL of inflation was only increased in the antireflux surgery group [20.5 mm<sup>2</sup>/mm Hg; 12.0-23.1;  $P < .01$ ] versus the healthy volunteer group [7.9 mm<sup>2</sup>/mm Hg; 6.8-12.5], while it remained unchanged in both sleeve gastrectomy and esophagectomy groups (Figures 1 and 2).

## 3.3 | Pyloric dysfunction after surgery at 40 mL inflation

Using the threshold of 10 mm<sup>2</sup>/mm Hg (ie, the 90% percentile of healthy subjects as previously reported<sup>7</sup>) to determine the normality of fasting pyloric distensibility among groups, 11/18 patients (61.1%) in the antireflux surgery group, 6/9 patients (75%) in the esophagectomy group, and 3/16 patients (18.7%) in the sleeve gastrectomy group ( $P < .001$ ) had decreased pyloric distensibility (Figure 3).

## 3.4 | Fasting pyloric distensibility and pressure at 10, 20, and 30 mL of inflation (Supporting information)

At 10 mL of inflation, fasting pyloric distensibility was only decreased in the antireflux surgery group [3.8; 1.9-9.1;  $P = .035$ ; Table S1] versus the healthy volunteer group [12.0; 9.2-17.0], while there was no difference in either sleeve gastrectomy or esophagectomy groups ( $P > .05$ ). Fasting pyloric pressure remained unchanged between the

**TABLE 1** Patients' characteristics

	Healthy volunteers	Antireflux surgery	Sleeve gastrectomy	Esophagectomy
Number	21	18	16	9
Age (y)	40 [29-58]	51 [43-66]	53 [40-61]	63 [60-73]*
Men/Women	8/13	8/11	4/12	7/2
Body mass index (kg/m <sup>2</sup> )	23.5 [21.9-26.0]	20.9 [19.1-23.9] <sup>#</sup>	29.1 [26.2-36.5]	22.9 [20.1-24.6]
GIQLI score	137 [131-140] <sup>§</sup>	61 [54-89]	77 [70-93]	77 [70-91]
Delay between surgery and pyloric studies (y)		4.5 [1.9-12.3] <sup>#</sup>	1.5 [1.0-2.2]	1.5 [0.5-4.0]

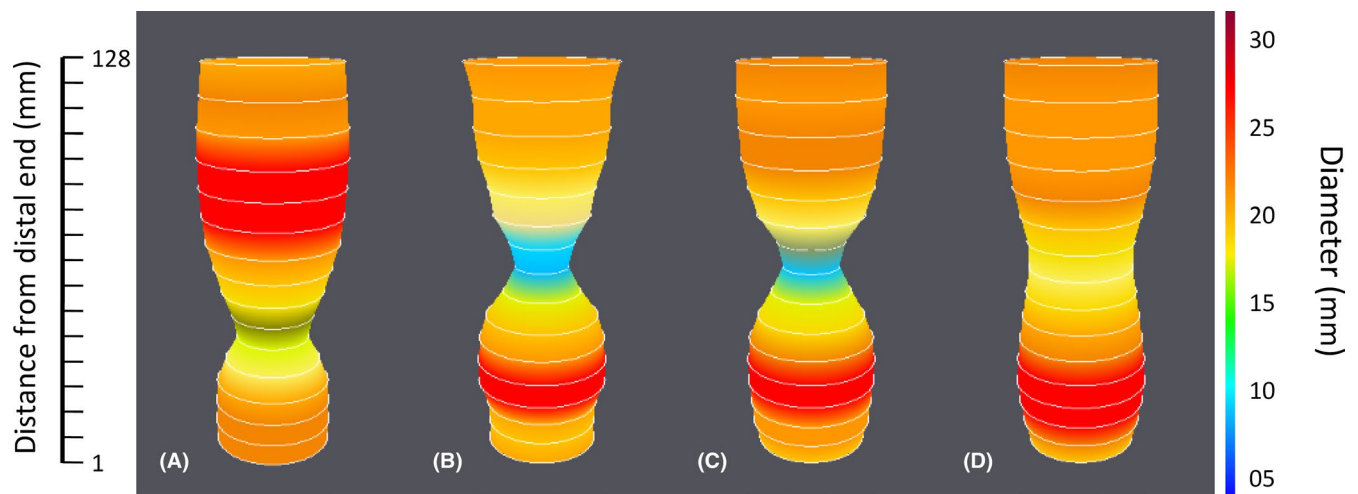
Note: Results are expressed either as number or as median [25th-75th percentile].

Abbreviation: GIQLI, Gastrointestinal Quality of Life Index.

\* $P < .05$  vs healthy volunteers.

<sup>#</sup> $P < .05$  vs sleeve gastrectomy.

<sup>§</sup> $P < .05$  vs all other groups.



**FIGURE 1** Representative recordings of fasting pyloric distensibility in a patient from the Nissen fundoplication (A), sleeve gastrectomy (B), and esophagectomy (C) group with an altered pyloric distensibility of respectively 8.9, 4.1, and 5.8 mm<sup>2</sup>/mm Hg and in a healthy volunteer with a normal pyloric distensibility of 32.5 mm<sup>2</sup>/mm Hg (D)

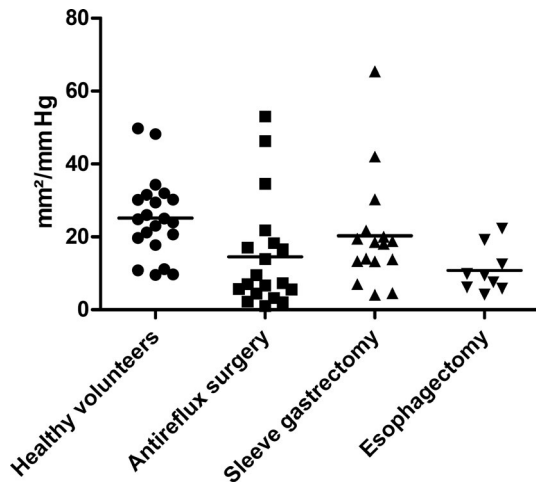
four groups at 10 mL of inflation. Increased fasting pyloric pressure [10.0; 6.6-14.5;  $P = .04$ ] and decreased fasting pyloric distensibility [5.0; 3.1-13.5;  $P < .01$ ] at 20 mL and 30 mL [with respectively 11.9; 8.9-12.8;  $P = .03$  and 7.0; 3.7-19.9;  $P < .01$ ] of inflation were only described in the antireflux surgery group vs healthy volunteers, while it remained unchanged in the other groups.

## 4 | DISCUSSION

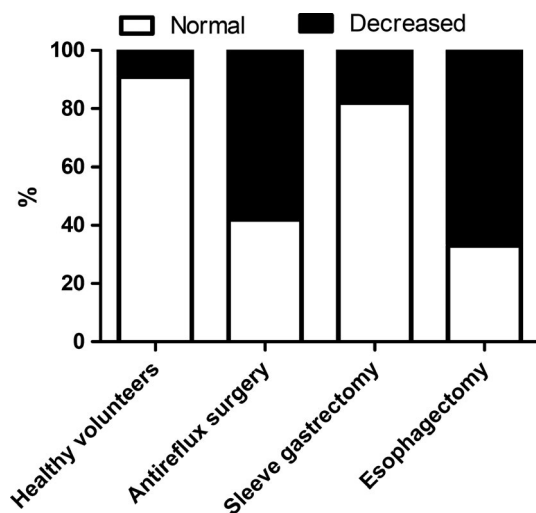
To our knowledge, this study is the first to have assessed pyloric sphincter characteristics using EndoFLIP<sup>®</sup> after gastric surgery. Decreased fasting pyloric distensibility at 40 mL of inflation was found in our study in the antireflux surgery and esophagectomy groups, but not in the sleeve gastrectomy group. Increased fasting pyloric pressure at 40 mL of inflation was only found in the antireflux surgery group. Using the threshold of 10 mm<sup>2</sup>/mm Hg of distensibility at 40 mL of inflation, altered fasting pyloric distensibility was found in 61.1% of

patients in the antireflux surgery group, 75.0% in the esophagectomy group, and 18.7% in the sleeve gastrectomy group in patients with dyspeptic symptoms. Even if these results need further confirmatory studies, this is the first evaluation of the percentage of pylorospasm diagnosed using EndoFLIP<sup>®</sup> system among patients with dyspeptic symptoms following upper gastrointestinal surgery. We recently reported that pyloric distensibility may be of use to better select patients undergoing intrapyloric botox.<sup>14</sup> Likewise, a previous report suggested that pyloric distensibility could also predict patient outcome after Gastric Per-Oral Endoscopic Pyloromyotomy (G-POEM).<sup>16</sup> Given the fact that the presence of altered pyloric distensibility was not observed in all patients, whatever the surgery type, this assessment may help in the future to better select patients who could benefit from pyloric intervention.

Esophagectomy surgery was mostly associated with altered pyloric distensibility in the present study, impacting 75% of patients with dyspeptic symptoms. In fact, thoracoabdominal esophagectomy is constantly associated with truncal vagotomy during the



**FIGURE 2** Pyloric distensibility at 40 mL (A) was decreased in the antireflux surgery group [7.5 mm<sup>2</sup>/mm Hg; 4.5-18.3;  $P < .01$ ] and in the esophagectomy group [9.5 mm<sup>2</sup>/mm Hg; 6.0-15.8;  $P < .05$ ] in comparison to healthy volunteers. Pyloric pressure (B) was only increased in the antireflux surgery group [20.5 mm<sup>2</sup>/mm Hg; 12.0-23.1;  $P < .01$ ] in comparison to healthy volunteers



**FIGURE 3** Percentage of patients with normal and decreased pyloric distensibility at 40 mL in the four groups of patients

procedure.<sup>17</sup> However, the pathophysiology of delayed gastric emptying following esophagectomy remains controversial. On the one hand, vagal damage following gastric tubulization is thought to affect gastric motility and to lead to pyloric denervation.<sup>18</sup> On the other hand, there is some evidence that motor activity of the gastric tube,<sup>19</sup> especially pyloric and antral motility, can recover at distance from surgery without reaching normality and this even after pyloroplasty.<sup>20</sup> Consequently, symptoms of delayed gastric emptying are frequent after esophagectomy, affecting 10%-50% of patients<sup>21</sup> among studies and are associated with worsened outcomes, poor quality of life, and higher rate of reoperation.<sup>22</sup> However, definitive diagnosis of gastroparesis following esophagectomy is difficult to assess because there is no normal value of gastric emptying measurement in asymptomatic patients with esophagectomy in the

literature. This explains why diagnosis of gastroparesis is, in most reports, only based on clinical evaluation.<sup>23</sup> In the present study, the rate of pylorospasm was particularly high in these patients, but all included patients reported symptoms of delayed gastric emptying. Recent meta-analyses<sup>23,24</sup> have attempted to evaluate the influence of systematic pyloric intervention during esophageal reconstruction on outcomes of esophagectomy. Their results showed that systematic pyloric intervention (including pyloromyotomy, pyloroplasty, digital fracture, and botox injection) did not influence the incidence of symptoms of delayed gastric emptying after esophagectomy. Moreover, systematic pyloric intervention can lead to complications like dumping syndrome or biliary reflux, not compensating unproven benefits. Therefore, there are arguments in order to better select candidates for pyloric drainage as not all patients presented pylorospasm in the present study, even if all patients were symptomatic.

Nissen fundoplication was also mainly associated (61.1% of patients) with decreased fasting pyloric distensibility in the present study. Even if diagnosis of gastroparesis can be done in case of delayed gastric emptying symptoms following surgery, the incidence of gastroparesis after Nissen fundoplication remains debated. A recent retrospective cohort which collected data from 3152 patients who underwent Nissen fundoplication found 3.8% of gastroparesis diagnosed following surgery, but the diagnostic of gastroparesis was in most cases based on the necessity of secondary pyloric intervention.<sup>5</sup> The incidence of patients with pylorospasm following Nissen fundoplication in our study was particularly high but all patients included had proven gastroparesis before investigation. It has been reported that pylorospasm can occur in 30%-50% of patients with gastroparesis in a study including three patients with postfundoplication gastroparesis<sup>7</sup> among 27 gastroparetic patients, using the same threshold of 10 mm<sup>2</sup>/mm Hg to assess pyloric dysfunction. Our results confirm these previous data and the higher number of patients with decreased pyloric distensibility could be explained by the fact that all our patients were symptomatic contrary to those in this study. Moreover, another study<sup>25</sup> showed that pyloroplasty can offer relief from postfundoplication gastroparesis symptoms in patients whose symptoms were improved after botulinum toxin injection. This study therefore suggests a better selection of patients undergoing targeted pyloric therapies in this subgroup of patients. Two previous studies investigated the potential predictive effect of pyloric distensibility on symptomatic response to pyloric therapies. The first one showed, in a prospective cohort of 35 gastroparetic patients, including six cases of postfundoplication gastroparesis, that decreased pyloric distensibility was associated with a better symptomatic response to intrapyloric botulinum toxin injections.<sup>14</sup> The second one investigated the efficacy of G-POEM in gastroparetic patients, showing in a small number of patients that decreased pyloric distensibility <9.2 mm<sup>2</sup>/mm Hg was associated with 3-month clinical efficacy.<sup>16</sup> These interesting results cannot yet be extrapolated to postfundoplication gastroparesis, but this will be the object of further studies. Lastly, pyloric dysfunction is not the only mechanism that could explain dyspeptic symptoms following Nissen fundoplication, indeed almost 38.1% of patients had normal pyloric



distensibility. Impaired gastric accommodation was found increased in post-Nissen dyspepsia patients.<sup>26</sup>

Among the three types of surgery in our study, sleeve gastrectomy had the lowest rate of decreased fasting pyloric distensibility with only 18.7% of patients. As sleeve gastrectomy is a frequent surgery due to a worldwide increase in bariatric surgery,<sup>27</sup> it is important to understand its influence on pyloric sphincter characteristics. In fact, the impact of sleeve gastrectomy on gastric emptying remains controversial in the literature. On the one hand, several studies have reported accelerated gastric emptying following sleeve gastrectomy.<sup>6,28</sup> This may result from the reduction in volume of the gastric reservoir which is specific to the proximal stomach which may lead to increased intragastric pressure after meals, resulting in accelerated passage of nutrients to the small bowel.<sup>29,30</sup> On the other hand, the resection of the gastric pacemaker zone during sleeve gastrectomy can result in aberrant distal ectopic pacemaking or bioelectrical quiescence according to results from a recent study.<sup>31</sup> However, the clinical relevance of this postoperative gastric dysrhythmia requires further investigations. Conversely, the literature regarding vagal nerve lesions and associated gastroparesis following sleeve gastrectomy remains scant. As for esogastrectomy, there is no normal value to assess gastric emptying in patients with sleeve gastrectomy. The low incidence of pylorospasm following sleeve gastrectomy in the present study suggests that vagal injury after sleeve gastrectomy remains exceptional, but mechanisms of residual pylorospasm (18.7% of patients) are still unclear in this subgroup of symptomatic patients.

EndoFLIP® system could be used in patients with dyspeptic symptoms following esogastric surgery. As it reflects vagotomy or gastroparesis, it could be complementary to gastric emptying. Moreover, it might help to better select patients undergoing treatments targeting pyloric therapies in case of pylorospasm, like botulinum toxin injections or G-POEM for example.<sup>14,16</sup> In a previous study including a small number of patients with postfundoplication gastroparesis, it was shown that an altered pyloric distensibility was associated with the symptomatic response to intrapyloric botulinum toxin injections but not a normal pyloric distensibility.<sup>14</sup> Moreover, our results suggest that vagal nerve injury was not present in all patients in the esophagectomy group, which is in contradiction with the performance of systematic vagotomy during laparotomy. This point will need further investigations to determine whether vagal nerve injury can affect other mechanisms than pylorospasm, like accommodation dysfunction.

A limitation of our study could be the small number of patients included which however is not different from that of a cohort found in the literature in evaluation of EndoFLIP® system.<sup>7,12</sup> This may also be related to the low incidence of delayed gastric emptying following esogastric surgery. A second limitation is that gastric emptying was not measured in patients with esophagectomy or sleeve gastrectomy. As previously outlined, normal values are lacking for this particular subgroup of patients. In addition, we did not perform correlation studies between pyloric studies and validated questionnaires like GCSI (Gastroparesis Cardinal Symptom Index) in the present study.

Last, we have not reported in the present study patients' follow-up after pyloric intervention. In fact, we only identified 20 patients with decreased pyloric distensibility which is too small a number to assess prospectively the predictive value of EndoFLIP® on symptoms.

## 5 | CONCLUSION

Decreased pyloric distensibility was found in the majority of patients with dyspeptic symptoms after antireflux surgery and esophagectomy, but not in all patients. In contrast, a minority of patients displayed altered pyloric distensibility after sleeve gastrectomy. This suggests that pylorospasm is not a frequent consequence of sleeve gastrectomy, and that this surgery is barely associated with vagal lesion. However, these first results warrant further confirmatory studies.

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## CONFLICT OF INTEREST

Guillaume Gourcerol has received consulting fees from Allergan. The other authors have no conflict of interest to declare.

## AUTHOR CONTRIBUTIONS

GG is the guarantor of article. GG conceptualised and designed the study; GG, CM, EH, and JJ performed patient recruitment and selection; GG and JJ involved in data acquisition: Endoflip measures; GG, AML, and CD performed gastric emptying; GG and CD analyzed data; GG, AML, and CD performed interpretation of data; GG and CD wrote the manuscript. All authors have approved the final version of the article, including the authorship list.

## ORCID

Charlotte Desprez  <https://orcid.org/0000-0002-1280-7675>

Chloé Melchior  <https://orcid.org/0000-0002-8146-1540>

Fabien Wuestenberghs  <https://orcid.org/0000-0001-6100-6017>

Jérémy Jacques  <https://orcid.org/0000-0003-4105-6804>

Anne-Marie Leroi  <https://orcid.org/0000-0002-6266-4203>

Guillaume Gourcerol  <https://orcid.org/0000-0001-8220-9155>

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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