Accepted Manuscript

Submission Date: 2024-09-18
Accepted Date: 2025-02-21
Accepted Manuscript online: 2025-02-24

Endoscopy

Reversible endoscopic gastroduodenal bypass: Endoscopic ultrasound-guided gastro-jejunostomy with pyloric exclusion for the treatment of persistent duodenal leaks after failed surgical repair

Kambiz Kadkhodayan, Saurabh Chandan, Artur Viana, Maham Hayat, Natalie Cosgrove, Mustafa A Arain, Deepanshu Jain, Abdullah Abassi, Sagar Pathak, Dennis Yang, Muhammad K Hasan, Armando Rosales, Jay Redan, Shayan Irani.

Affiliations below.

DOI: 10.1055/a-2544-8507

Please cite this article as: Kadkhodayan K, Chandan S, Viana A et al. Reversible endoscopic gastroduodenal bypass: Endoscopic ultrasound-guided gastro-jejunostomy with pyloric exclusion for the treatment of persistent duodenal leaks after failed surgical repair. Endoscopy 2025. doi: 10.1055/a-2544-8507

Conflict of Interest: Shayan Irani, MD is a consultant for Boston Scientific, Gore, and
Conmed. Dennis Yang, MD is a consultant for Microtech, Medtronic, Olympus, FujiFlim, 3dmatrix, ERBE and Aspero Medical. Mustafa Arain is a con-
sultant for Cook, Boston Scientific and Olympus. Muhammad Hasan, MD is a consultant for Boston Scientific, Olympus and Microtech. Natalie Cosgrove is a consultant for Boston Scientific and Olympus, The
remaining authors have no conflict of interest to declare.

Abstract:
Background: Post-surgical leaks following surgical repair of acute duodenal perforations carry high mortality. Reversible endoscopic gastroduodenal bypass (REGB) is a novel procedure that helps divert the acid-rich gastric stream away from the affected duodenum to promote tissue healing at the ulcer site.
Methods: REGB is a single-session, two-step procedure involving the creation of an EUS-guided gastrojejunostomy using a lumen-apposing metal stent, followed by endosuturing and closure of the pylorus to achieve complete duodenal bypass. The outcomes of REGB and its reversal were prospectively evaluated in six patients with persistent post-surgical duodenal leaks.
Results: REGB was technically successful in all six patients (100%) with no procedure-related adverse events. All patients resumed oral intake within 3 days, experienced significant reductions in surgical drain output, and were discharged. One patient with metastatic breast cancer did not undergo REGB reversal. Amongst five patients who underwent REGB-reversal after a mean of 52.6 days, technical success was achieved in all 5 patients (100%), with complete healing of duodenal ulcers, absence of leaks on fluoroscopy, and resumption of a solid food diet.
Conclusion: REGB is a technically feasible, reversible, and minimally invasive alternative for managing post-surgical duodenal leaks. Further studies are needed to validate its safety and efficacy.

Corresponding Author:
Dr. Kambiz Kadkhodayan, AdventHealth Orlando, Center for Interventional Endoscopy, 601 E. Rollins St., 32803-1489 Orlando, United States, kamkad@gmail.com

Affiliations:
Kambiz Kadkhodayan, AdventHealth Orlando, Center for Interventional Endoscopy, Orlando, United States
Kambiz Kadkhodayan, AdventHealth Orlando, Center For Interventional Endoscopy, Orlando, United States

Saurabh Chandan, AdventHealth Orlando, Center for Interventional Endoscopy, Orlando, United States
[...]
Shayan Irani, Virginia Mason Medical Center, Gastroenterology and Hepatology, Seattle, United States

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age	68	82	72	76	84	41
Sex	M	F	M	M	F	M
Indication	Duodenal bulb ulcer perforation, post-op leak. Bile duct injury – required ERCP with stent	Duodenal bulb ulcer perforation, post-op leak	Duodenal (second part) ulcer perforation with abscess.	Duodenal bulb ulcer perforation, post-op leak.	Duodenal bulb ulcer perforation, post-op leak.	Duodenal bulb perforation with post-op leak. Concern for bile duct leak, required ERCP with stent
Time from surgical repair to REGB procedure	20 days	15 days	7 days	14 days	15 days	3 days
Technical Success of REGB procedure	Yes	Yes	Yes	Yes	Yes	Yes
Adverse events related to REGB procedure	No	No	No	No	No	No
Clinical success of REGB procedure	Yes	Yes	*Yes*	Yes	Yes	Yes
Time from REGB to reversal procedure	50 d	49 d	72 d	50 d	NA ++	42 d
Technical success of reversal procedure	Yes	Yes	*Yes*	Yes	NA ++	Yes
Adverse events related to reversal procedure	No	No	*No*	Yes +	NA ++	No
Clinical success of reversal procedure	Yes Resolution of ulcer and bile leak	Yes	*Yes*	Yes	NA ++	Yes Resolution of ulcer and bile leak
Weight change between the REGB and reversal procedure (Kg)	+2 kg	- 12.9 kg	*- 14 kg*	-9 kg	NA++	- 0.6 kg

+ Patient 4 developed a mucosal bridge at the pylorus. This was managed endoscopically with a scissor type electrosurgical knife. Of note, the mucosal bridges developed around a prior pyloric channel ulceration.

++ Patient 5 was discharged to hospice due to metastatic breast cancer. She opted not to have the reversal procedure and died of unrelated causes 5 months later.

Supplementary Table 1: Patient outcomes after REGB and REGB-reversal

Reversible endoscopic gastroduodenal bypass: Endoscopic ultrasound-guided gastro-jejunostomy with pyloric exclusion for the treatment of persistent duodenal leaks after failed surgical repair: A pilot feasibility study

ABSTRACT:

Background: Post-surgical leaks following surgical repair of acute duodenal perforations carry high mortality. Reversible endoscopic gastroduodenal bypass (REGB) is a novel procedure that helps divert the acid-rich gastric stream away from the affected duodenum to promote tissue healing at the ulcer site.

Methods: REGB is a single-session, two-step procedure involving the creation of an EUS-guided gastrojejunostomy using a lumen-apposing metal stent, followed by endosuturing and closure of the pylorus to achieve complete duodenal bypass. The outcomes of REGB and its reversal were prospectively evaluated in six patients with persistent post-surgical duodenal leaks.

Results: REGB was technically successful in all six patients (100%) with no procedure-related adverse events. All patients resumed oral intake within 3 days, experienced significant reductions in surgical drain output, and were discharged. One patient with metastatic breast cancer did not undergo REGB reversal. Amongst five patients who underwent REGB-reversal after a mean of 52.6 days, technical success was achieved in all 5 patients (100%), with complete healing of duodenal ulcers, absence of leaks on fluoroscopy, and resumption of a solid food diet.

Conclusion: REGB is a technically feasible, reversible, and minimally invasive alternative for managing post-surgical duodenal leaks. Further studies are needed to validate its safety and efficacy.

INTRODUCTION:

Duodenal perforation is a common surgical emergency with a mortality rate that ranges from 4% to 30% in Western countries. [1] Common etiologies include peptic ulcer disease, abdominal trauma, complications from abdominal surgery or gastrointestinal procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) etc. [2,3] While primary surgical closure with an omental patch is the preferred treatment for simple duodenal perforations, data regarding the optimal management for large duodenal perforations remains limited. Reported strategies include duodenojejunostomy, pedicled grafts, pyloric exclusion with gastrojejunostomy and drain placement, gastric body partition, and in extreme cases, pancreaticoduodenectomy. Post-surgical complications such as perforation, bleeding and postoperative duodenal leaks, in particular, are associated with significant mortality and often necessitate reoperation. [4,5] Challenges associated with a repeat operation in such patients include adhesions between abdominal viscera and the undersurface of the anterior abdominal wall, a condition widely known as "frozen abdomen", poor tissue quality, and medical deconditioning especially in patients with multiple comorbidities and poor nutritional status. Given the high morbidity associated with surgical re-exploration, clinicians are increasingly considering endoscopic therapies as a viable alternative.

Duodenal diversion via gastrojejunostomy was originally conceived in the early 1900s. A simple, yet elegant technique of surgically excluding the duodenum was first reported by Vaughan et al. in 1977. [6] The operation consisted of primary repair of the duodenal defect, followed by closure of the pylorus via a gastrotomy that served as a site for gastro-jejunal anastomosis. Pyloric exclusion offers a valuable approach in the management of duodenal perforations. While studies have reported mixed outcomes, some reporting no mortality benefit compared to primary repair and others indicating increased complications or prolonged hospital stays, pyloric exclusion remains a viable approach to organ preservation. In cases where pyloric exclusion is not performed as part of the primary operation and a leak develops, surgical options for repair become limited, often necessitating more extensive and non-organ sparing interventions. [7,8]

One of the advantages of enteric stream diversion following surgical duodenal leak repair, is that it may help facilitate mucosal healing by acting as a "protective barrier" that prevents the ulcer bed from exposure to gastric acid. This is particularly important in patients who are refractory to acid suppressive medical therapy such as proton pump inhibitors (PPI). Such patients may not experience a true reduction in gastric pH following standard PPI therapy. In such patients, diversion of the acid rich enteric stream into the jejunum may result in a higher pH in the duodenum, reduction of duodenal inflammation, promotion of granulation tissue formation and ultimately restoration of the duodenal mucosal integrity. [9,10] Furthermore, the absence of mechanical pressure at the ulcer site that is caused by ingested solid food that patients with stable fistulas are generally started on, may also promote healing.

The endoscopic equivalent of surgical pyloric exclusion, by means of the reversible endoscopic gastro-duodenal bypass (REGB) procedure, is a single-session procedure involving the application of an EUS-guided gastrojejunostomy (EUS-GJ) to result in partial diversion of the gastric stream toward the proximal jejunum, followed by endoscopic closure of the pylorus with the overstitch device, resulting in complete diversion of the antegrade gastric stream away from the duodenum. [11] This novel endoscopic approach offers a technically feasible and less morbid alternative to open surgical reintervention in patients with post-operative duodenal leaks. We describe our initial experience with six patients who successfully underwent REGB at our center.

METHODS:

Design:

The study was conducted at a large tertiary referral center. Data regarding patient demographics, procedural details and follow-up was prospectively collected.

Patient Characteristics:

A total of 6 consecutive patients (4 males, 2 females), aged 41 to 84 years, with acute perforated duodenal peptic ulcers were included. All patients experienced a persistent leak following primary surgical repair with an omental patch and high-dose PPI therapy. All patients underwent the REGB procedure at a median interval of 12.3 days (mean: 14.5 days) following primary surgical repair. The median time between REGB and its reversal procedure was 50 days (mean: 52.6 days).

Procedure Description:

Procedure 1: Reversible Endoscopic Gastroduodenal Bypass (REGB) (Fig 1)

Step 1: using a curvilinear echoendoscope, a suitable loop of proximal jejunum was identified. An EUS-GJ was then performed using the wireless EUS-guided gastroenterostomy simplified technique (WEST) and a 20 mm * 10 mm lumen apposing metal stent (LAMS) (Fig 2a). [11]

Step 2: with the help of an endoscopic suturing device (Appolo OverStitch, Boston Scientific, Marlborough, MA), transmural sutures were applied to the pyloric ring in a continuous fashion using a 2.0 polypropylene suture (Fig 2b). This was followed by the application of a second layer of transmural sutures at the antrum 2-3 cm above the first layer (Fig 2c,3).

It is important to note that the pylorus was not de-epithelialized prior to suturing. This allows the sutures to be comfortably removed during the subsequent reversal procedure. Additionally, we were cautious not to apply excessive pressure on the newly placed LAMS while suturing the pylorus. This was accomplished by keeping the patient in a supine or partial left-lateral position, keeping the endoscope in the “short” position, and when needed, tilting the fluoroscopy bed in a direction where gravity helps keep the endoscope away from the LAMS (Fig 4a). At the end of procedure 1, complete bypass of the duodenum was confirmed in all patients via contrast injection and fluoroscopy (Fig 4b).

Following the REGB procedure, patients were started on a diet and the surgical drain output was clinically monitored. Patients were scheduled for a reversal procedure after the JP drain output had consistently decreased below 30 ml in 24 hours.

Procedure 2: Reversal of the REGB procedure (Fig 5)

Step 1: the polypropylene sutures were cut using standard endoscopic scissors (Fig 3d,3e). This results in re-opening of the pylorus and restoration of the transpyloric stream. The duodenal peroration site was visually examined to ensure complete healing , and a persistent duodenal leak was excluded on fluoroscopy via intraluminal contrast injection, before proceeding with step 2.

Step 2: using rat toothed forceps and gentle backward traction, the LAMS was removed (Fig 3f). Following this, surgical drains were removed under fluoroscopy.

Completion of step 2, and spontaneous closure of the gastro-jejunal fistula, results in complete restoration of the transpyloric stream, and reversal of the duodenal bypass (Fig 6) (Video).

Outcomes Assessed:

Technical success was defined as completion of all planned steps of procedure 1 (REGB) and procedure 2 (reversal of REGB). Completion of duodenal bypass after procedure 1, and reversal of duodenal bypass after procedure 2 were confirmed via intraprocedural injection of water-soluble contrast and fluoroscopy. Clinical success for procedure 1 was defined as the ability to start an oral diet, significant decrease in the surgical drain output (to less than 50% pre-procedure) and ability to discharge the patient from the hospital. Clinical success for procedure 2 was defined as complete healing of the duodenal ulcer, absence of a duodenal leak on fluoroscopy and the ability to restart a solid food diet. Additional parameters such as procedure related adverse events, body weight etc. were recorded.

RESULTS:

Procedure 1 (REGB) was technically successful in 6 patients (100%). There were no procedure related adverse events. All 6 patients (100%) were started on an oral diet within 3 days of the procedure, experienced significant decreases in their JP drain output and were discharged from the hospital. After the first procedure, one patient with metastatic breast cancer elected for hospice care, chose not to undergo the procedure 2 and died of unrelated causes 5 months later. Procedure 2 (REGB reversal) outcomes were assessed in the remaining 5 patients. The mean time to bypass reversal was 52.6 days (range 42- 72 days). Technical success was achieved in all 5 patients (100%). All 5 patients (100%) had complete healing of the duodenal ulcers on endoscopy, absence of a duodenal leak on fluoroscopy and were restarted on a solid food diet (Supplementary table 1). The average change in body weight between procedure 1 (REGB) and procedure 2 (REGB reversal) was -10.7 kg (range + 2 kg to -14 kg). Three patients had a repeat endoscopy in 3-6 months that revealed spontaneous closure of the gastro-enteric fistula.

DISCUSSION:

Our initial single center experience of six patients with acute duodenal perforations who developed post-surgical leaks highlights the potential of REGB an endoscopic therapeutic alternative to surgical re-intervention. The procedure can be performed in a single session with technical ease and is associated with high clinical success. Key advantages of this novel approach are that it is minimally invasive, avoids the need for a repeat surgery that can be highly morbid and technically challenging, is organ-sparing, and perhaps most importantly, it is reversible and restores normal anatomic and physiological function after resolution of the duodenal leak.

Omental patch repair (omentopexy) via laparotomy remains a standard intervention for perforated duodenal ulcers, but the incidence of post-operative leaks remains high. Studies on patients with perforated peptic ulcers treated by omental patch repair have estimated a

4%-7.6% leak rates with mortality ranging between 29.4%-55.6% in patients who experience a leak. [12,13] Several factors have been attributed to incidence of leaks after surgery for duodenal ulcer perforations, such as patient factors (age, shock on presentation, malnutrition, pre-existing co-morbidities, low hemoglobin and low serum albumin), poor surgical technique, large size of the perforation, delay in seeking medical attention and delay in diagnosis and surgery. [14] Given the limitations and high morbidity associated with surgical re-exploration, especially among high-risk individuals, REGB may be a suitable therapeutic modality in such patients.

In a large study of over 700 patients with a perforated peptic ulcer (PPU) who underwent surgery with either a laparoscopic or open laparotomy approach, reported that 17·1% patients had re-operative surgery, the most common reason for which was reperforation (5·9%), followed by wound dehiscence (4·7%). [15] This is of particular importance as surgical re-intervention in patients with duodenal leaks following surgical repair maybe particularly challenging given the possibility of a "frozen abdomen", characterized by the presence of dense adhesions among abdominal viscera and poor nutritional status. [16] In this regard, an endoscopic approach utilizing REGB completely circumvents the operative field and maybe a potentially safer option.

It is important to note that patients in our series lost a significant amount of weight between the first and second procedure. Potential reasons for this weight loss could be metabolic stress, catabolic state related to starvation, calorie restriction and exclusion of absorptive mucosa in the duodenum. Of note, the patients regained almost all the lost weight at 3 months follow up after the bypass was reversed.

Our study has several limitations that warrant consideration. First, our report is a pilot feasibility study with a small sample size that limits generalizability of the findings. Second, all REGB procedures were performed at a tertiary referral center by an experienced advanced endoscopist (KK) and may not reflect outcomes that are achievable in community or less-specialized settings. Third, we were not able to systematically assess protein malnutrition or other nutritional deficiencies that may result from duodenal exclusion, which could impact patient recovery. Fourth, the follow up period in this study was short, preventing assessment of long-term outcomes such stricture formation and quality of life scores. Fifth, the majority of patients described here had perforations and leaks located in the duodenal bulb and it is unclear if the duodenal bypass will be helpful in perforations of the distal duodenum that receives a continuous flow of bile and pancreatic juices. Sixth, the procedure requires additional training in therapeutic endoscopy, interventional EUS and endoscopic suturing. Technical feasibility and outcomes of REGB may vary significantly with operator experience, and the steep learning curve associated with this procedure may hinder widespread adoption. Finally, the study did not evaluate the cost-effectiveness of REGB compared to surgical re-intervention. These limitations highlight the need for larger, multi-center studies with longer follow-up to validate the findings and assess the broader applicability of the procedure.

CONCLUSION:

REGB is a technically feasible and clinically successful therapeutic intervention for patients with post-operative duodenal bulb leaks. Further larger studies are needed to evaluate the procedure's safety, efficacy and long-term outcomes.

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LEGANDS

Figure 1: Illustration of both steps of the REGB procedure.

Figure 2: (a) Fluoroscopy image of Procedure 1 (REGB) Step 1: LAMS placement. The image shows the LAMS being placed through the distal gastric body into a loop of proximal jejunum (black arrow). (b) Endoscopy image of procedure 1 (REGB) step 2: The first layer of transmural sutures is applied at the pylorus. The suture starts and ends at the antrum without directly engaging the pyloric ring (green dots). The remaining suture bites engage the pyloric ring (blue dots). (c) Endoscopy image of procedure 1 (REGB) step 2: The second layer of transmural sutures is applied 2-3 cm above the first layer. (d) Endoscopy image of Procedure 2 (REGB-reversal) Step 1: Cutting of the pyloric sutures using endoscopic scissors. (e) Endoscopy image after cutting the first layer of sutures (blue ring), exposing the second layer of sutures (green ring), which are subsequently cut using endoscopic scissors. (f) Endoscopy image demonstrating the removal of the LAMS using rat-toothed forceps with gentle backward traction.

Figure 3: Illustration of the suturing technique used for closure of the pylorus.

Figure 4: (a) Fluoroscopy image demonstrating the gastroscope in a “short” position. The shaft of the scope is located away from the LAMS. (b) Intraprocedural fluoroscopy image demonstrating complete bypass of the duodenum. The injected water-soluble contrast flows through the LAMS into the proximal small bowel, with the patient in a reverse Trendelenburg position. No contrast passes through the pyloric sutures into the duodenum.

Figure 5: Illustration of the REGB reversal procedure.

Figure 6: Illustration depicting complete reversal of the REGB procedure and restoration of transpyloric flow.

Video: Demonstration of the REGB and REGB-reversal procedures.

VIDEO TEXT

00:10 – 00:22 The endoscope was advanced into the duodenal bulb and reveals a persistent transmural defect (blue arrows) at the site of the previously repaired duodenal ulcer peroration.

00:23- 00:28 Water soluble contrast was injected into the duodenum and reveals extraluminal spillage (blue arrow), consistent with a post-operative leak.

00:29- 01:15: -EUS-GJ was then performed using the wireless EUS-guided gastroenterostomy simplified technique (WEST) and a 20 mm * 10 mm lumen apposing metal stent (LAMS) is placed through the distal gastric body into the proximal jejunum.

01:16- 01:17: The echoendoscope and all accessories were then withdrawn from the patient.

01:27- 01:18: A first layer of transmural sutures is applied to the pylorus.

01:29- 01:31: Both the first and last suture bites are applied along the anterior and posterior side of the antrum, approximately 1 cm away from the pylorus (green dots). The remaining suture bites are applied through the pyloric ring (blue dots)

01:32- 01:42: The endoscope is kept in a “short” position and away from the LAMS throughout the suturing.

01:42 – 01:58 This is accomplished by keeping the patient supine and tilting the fluoroscopy table as needed.

02:18- 02: 37: As seen here, the first and last suture bites are taken in the antrum.

02:38- 02:50: After completing the first layer of sutures, a cinch is applied.

02:54- 03:33: Using the pattern described there, a second layer of transmural sutures are applied 2-3 cm away from the pylorus.

03:34- 03:44: Water soluble contrast is injected into the stomach with the patient in a supine reverse Trendelenburg position.

03:44- 03:52: This confirms complete diversion of the enteric stream into the small bowel via the LAMS and away from the duodenum.

03:58- 04:02: On repeat endoscopy approximately 6 weeks later, we visualize a mature gastro-jejunal tract.

04:03- 04:07: As seen here, the pyloric sutures are in-tack and the pylorus remains closed.

04:07- 04:012: Injected soluble contrast does not pass into the duodenal bulb, indicating an intact suture line.

04:13- 04:20: Standard endoscopic scissors are then used to cut the outler later of sutures. Cutting the suture in a single location is usually adequate.

04:21- 04:34: Gentle pressure forward pressure is applied with the endoscope and frequiently results in separation of the sutures that are then easy to cut it needed.

04:36- 04:40: Once the outer layer of sutures have been cut (blue rung), the inner layer of sutures are exposed (green ring).

04:36- 04:49: In this case, we were able to advance the gastroscope into the duodenal bulb with gentle pressure without cutting the pyloric sutures. This is not always the case.

04:50- 05:00: Compared to 6 weeks ago, the duodenal bulb appears significantly less erythematous and the duodenal defect appears completely closed (arrows)

05:01- 05:07: Contrast injection reveals no extraluminal spillage, confirming complete closure of the duodenal defect and absence of a leak.

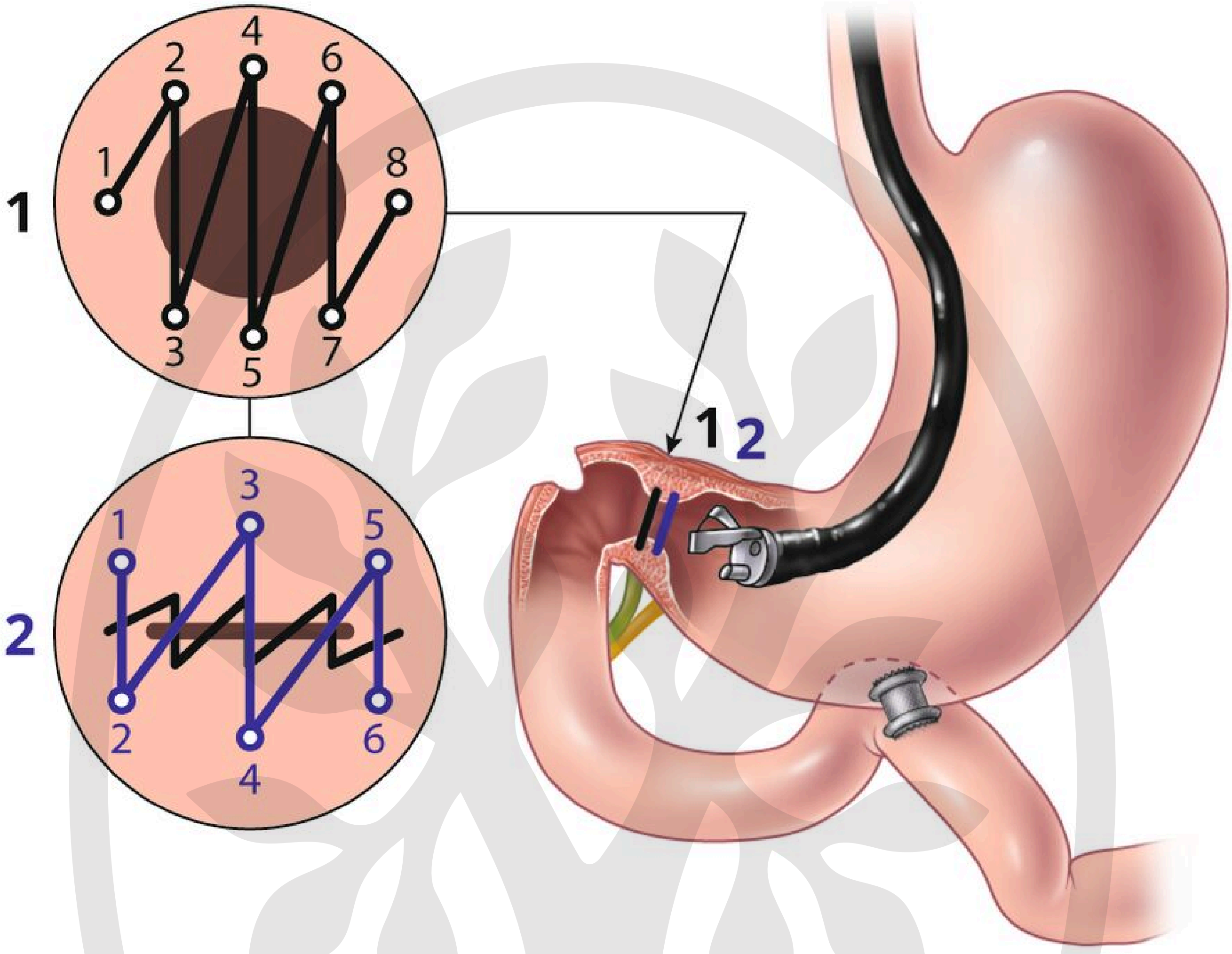
05:08- 05:22: The pyloric sutures are then cut and sutures removed using a standard rat toothed forceps.

05:27- 05:30: As seen here, after removal of the sutures, the pylorus returns to its native anatomical state.

05:31- 05:37: The LAMS is then removed with gently traction using a rat toothed forceps.

05:38- 05:42: Here we visualize the GJ fistula, that will eventually close spontaneously.

05:43- 05:42: The illustration depicts complete reversal of the duodenal bypass, and restoration of native transpyloric flow once the REGB has been reversed.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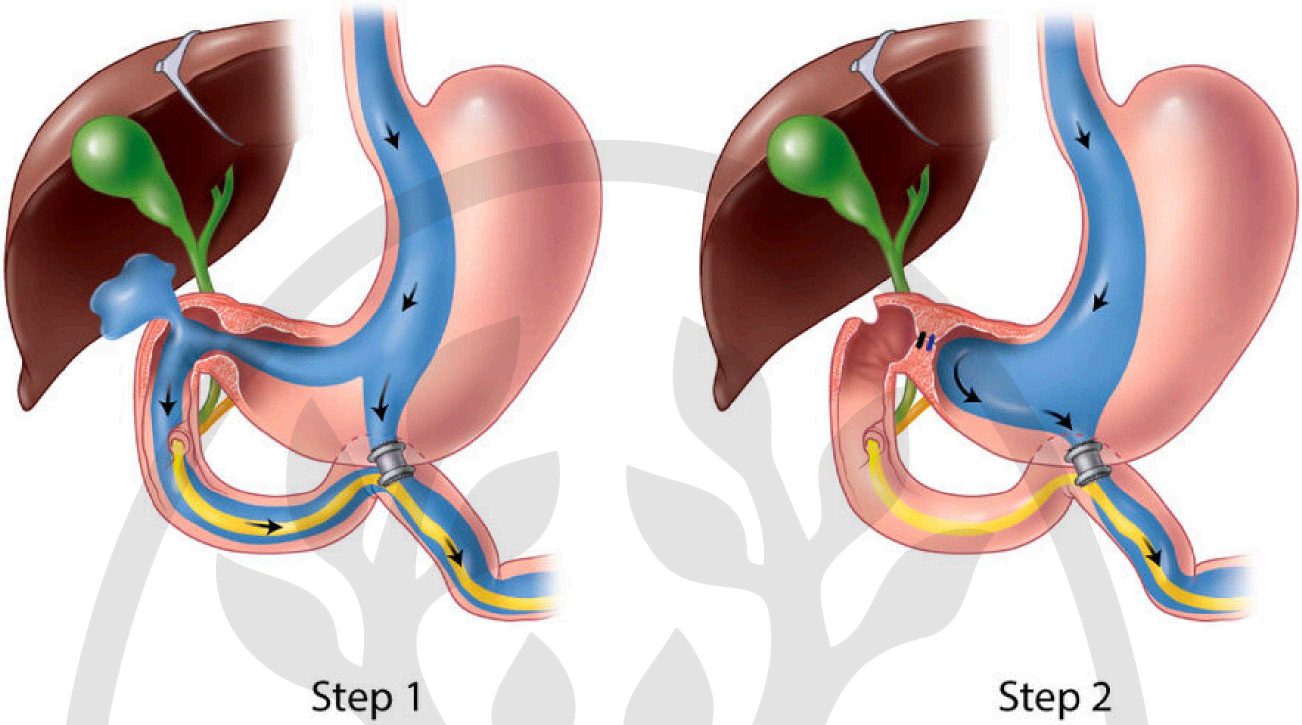
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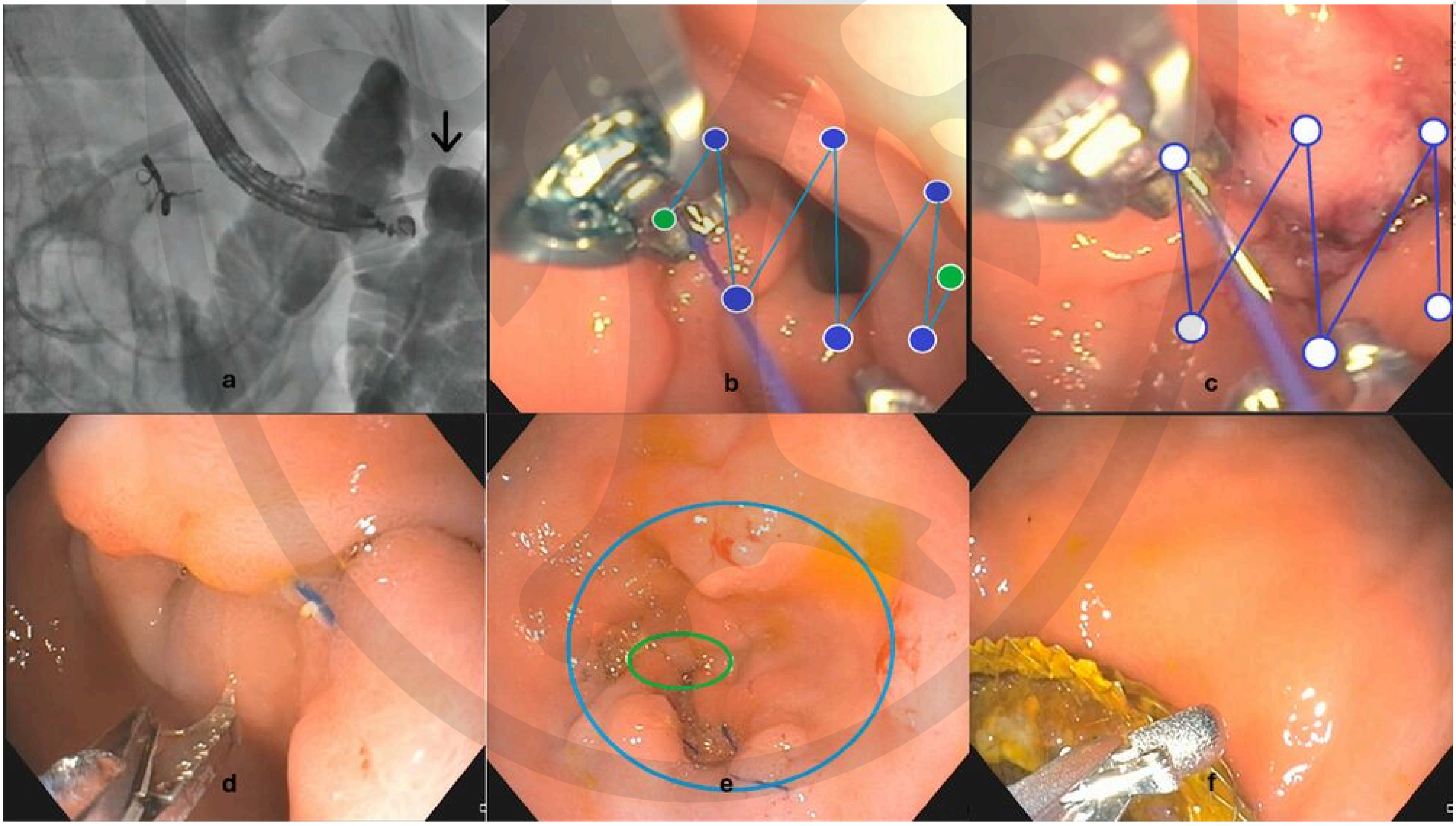
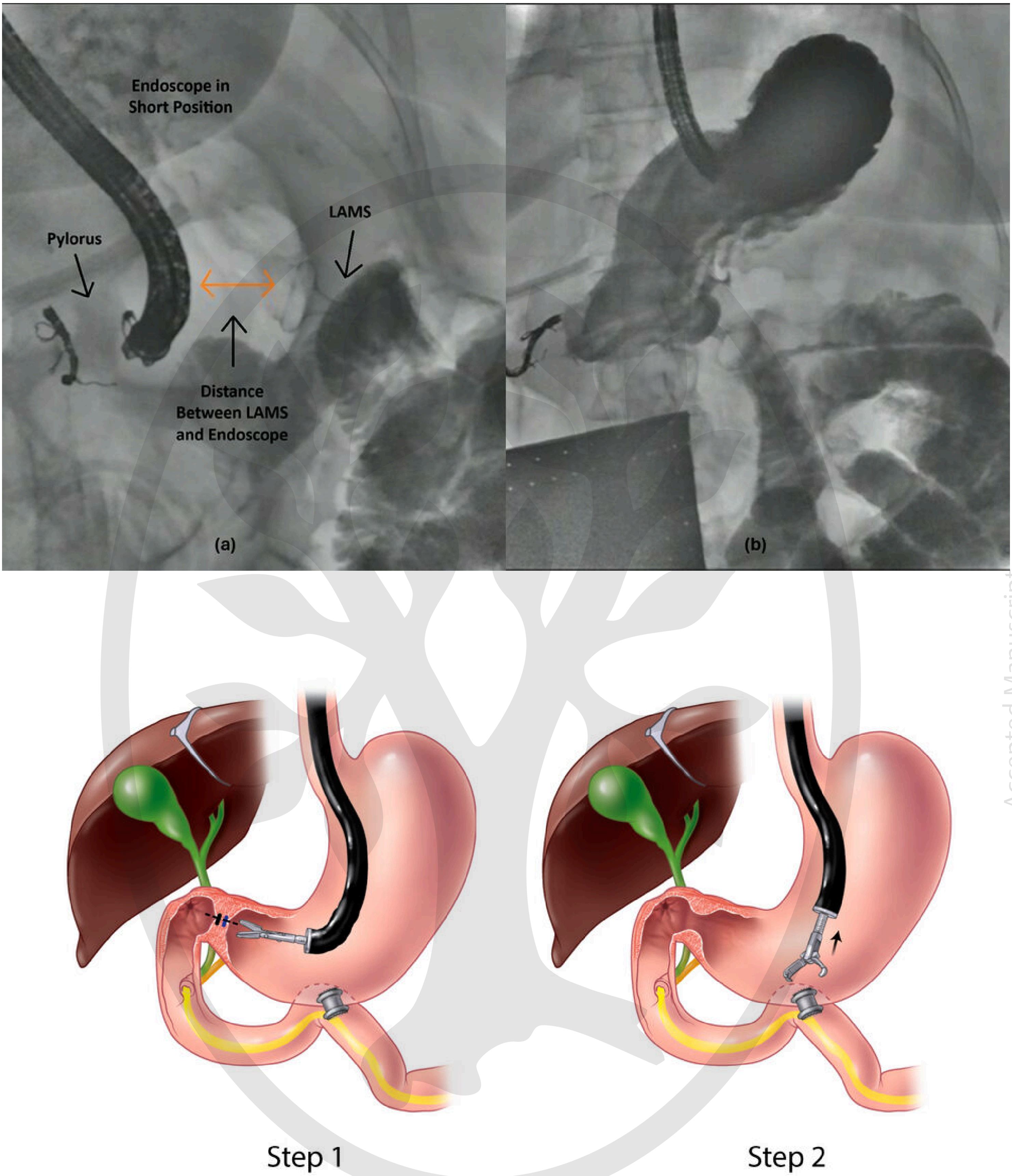
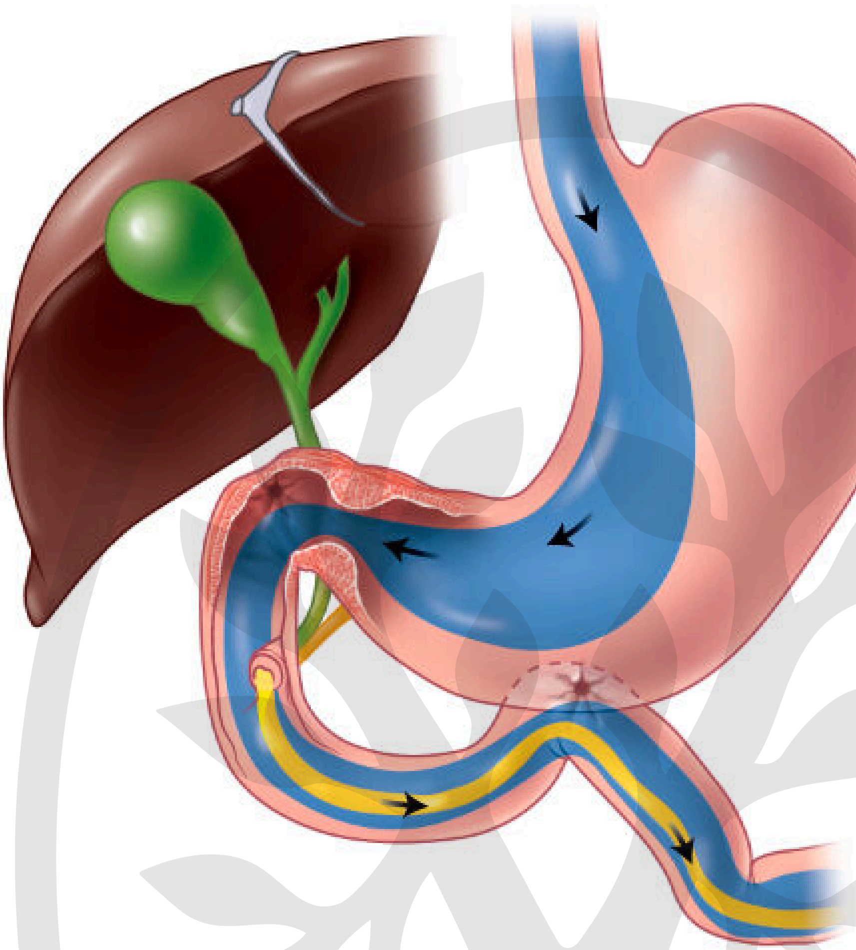
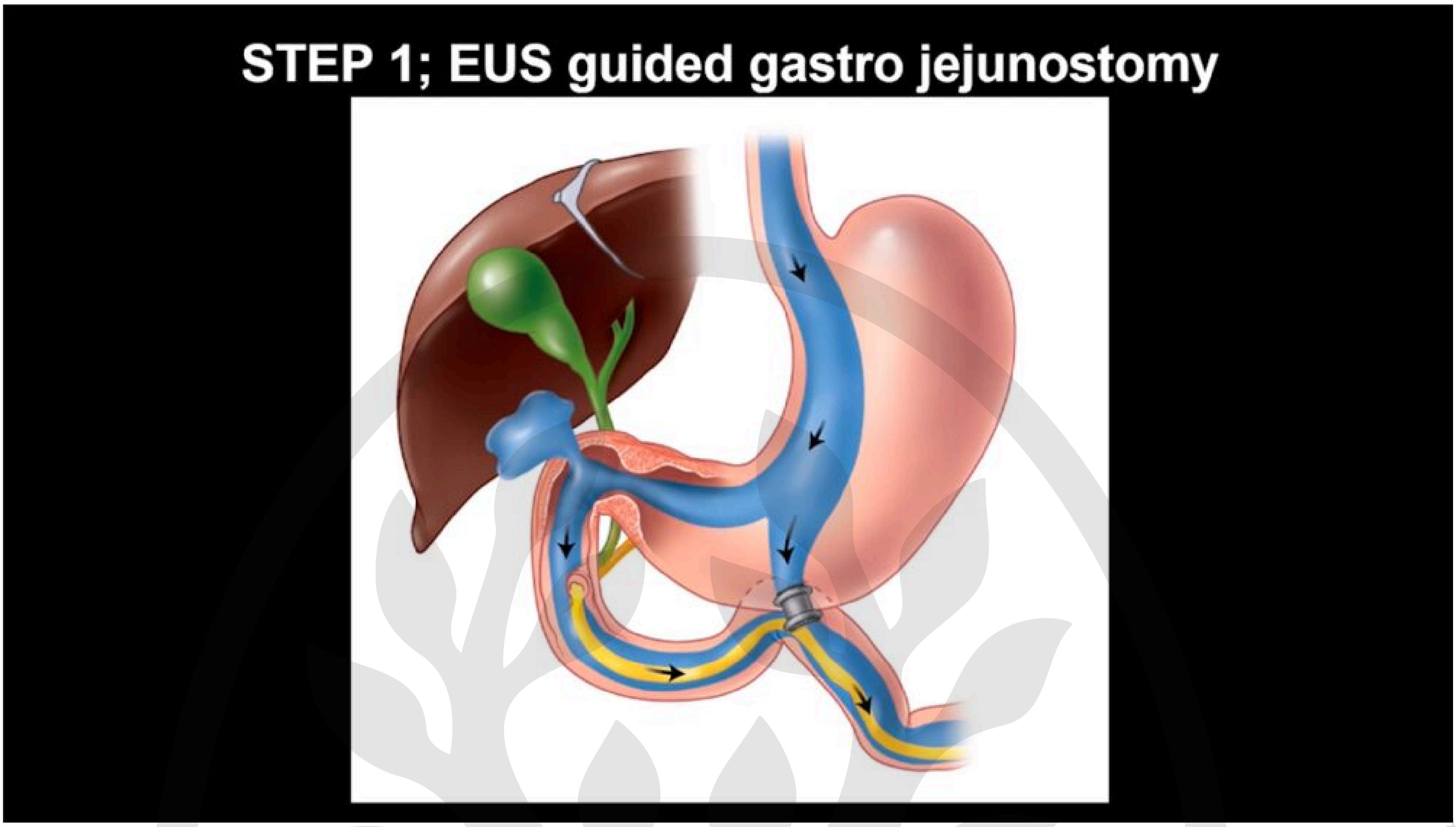



Endoscope in Short Position
Pylorus
LAMS
Distance Between LAMS and Endoscope
(a)
(b)
Step 1
Step 2




STEP 1; EUS guided gastro jejunostomy