Clinical Science

Enhanced postoperative recovery pathways in emergency surgery: a randomised controlled clinical trial

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Perforated ulcer; Peptic ulcer disease; Enhanced recovery; Fast-track surgery; Nasogastric tube

Abstract

BACKGROUND: Enhanced recovery pathways are now widely used in elective surgical procedures. The feasibility of enhanced postoperative recovery pathways in emergency surgery for perforated peptic ulcer disease was investigated in this randomized controlled clinical trial.

METHODS: Patients with perforated peptic ulcer disease who underwent laparoscopic repair were randomized into 2 groups. Group 1 patients were managed with standard postoperative care and group 2 patients with enhanced postoperative recovery pathways. The primary endpoints were the length of hospital stay and morbidity and mortality.

RESULTS: Forty-seven patients were included in the study. There were 26 patients in group 1 and 21 in group 2. There were no significant differences in the morbidity and mortality rates, whereas the length of hospital stay was significantly shorter in group 2.

CONCLUSIONS: The application of enhanced postoperative recovery pathways in selected patients with perforated peptic ulcer disease who undergo laparoscopic Graham patch repair seems feasible.

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The rate of elective surgical procedures for peptic ulcer disease (PUD) has dramatically decreased since highly effective medical therapies became widely available.1 However, the rate of emergency surgery for acute complications of PUD such as bleeding and perforation has remained stable and may have actually increased.2 Perforation occurs in about 2% to 10% of patients with PUD.3 Perforated peptic ulcer disease (PPUD) is associated with a 6% to 30% mortality rate and is responsible for more than 70% of deaths associated with PUD.3,4

The surgical treatment of PPUD has evolved in parallel to the advances in the medical treatment of PUD. Because the eradication of Helicobacter pylori and the potent acid-reducing agents can successfully cure the vast majority of patients with PUD, simple procedures such as primary repair or Graham patch repair are now the preferred methods for surgical treatment of PPUD.5 Furthermore, open procedures have in the most part been replaced by laparoscopic techniques.6,7 In contrast, the postoperative management of PPUD patients has remained virtually unchanged.8 The standard postoperative management of PPUD patients is predominantly based on traditional practices rather than being evidence based.8

Traditional surgical practices are now being re-examined in light of new evidence-based surgical facts.9 Enhanced...
recovery after surgery (ERAS) pathways, which originated in the 1990s and have been increasingly adopted over time, are the end products of this new perspective in surgery. The ERAS pathways involved in the pre-, intra-, and postoperative period are usually gathered in an integrated ERAS program in which both health care professionals and patients have active roles. The evidence-based components of the ERAS program were shown in Table 1. Although the ERAS program is widely used in elective procedures in many surgical subspecialties, the place of this program in emergency surgery remains uncertain probably because of the significant challenges in applying all ERAS pathways in the emergency setting. Nevertheless, the ERAS program is often modified in elective procedures on an individual and/or institutional basis and thus may also have a role in the emergency setting albeit in a modified form. The aim of this randomized controlled clinical trial was to investigate the feasibility of enhanced postoperative recovery pathways in patients who underwent laparoscopic repair for PPUD.

**Methods**

**Study design, eligibility, randomization, and exclusion criteria**

This study was a prospective, single-center, randomized controlled, nonblinded clinical study. The aim of the study was to evaluate the safety and efficacy of enhanced postoperative recovery pathways in patients who underwent laparoscopic Graham patch repair (LGPR) for PPUD. Patients who were diagnosed with PPUD between May 2012 and January 2013 were recruited for the study. The Institutional Review Board of the Dr. Sadi Konuk Training and Research Hospital, Istanbul, Turkey, approved this study (approval ID: 2012-08-01). The study was also registered at www.clinicaltrials.gov (ClinicalTrials.gov identifier: NCT01620671).

Each patient was provided with detailed information about the study and was requested to sign an informed consent form. Hospital staff involved in the patients’ care was informed about the study and was requested to sign an informed consent form. Hospital staff involved in the patients’ care was informed about the study design and the nature of the randomization. Patients received detailed information regarding their postoperative care including contact details of the medical and research staff in case of complications after hospital discharge. The involvement of the researchers was allowed only in the pre- and intraoperative course and was avoided in the postoperative management of patients including the evaluation of fitness for discharge.

Patients with a perforated ulcer less than 10 mm in size who underwent LGPR were included in the study. The patients were randomized into 2 groups according to their 5-digit hospital registry number, which was automatically given by the computer-based data processing system at admission. Randomization was made at the end of the surgical procedure. Patients with odd and even protocol numbers were included in groups 1 and 2, respectively. Group 1 was the control group and received standard postoperative care, and group 2 was the ERAS group. The surgical team was blinded to this protocol number and was not informed until the end of the surgical procedure.

The exclusion criteria were as follows: (1) refusal to join the study or sign the informed consent form; (2) age younger than 15 years; (3) the presence of any psychiatric or neurologic disease; (4) class 3 and 4 surgical patients according to the classification of The American Society of Anesthesiologists; (5) septic shock on admission; (6) pregnancy; (7) predisposing factors for impaired wound healing (eg, chronic use of steroids); (8) peptic ulcers that were simultaneously bleeding and perforated; (9) multiple perforated peptic ulcers; (10) spontaneously sealed-off perforated ulcers that were diagnosed either preoperatively or during surgery and that did not require surgical repair; (11) conversion to open technique; (12) perforated ulcers that were not amenable to Graham patch repair because of size or technical considerations; and (13) malignant ulcers confirmed by histopathological examination if biopsied for a high index of suspicion for malignancy.

**Preoperative course**

Preoperative preparation was identical in both groups and included the placement of a nasogastric tube, the administration of crystalloids for fluid replacement, intravenous antibiotic therapy with cefuroxime (1,500 mg every 12 hours [Contramal; Abdi Ibrahim, Istanbul, Turkey]), intravenous pain relief with tramadol (100 mg every 6 hours [Contramal; Abdi Ibrahim, Istanbul, Turkey]), and

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<td>Information and counseling</td>
<td>Fluid optimization Maintenance of normothermia regional anesthesia</td>
<td>Multimodal, opioid-sparing analgesia</td>
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<td>Optimization of organ function</td>
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<td>Minimally invasive surgery Oxygen therapy</td>
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<td>Antibiotic prophylaxis Thromboprophylaxis</td>
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<td>Carbohydrate loading</td>
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<td>Early mobilization</td>
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Discharge criteria

**Table 1** The evidence-based components of the ERAS program

ERAS = enhanced recovery after surgery.
Surgical technique

All of the surgical procedures were performed under general anesthesia. The procedure was performed by either the attending surgeon or a trainee under the supervision of the attending surgeon. The preferred position for surgery was a Lloyd-Davies position with a 15° reverse Trendelenburg tilt and the operating surgeon standing between the patient’s thighs.

Pneumoperitoneum was established with carbon dioxide via either a Veress needle or the Hasson method. An 11-mm optical trocar was introduced through a subumbilical incision. Two 5-mm working trocars, one in the right upper quadrant and one in the left upper quadrant, were placed under direct vision. If necessary, an additional 5-mm epigastric trocar was introduced to facilitate retraction of the liver with a blunt-tipped instrument.

The first portion of the duodenum and the anterior surface of stomach were explored. Exploration of the posterior surface of the stomach and small bowel was considered only if the aforementioned sites were clearly intact. If the perforated peptic ulcer appeared to have sealed spontaneously, its integrity was tested by filling the stomach with diluted methylene blue and then occluding the gastrointestinal lumen both proximally and distally to the perforation site with a surgical instrument to increase pressure. If no leak was observed, the sealed-off perforation was left untreated; otherwise, it was treated with LGPR. If the perforated peptic ulcer was located in the stomach, at least 2 tissue samples were obtained from different edges of the ulcer for histopathological examination before surgical repair was executed.

LGPR was the preferred surgical procedure for all cases. The full-thickness bites were placed approximately 10 mm away from the edges of the perforation from one margin to the other to avoid passing the sutures through the inflamed, friable tissue. The preferred suture material was 3/0 silk. Two or 3 sutures were placed parallel to the longitudinal axis of the gastrointestinal tube and were laid out on each side of the perforation. A viable piece of the omentum of appropriate length was prepared. The omental flap was placed on the perforation site and was secured to cover the perforation by intracorporeal knotting of the previously placed sutures.

If an intra-abdominal abscess was detected, it was drained. The peritoneal cavity was irrigated with warm saline. The patient’s position was then changed to aspirate as much of the intraperitoneal fluid as possible. Finally, a Jackson-Pratt–type drain was placed in the subhepatic area.

Intravenous acid-reducing therapy with pantoprazole (40 mg every 12 hours [Pantpas; Nycomed GmbH, Singen, Germany]). Patients older than 45 years and who had risk factors for venous thrombosis received subcutaneous thromboprophylaxis with enoxaparin (.4 mL/d [Clexane; Sanofi Aventis, Istanbul, Turkey]).

Postoperative course in the control group

The control group (group 1) underwent standard perioperative management. These patients left the operating room with their nasogastric tube in place. The urinary catheter was removed on postoperative day 1. Postoperative pain was managed with tramadol (100 mg every 6 hours intravenously). Intravenous metoclopramide (10 mg every 8 hours; Metpamid, Yeni Ilac, Istanbul, Turkey) was administered for the first 2 postoperative days. The intravenous acid-reducing therapy with pantoprazole (40 mg every 12 hours) was continued throughout the hospital stay. The nasogastric tube was not withdrawn until the drainage was less than 300 mL/d. Oral intake of liquids was started after active bowel movements had begun. The subhepatic drain was withdrawn 12 hours after the initiation of oral intake. After the oral feeding had been initiated, tramadol was switched to oral acetaminophen (500 mg every 6 hours [Parol; Atabay, Istanbul, Turkey]).

Postoperative course in the enhanced recovery after surgery group

The ERAS group (group 2) had an enhanced postoperative recovery protocol. The gastric content was aspirated via the nasogastric tube by the anesthesiologist at the end of the procedure, and the nasogastric tube was withdrawn in the operating room immediately after the patient had recovered from anesthesia. The postoperative management is summarized in Table 2. The discharge criteria were complete tolerance to oral feeding, the presence of active bowel sounds regardless of flatus or defecation, and the absence of any postoperative complications.

Common practices in both groups

The oral intake was immediately stopped in patients who exhibited signs of postoperative ileus. Postoperative ileus was defined as a silent abdomen without any signs of surgical site infection (SSI) and with 1 of the following criteria: (1) nasogastric drainage of more than 300 mL/d or the need for nasogastric tube reinsertion for recurrent vomiting; (2) abdominal distention; and (3) failure to pass wind or stool until the end of postoperative day 3. In patients who developed postoperative ileus, oral feeding was reinitiated after nausea and vomiting had completely subsided and active bowel sounds had been detected.

In the control group, patients were discharged only after showing complete tolerance to oral feeding and the passage of wind or stool in the absence of any postoperative complications. The discharge criteria in the ERAS group was similar to that of the control group except the presence of active bowel sounds regardless of flatus or defecation was used as an endpoint for bowel function.

All patients were prescribed oral acetaminophen (500 mg on demand) and oral moxifloxacin (400 mg daily [Moxifor;
Biofarma, Istanbul, Turkey]. Patients were also advised to continue oral acid-reducing therapy with pantoprazole (40 mg every 12 hours [Pantpas]) for at least 3 months. Patients were asked to return for stitch removal on the postoperative day 8 and for follow-up gastroscopy 6 weeks after discharge.

Endpoints

The primary endpoints were the length of hospital stay and morbidity and mortality during the first 30 days after surgery. Morbidities included superficial and organ/space-type SSIs, postoperative ileus, pulmonary complications including atelectasis and pleural effusion, postoperative bleeding, and incarcerated trocar site hernia. Organ/space-type SSIs were further divided into 2 subgroups: SSI with omentopexy-site leak and SSI without leak.

The secondary endpoints were the time elapsed until the resumption of oral feeding, the need for nasogastric tube reinsertion, the readmission rate, and the reoperation rate. To make sure that all readmissions were recorded, patients were asked during admission for follow-up gastroscopy whether or not they had sought medical attention from another health institute. Patients who readmitted to another hospital and those who did not return for follow-up gastroscopy were considered lost to follow-up.

Statistical analysis

Data were collected on standard forms, which were prepared by the researchers. These forms were filled out by the clinicians who did not engage in the study and were regularly entered into the computer database of the hospital by the researchers.

The required sample size in each group was calculated with PASS 11 (NCSS Statistical Software, Kaysville, UT). Only the length of hospital stay was used for power analysis because it was the only primary outcome measure that was predictable. For this purpose, the medical records of patients who had undergone LGPR for PPUD between January 2009 and January 2012 were reviewed. The mean length of hospital stay in these patients was estimated to be 6.1 ± 2.3 days. The clinically relevant difference was determined as 2 days. The predicted length of hospital stay in the ERAS group was 4 days with a clinically relevant difference of 1 day. The level of significance was set to 5% and the power of test as 90%. According to these data, the required sample size in each group was calculated as 16. However, the recruitment process was not ended until the number of subjects had reached 20 in each group in order to increase the power of the study.

Statistical analysis was performed using SPSS statistical software (version 8.0; SPSS Inc, Chicago, IL). Discrete variables are expressed as counts and percentages. Continuous data are expressed as means with standard deviation, with calculation of the probability value to measure the significance of differences. The Student t test was used for comparisons of continuous variables. The Mann-Whitney U test was used for other nonparametric quantitative data. A P value less than .05 was considered statistically significant.

Results

The details of the enrollment process are shown on a CONSORT 2010 flow diagram in Fig. 1.²² Twenty-six patients in the control group and 21 in the ERAS group were considered for statistical analysis.
The female-to-male ratio in the control and ERAS groups was 6 of 20 and 5 of 16, respectively. The mean age of patients in the control and ERAS groups was 37.8 ± 14.3 years (range 18 to 71 years) and 35.4 ± 13.2 years (range 18 to 66 years), respectively (P = .56). PPUD was located in the anterior surface of the duodenal bulb in 42 patients and in the pyloric region in 5 patients, 2 of whom were in the control group. The results of primary and secondary endpoints are shown in Tables 3 and 4.

One patient in the control group developed a superficial-type SSI in the umbilical wound. This was managed by local wound care in an outpatient setting.

Postoperative ileus occurred in 5 patients in the control group and in 2 patients in the ERAS group. Four patients in the control group had a postoperative ileus episode during the hospital stay, whereas 1 patient in the control group and both patients in the ERAS group developed postoperative ileus after discharge. The patients who re-presented to the emergency department were rehospitalized. All of the patients with postoperative ileus underwent a detailed clinical evaluation and contrast-enhanced abdominal computed tomographic (CT) imaging to rule out any septic foci. All patients responded to conservative treatment including nasogastric decompression, bowel rest, and fluid replacement.

One patient in the control group developed an organ/space-type SSI that occurred because of an omentopexy-site leak. The leak started during the first postoperative day. The patient underwent immediate reoperation. Laparoscopic exploration revealed that the omental flap used for LGPP was necrotic. The stomach was filled with diluted methylene blue, and a leak from the LGPR site was confirmed. The necrotic omental flap was excised, and a new LGPR was performed using a viable omental flap. However, on postoperative day 4, the patient complained of abdominal pain. Contrast-enhanced abdominal CT imaging revealed a subhepatic abscess and no contrast extravasation. Percutaneous drainage of the collection was performed under sonographic guidance by an interventional radiologist. The drainage catheter was withdrawn on postoperative day 14, and the patient was discharged on postoperative day 15.

Figure 1  The details of the enrollment process shown on the CONSORT 2010 flow diagram. ASA = American Society of Anesthesiologists; GPR = Graham patch repair; NG = nasogastric.
An organ/space-type SSI occurred because of an omentopexy-site leak in 1 patient in the ERAS group. The leak started on postoperative day 4 and manifested itself as biliary drainage through the abdominal drain. Contrast-enhanced abdominal CT imaging revealed minimal contrast extravasation, intraperitoneal collection in Morrison’s pouch, and normal findings in the other sites of the abdomen. Because there were no clinical signs of diffuse peritonitis, percutaneous drainage of the collection was performed under sonographic guidance by an interventional radiologist. The leak subsided and then ceased on postoperative day 11. The abdominal drain and percutaneous drainage catheter were withdrawn on postoperative days 12 and 15, respectively. The patient was discharged on postoperative day 17.

One patient in each group developed an organ/space-type SSI that occurred without evidence of a leak. The patient in the control group readmitted to the emergency department on postoperative day 12, whereas the patient in the ERAS group readmitted on postoperative day 11. Contrast-enhanced abdominal CT imaging revealed a subdiaphragmatic abscess but no contrast extravasation in both patients. The patients were rehospitalized, and intravenous parenteral antimicrobial therapy with piperacillin-tazobactam (4,500 mg every 8 hours [Tazocin, Wyeth, Istanbul, Turkey]) was immediately started. In both patients, the intra-abdominal abscess was drained percutaneously under sonographic guidance by the interventional radiologist. Once the drainage had become serous, the presence of another septic foci was ruled out by the interventional radiologist, and the drainage catheter was removed.

One patient in the control group developed postoperative bleeding. The source of bleeding was the epigastric port site and was controlled by executing laparoscopic-assisted deep fascial sutures. The patient did not require blood transfusion and was discharged without any further complications.

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<thead>
<tr>
<th>Table 3</th>
<th>The results of the primary endpoints</th>
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<tr>
<td></td>
<td>Group 1 (n = 26)</td>
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<tr>
<td>Length of hospital stay (d) (mean, range)</td>
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<tr>
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<tr>
<td>Without leakage</td>
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<tr>
<td>Postoperative bleeding</td>
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<tr>
<td>Incarcerated trocar site hernia</td>
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<td>Mortality</td>
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*Statistically significant.

Table 4 | The results of the secondary endpoints |
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<tr>
<td>Time to start oral intake (d) (mean, range)</td>
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<td>Need for extra or opioid analgesics</td>
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*Statistically significant.
One patient in the ERAS group was readmitted to the emergency department with swelling and pain in the umbilical port site on postoperative day 9. Combined clinical and sonographic evaluation revealed an incarcerated trocar site hernia. The incarcerated bowel segment was ischemic but viable, and, therefore, no bowel resection was necessary. Primary repair was considered for the hernia defect. The postoperative period was uneventful, and the patient was discharged 2 days after the reoperation.

One patient in group 1 developed chest pain on postoperative day 3. A cardiologist was consulted, and the patient was diagnosed with acute myocardial infarction. The patient was transferred to the critical care unit. However, the patient died on postoperative day 4.

**Comments**

Age older than 60 years, shock on admission, and concomitant systemic diseases are well-established risk factors that influence outcomes of patients who undergo emergency surgery for PPUD. The favorable outcomes in the present study were most likely caused by the fact that almost all patients with these risk factors were excluded. Likewise, the overall mortality rate (2%) and the mortality rate of each group (4% and 0%) were less than that previously reported in the literature (6% to 30%).

Because gastrointestinal motility may take up to several days to recover because of diffuse peritonitis, patients who undergo emergency surgery for PPUD are generally subjected to nasogastric decompression for at least 48 hours and are kept nil by mouth until the third postoperative day. Thus, the intraluminal pressure is reduced, which is believed to prevent anastomotic complications and vomiting and aspiration.

However, a recent meta-analysis showed that nasogastric decompression not only prolongs paralytic ileus and the length of time to start oral feeding but also has no impact on anastomotic complications after gastrectomy for gastric cancer. Another meta-analysis of the Cochrane database reported that prophylactic nasogastric decompression does not prevent aspiration and may even lead to an increase in pulmonary complications after major abdominal surgery. In fact, there is an increasing trend toward omitting routine nasogastric decompression within the postoperative period even in patients who undergo major upper alimentary tract surgery.

Grantcharov and Kehlet reported the surgical outcomes of 32 patients who underwent elective laparoscopic gastric surgery with ERAS pathways for various etiologies. Routine nasogastric decompression was omitted and early oral feeding (ie, as soon as 24 hours after the surgery) was considered in all patients. They found that ERAS pathways decreased the length of hospital stay and resulted in a comparable morbidity rate with that of standard postoperative care. Kim et al published a randomized controlled clinical trial evaluating the safety and efficacy of fast-track surgery in patients who underwent laparoscopic gastrectomy for gastric cancer. The patients in the fast-track arm of the study started clear liquids 48 hours after surgery and did not undergo nasogastric decompression in the postoperative period. When compared with the patients who underwent traditional perioperative management, the fast-track patients had significantly shorter hospital stays with comparable morbidity and mortality. Numerous other studies have also validated the feasibility of ERAS pathways in gastric surgery.

Because the aforementioned studies focused solely on elective surgical procedures, one may speculate that the presence of peritonitis is underestimated. Although primary repair or Graham patch repair of a perforated peptic ulcer less than 1 cm in size is not technically challenging, the concern is repairing a gastrointestinal wound with inflamed edges on a relatively ischemic tissue in an abdomen with diffuse peritonitis. Moreover, a leakage through the surgical repair site may require further surgical procedures, some of which are associated with considerable morbidity and mortality. However, the present study showed that neither nasogastric decompression nor the nil by mouth policy had an impact on the morbidity rate in patients who underwent LGPR for PPUD.

Spontaneously sealed-off PPUD, a well-known clinical entity, deserves consideration given the concerns about performing surgical repair in the presence of diffuse peritonitis. In nearly 50% of patients with PPUD, the perforation is found to be spontaneously sealed off at surgical exploration, and a minority of these spontaneously sealed-off PPUDs are secure enough to be left untreated. This means that a PPUD may be sealed off even in the presence of diffuse peritonitis and without nasogastric decompression until admission to the hospital. This argues for the security of surgical repair, which is at least as secure as a spontaneous closure.

We found that postoperative ileus occurred less frequently in the ERAS group. Because each group was similar in terms of inclusion criteria and the surgical technique used, the significant decrease in the rate of postoperative ileus was attributed to the omission of routine nasogastric decompression, early oral feeding, and the use of nonsteroidal anti-inflammatory drugs for postoperative pain. First, unlike the control group, active bowel sounds were used as an endpoint for bowel function instead of commonly used parameters such as flatus and bowel movements in the ERAS group. The logic behind this was to reduce the risk and the duration of postoperative ileus by stimulating a reflex that would produce coordinated propulsive activity and elicit the secretion of gastrointestinal hormones that have positive effects on bowel motility. Second, the use of opioid analgesics and routine nasogastric decompression have been shown to increase the duration of postoperative ileus and the length of time to resume oral feeding after major abdominal surgery.

The leak that occurred on postoperative day 1 was attributed to technical failure because the sutures that were
used to anchor the omental patch in place were too tight, which eventually resulted in the strangulation of the omental patch. This can partially be explained by poor tactile feedback associated with laparoscopic surgery. The risk of strangulation of the omental patch in classical Graham omental patch repair has been highlighted, and a modified Graham patch repair has been advocated whereby the omental flap is tacked after primary repair. Nonetheless, we have encountered this complication only extremely rarely because our policy is to tie the knots only tight enough to hold the omental flap in place per the original description of Graham patch repair.

The present findings should be interpreted within the limitations of the study. First, the exclusion of patients with poor surgical risk, particularly those who were American Society of Anesthesiologists class 3 to 4 and those who were late in the course of the disease with septic shock, led to unexpectedly favorable surgical outcomes for PPUD in our series. A follow-up clinical study including patients with a poor surgical risk who might gain from enhanced recovery pathways is warranted because such patients constitute the majority of patients with PPUD under normal circumstances. Second, we instigated a major deviation from the ERAS program by omitting the incorporation of the pre-, intra-, and postoperative components. These components are strictly related to each other, and, therefore, their omission may have complicated the findings. Nevertheless, this study was the first to investigate the feasibility of using enhanced recovery pathways in emergency gastric surgery and provides a foundation for future studies focusing on the applicability of ERAS in emergency surgery.

In conclusion, enhanced postoperative recovery pathways seem safe and feasible in a highly selected subset of patients undergoing LGPR for PPUD. Routine nasogastric decompression and delayed oral feeding may be unnecessary because these applications increase the length of hospital stay without having a positive impact on the rates of morbidity and mortality.

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References