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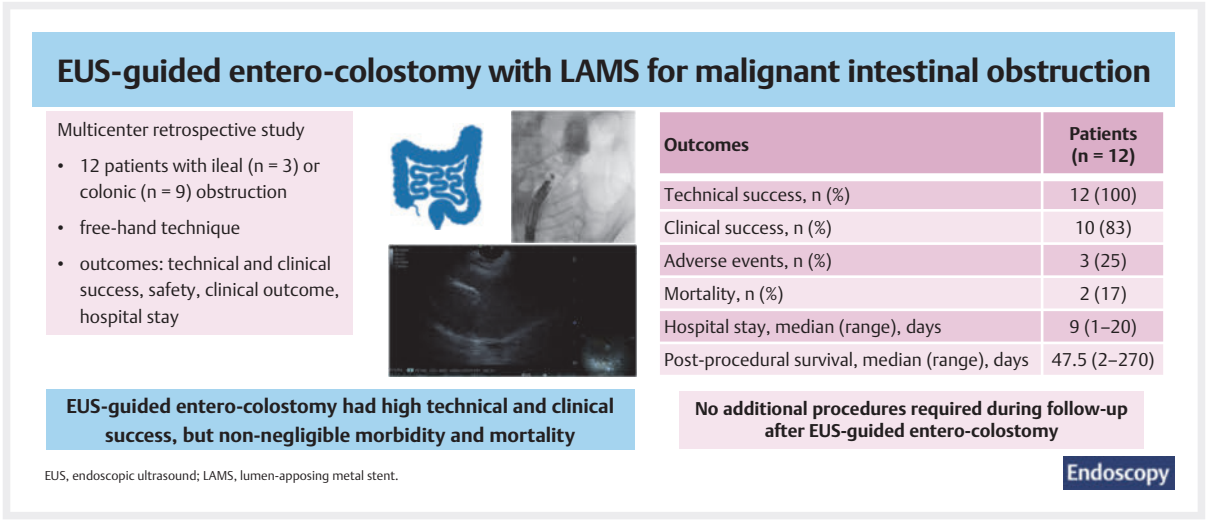
Endoscopic ultrasound-guided entero-colostomy with lumen-apposing metal stent as a rescue treatment for malignant intestinal occlusion: a multicenter study

GRAPHICAL ABSTRACT



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ABSTRACT

Background Surgery is the first-choice treatment for malignant intestinal obstruction (MIO); however, many patients are deemed unfit for surgery. Endoscopic ultrasound-guided entero-colostomy (EUS-EC) with a lumen-apposing metal stent (LAMS) could represent a new treatment option.

Methods Consecutive patients undergoing EUS-EC for MIO from November 2021 to September 2023 at four European tertiary referral centers were retrospectively enrolled. Multidisciplinary meetings determined whether patients were unsuitable for surgery or colonic stent placement, or refused surgery. The primary outcome was technical success of EUS-EC and secondary outcomes were clinical outcome, safety, and hospital stay.

Results 12 patients were enrolled (median age 72.5 [range 42–85] years; 58.3% female). Colonic adenocarcinoma was the primary tumor in 75.0% of patients and 91.7% had stage IV disease. Technical success was 100%. No LAMS misdeployment or other procedural adverse events occurred; three patients (25.0%) had severe post-procedural complications. Clinical success was achieved in 10 patients (83.3%), with 5 (50.0%) resuming chemotherapy after the procedure. Median post-procedural hospital stay was 9 (1–20) days and median overall survival was 47.5 (2–270) days.

Conclusions EUS-EC was a feasible technique and could be considered a possible alternative to standard approaches for MIO in highly selected patients.

Introduction

Endoscopic ultrasound (EUS)-guided lumen-apposing metal stent (LAMS) placement has been applied well beyond drainage of pancreatic fluid collections and walled-off necrosis [1]. Indeed, the European Society of Gastrointestinal Endoscopy (ESGE) has suggested other uses, such as EUS-guided gastroenterostomy [2, 3, 4].

Malignant intestinal obstruction (MIO) includes small-bowel and colonic obstruction. MIO is a relevant problem for patients with advanced malignancy as it is associated with the need to interrupt ongoing chemotherapy, worsening quality of life, and other life-threatening complications [5]. MIO represents the most common indication for palliative surgical consultation, but a high proportion of patients are deemed unfit for surgery (6.2%–50%) [5, 6]. Endoscopic procedures are alternative treatments for unfit patients or those declining surgery [7, 8]. Current endoscopic approaches have several limitations, and include enteral stenting and placement of percutaneous endoscopic gastrostomy tubes [7, 8, 9]. Based on EUS-guided gastroenterostomy outcomes [4], the recently proposed EUS-guided transmural stenting for by-passing MIO seems a better endoscopic solution [10]. Indeed, a few studies have suggested the feasibility of EUS-guided entero-colostomy (EUS-EC) [11, 12, 13].

The primary aim of the present study was to assess the technical success of EUS-EC in patients with MIO who are unfit for surgery. Secondary aims included safety of the procedure, symptom relief, time to refeeding, duration of hospital stay, and clinical outcome.

Methods

Study population

Consecutive patients with MIO undergoing EUS-EC from November 2021 to September 2023 at four different European centers were retrospectively enrolled.

All cases were discussed in multidisciplinary meetings. Patients considered unfit or refusing surgery and in whom colonic stent placement was considered at high risk of failure or complications [6, 9] were enrolled. All procedures were performed by four experienced endosonographers at high-volume interventional endoscopy centers. All operators had >10 years' experience, having performed >400 interventional EUS procedures per year, with >50 LAMS placements before the study period.

Inclusion criteria were: 1) symptomatic malignant colonic obstruction or malignant small-bowel obstruction; 2) computed tomography (CT) scan showing ileal or colonic MIO with dilated intestinal loops within 7 days before the procedure; 3) multidisciplinary meeting discussion before the procedure; 4) unfit for surgery; 5) colonic stent placement deemed unsafe; 6) informed consent. Exclusion criteria were: 1) acute MIO requiring emergency treatment; 2) unavailability of CT scan within 7 days; 3) rectal malignancy.

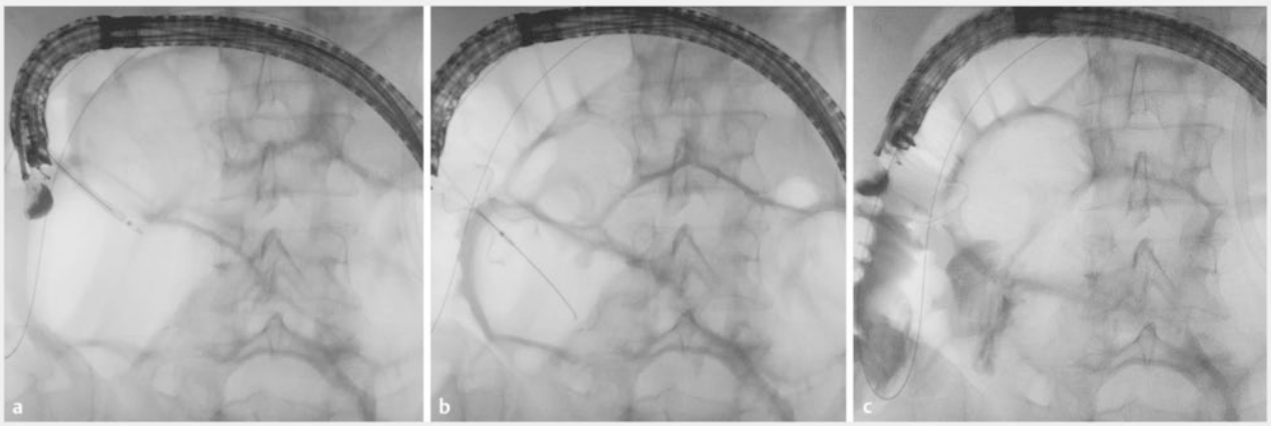
The study was approved by the Territorial Ethic Committee of Lazio Area 2 (81.23OSS). All patients gave consent for data collection for research purposes and to undergo the procedure.

Definitions

Technical success was defined as the ability to deploy the LAMS between the colon and the colonic or small-bowel target, proven by observation of intestinal material passing through the stent. Clinical success was defined as resolution of MIO for at least 2 weeks after the procedure. Resolution of MIO was defined as the combination of resolution of occlusive symptoms and passage of feces. Adverse events were classified and graded according to the Adverse Events in GI Endoscopy (AGREE) classification [14].

EUS-EC with LAMS: procedure technique

All procedures were performed with patients under deep sedation. EUS-EC with LAMS was performed using a transanal approach. All patients underwent bowel preparation by enema before the procedure. Endoscopic access was first obtained



▶ **Fig. 1** Sequential steps in the deployment of a lumen-apposing metal stent (LAMS) under fluoroscopic guidance. **a** After reaching the right colon, an electrocautery-enhanced LAMS is advanced toward the target bowel segment, proximal to the malignant stenosis. **b** The LAMS is then released between the target distal ileum and the right colon. **c** Technical success is then confirmed by passage of contrast through the LAMS into the distal ileum with no extraluminal spillage.

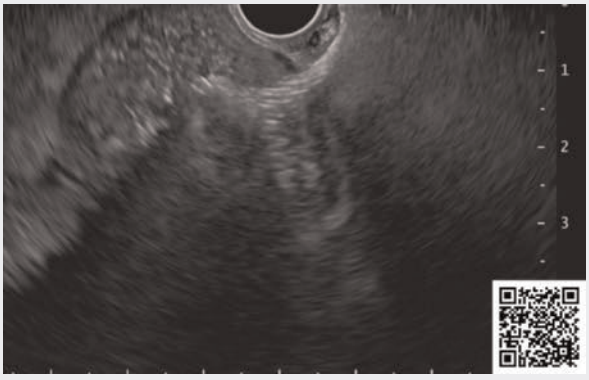
with a standard colonoscope (CF/PCF – Olympus, Tokyo, Japan; EC-760R V/M – Fujifilm Corp., Tokyo, Japan) for washing and exploration. In cases with angulated colonic flexures or sigmoid colons, a 0.035-inch guidewire was released to the appropriate colonic target. Use of endoscopic flexible overtubes was allowed. Therapeutic linear echoendoscopes were used in all patients (GF-UCT180 – Olympus; EG-580UT – Fujifilm Corp.) and were advanced transanally under fluoroscopic guidance until visualization of an adequate colonic or small-bowel target (dilated bowel tract nearest to the colonic segment).

A cautery-enhanced LAMS (AXIOS Stent and Electrocautery Enhanced Delivery System – Boston Scientific, Marlborough, Massachusetts, USA; Hot SPAXUS – Taewoong Medical, Gyeonggi-do, South Korea) was directly deployed under EUS and fluoroscopic visualization using a free-hand technique to create an anastomosis between the colon and dilated small bowel (▶ **Fig. 1**, **Video 1**) or colonic segment proximal to the stenosis (**Fig. 1s**, **Fig. 2s a**; see the online-only Supplementary material). Minimal carbon dioxide insufflation was applied during the procedure to reduce the risk of perforation. LAMS placement was confirmed by direct visualization of feces passing through the LAMS (**Fig. 2s b**) and by administration of contrast through the LAMS. Fluoroscopy at the end of the procedure was performed to confirm the absence of abdominal free air.

Intravenous antibiotic treatment with broad coverage for anaerobic and Gram-negative bacteria was ongoing or administered periprocedurally. Repeat CTs were performed for suspected complications.

Statistical analysis

Data were expressed as median (range) for continuous variables and as number (percentage) for categorical variables. Statistical analysis was performed with IBM SPSS statistical software, version 26.0 (IBM Corp., Armonk, New York, USA).



Video 1 Endosonographic image of an endoscopic ultrasound-guided entero-colostomy with a 20×10-mm lumen-apposing metal stent.
Online content viewable at:
https://doi.org/10.1055/a-2354-3352

Results

Study population

Overall, 12 consecutive patients undergoing EUS-EC with LAMS were enrolled at four European centers (**Table 1s**). Clinical characteristics of enrolled patients are summarized in ▶ **Table 1** and **Table 1s**. A total of 11 patients (91.7%) had stage IV disease. MIO included three malignant small-bowel obstructions (25.0%) and nine malignant colonic obstructions (75.0%). Indication for EUS-EC was MIO due to carcinosis in seven patients (58.3%) and primary tumor in five (41.7%). In all patients, colonic stent placement was considered to be at high risk of failure or complications. Indeed, in the nine patients with malignant

▶ **Table 1** Study population demographic and clinical characteristics.

	Patients (n = 12)
Male sex, n (%)	5 (41.7)
Age, median (range), years	72.5 (42–85)
Primary tumor, n (%)	
▪ Colonic adenocarcinoma	9 (75.0)
▪ Ovarian adenocarcinoma	2 (16.7)
▪ Cholangiocarcinoma	1 (8.3)
Cause of MIO, n (%)	
▪ Carcinosis	7 (58.3)
▪ Primary tumor	5 (41.7)
Malignancy duration, median (range), months	13 (1–108)
Ascites, n (%)	5 (41.7)
Carcinosis, n (%)	10 (83.3)
Location of obstruction, n (%)	
▪ Ileum	3 (25.0)
▪ Ascending colon	2 (16.7)
▪ Transverse colon	1 (8.3)
▪ Left colon	3 (25.0)
▪ Sigmoid colon	3 (25.0)

MIO, malignant intestinal occlusion.

▶ **Table 2** Procedure characteristics and patient outcomes.

	Patients (n = 12)[1]
LAMS size, n (%)	
▪ 15×10 mm	5 (41.7)
▪ 20×10 mm	5 (41.7)
▪ 16×20 mm	2 (16.7)
LAMS release site, n (%)	
▪ Right colon	2 (16.7)
▪ Transverse colon	1 (8.3)
▪ Left colon	2 (16.7)
▪ Sigmoid colon	2 (16.7)
▪ Rectum	5 (41.7)
Antibiotic prophylaxis, n (%)	12 (100)
Time to refeeding, median (range), days	1 (1–2)
Length of hospital stay, median (range), days	9 (1–20)
Death, n (%)	5 (41.7)
▪ Sepsis	2 (40.0)
▪ Malignancy progression	3 (60.0)
Overall post-procedural survival, median (range), days	47.5 (2–270)

LAMS, lumen-apposing metal stent.
[1]Percentages may not total 100% due to rounding.

colonic obstruction, three stenoses (33.3%) were located in the right colon in the presence of diverticular disease, and six (66.7%) were in the left colon (colonic adenocarcinoma n = 3; carcinosis n = 3), all of which were long and/or severely angulated. In all patients, MIO was newly diagnosed and the decision to perform a primary EUS-EC was shared in a multidisciplinary consultation. Other treatments (i. e. surgery) were ruled out for clinical reasons or were refused by the patient. The median time between MIO symptom onset and EUS-EC was 7.5 (range 4–20) days.

Procedure

Procedural characteristics are summarized in ▶ **Table 2**. The rectum was the most common segment used for LAMS deployment (five patients [41.7%]). The anastomosis was performed between the colon and the small bowel or a colonic segment proximal to the stenosis in seven (58.3%) and five (41.7%) patients, respectively.

The LAMS used was the Hot AXIOS stent in 10 patients (83.3%) and the Hot SPAXUS stent in 2 (16.7%). Antibiotic treatment was ongoing at the time of the procedure in all patients.

Technical success was achieved in all 12 procedures (100%) (▶ **Table 3**). No LAMS misdeployment or other procedural adverse events occurred. There were three post-procedural complications recorded (25.0%), including one sepsis (grade II), which was successfully treated with antibiotics, and two severe sepsis (grade V), which led to death [14]. Clinical success was observed in 10 patients (83.3%). The two patients with clinical failure died soon after the procedure (1 and 5 days, respectively) due to adverse events.

Outcomes

Of the 10 patients discharged from the hospital, 5 (50.0%) were rehospitalized. Only one of the patients was rehospitalized due to subocclusive symptoms, which occurred, presumably, after a meal rich in insoluble fiber; however, reintervention was not required as spontaneous resolution was confirmed by CT scan. Other causes of rehospitalization included nephrostomy displacement (1 [20.0%]), chemotherapy toxicity (1 [20.0%]), hydroureteronephrosis (1 [20.0%]), and acute kidney failure (1 [20.0%]). The median time from post-procedural discharge to rehospitalization was 25 (range 14–150) days, while median rehospitalization stay was 1 (range 1–25) day.

Of the 10 patients, 5 (50.0%) resumed chemotherapy within 1 month from the procedure and all (100%) tolerated oral feeding until the last follow-up or death.

Overall, five patients died during follow-up. The causes of death and post-procedural survival are reported in ▶ **Table 2**.

▶ **Table 3** Clinical characteristics and outcomes of patients undergoing endoscopic ultrasound-guided ileo-colostomy or colo-colostomy.

	Ileo-colostomy (n = 7)[1]	Colo-colostomy (n = 5)[1]
Age, median (range), years	71 (42–85)	74 (63–83)
Primary tumor, n (%)		
▪ Colonic adenocarcinoma	6 (85.7)	3 (60.0)
▪ Ovarian adenocarcinoma	0 (0)	2 (40.0)
▪ Cholangiocarcinoma	1 (14.3)	0 (0)
Carcinosis, n (%)	2 (28.6	3 (60.0)
Location of obstruction, n (%)		
▪ Ileum	3 (42.9)	0 (0)
▪ Right colon	2 (28.6)	0 (0)
▪ Transverse colon	1 (14.3)	0 (0)
▪ Left colon	1 (14.3)	0 (0)
▪ Sigmoid colon	1 (14.3)	2 (40.0)
▪ Rectum	0 (0)	3 (60.0)
LAMS size, n (%)		
▪ 15×10 mm	3 (42.9)	2 (40.0)
▪ 20×10 mm	2 (28.6)	3 (60.0)
▪ 16×20 mm	2 (28.6)	0 (0)
Proximal LAMS target, n (%)		
▪ Right colon	2 (28.6)	0 (0)
▪ Transverse colon	1 (14.3)	0 (0)
▪ Left sided colon	2 (28.6)	0 (0)
▪ Sigmoid colon	1 (14.3)	1 (20.0)
▪ Rectum	1 (14.3)	4 (80.0)
Technical success, n (%)	7 (100)	5 (100)
Clinical success, n (%)	5 (71.4)	5 (100)
Adverse events, n (%)	3 (42.9)	0 (0)
Time to refeeding, median (range), days	1 (0–1)	1 (1–2)
Length of hospital stay, median (range), days	9 (1–20)	9 (2–20)
Death, n (%)	3 (42.9)	2 (40.0)
Survival post-procedure, median (range), days	30 (2–90)	90 (30–270)

LAMS, lumen-apposing metal stent.
[1]Percentages may not total 100% due to rounding.

EUS-guided ileo-colostomy vs. colo-colostomy

Clinical characteristics and outcomes of patients undergoing EUS-guided ileo-colostomy and colo-colostomy have been reported separately in ▶ **Table 3** and **Table 2s**.

Discussion

The first-choice treatment for MIO is palliative surgery, which is frequently burdened by high operative risk [5, 6]. According to the ESGE guidelines, for obstructive left colon cancer, use of intraluminal self-expandable metal stents is recommended [9]; however, this approach carries possible long-term oncological disadvantages [6, 15]. Alternatively, right hemicolectomy represents the procedure of choice for obstructive right colon cancer, while intraluminal stent placement, although feasible, has higher risks and lower efficacy [5, 6].

Recently, EUS-guided anastomosis with LAMS has been applied for treatment of colonic and distal small-bowel malignant strictures [10], with technical and clinical success rates in the range of 80%–100% and 70%–92.3%, respectively [11, 12]. Overall, no intraprocedural complications and few post-procedural adverse events were reported (10%–15.4%) [11, 12].

In the present study including 12 patients undergoing EUS-EC with LAMS, we confirmed the high technical success (100%) of the procedure. In contrast to previous studies [11, 12], all procedures achieved direct placement of the stent at the first attempt using a free-hand technique to minimize the infectious risk deriving from possible peritoneal spillage of feces.

As suggested in prior studies [11, 12], the high technical success may be due to appropriate patient selection, based on radiological evidence of clear signs of bowel occlusion, which is essential to ease ultrasonographic identification of a target proximal to the MIO site.

The use of large-caliber LAMSs in the current study led to a high clinical success rate (83.3%), characterized by rapid symptom resolution and allowing an oral diet to be resumed the day after the procedure. This may explain the sustained clinical effectiveness of this technique. Indeed, further hospitalizations for MIO recurrence were not required. Only one patient was re-hospitalized for subocclusion, with spontaneous resolution. Considering the other therapeutic options available for treatment of MIO, EUS-EC may allow a better quality of life in the end-of-life setting, avoiding major surgical interventions and permitting oral feeding until the end.

We confirmed the satisfactory safety profile of EUS-EC, with no procedural stent-related adverse events and few post-procedural complications, which, though severe (grade II and V) [15], were in accordance with the US case series [11, 12].

In contrast to previous studies [11, 12], we performed five colo-colostomy (41.7%) and seven ileo-colostomy (58.3%) procedures. In both procedures, the technique applied was broadly the same and most of the outcomes were comparable. However, postoperative sepsis was reported only in patients undergoing ileo-colostomy (n = 3). Even though the limited study population prevented us from performing a reliable statistical comparison, the greater vascularization of the small bowel, which could facilitate bacterial translocation, may be implicated in this observation. The possible role of paromomycin use in preventing this complication may be investigated.

Owing to the different characteristics of MIO, it appears difficult to standardize the EUS-EC technique. The small variations introduced in every procedure underline the need for the op-

erator to be experienced in operative and fluoroscopy-aided endoscopy. Overall, considering the outcomes of patients undergoing EUS-guided colo-colostomy and ileo-colostomy, we suggest that the easiest target available should be preferred.

One potential main limitation of EUS-EC may be that it is impossible with the currently adopted technique to precisely identify the target small-bowel loop. Fluoroscopy and CT scan images are useful for choosing the most distal small-bowel segment possible, to minimize the risk of malabsorption. Moreover, the experience of the endosonographer should help to lower the risk of targeting a proximal intestinal loop.

To the best of our knowledge this is one of the first and largest European studies investigating the role of EUS-EC for MIO palliation. Limitations of the study include the small study population and the heterogeneity of patients and procedures; however, this reflects the real-world application of this novel technique. The main strengths of the study are the multicenter patient population, which gives further reliability to our results, and the comparison between ileo-colostomy and colo-colostomy.

In conclusion, we confirmed the feasibility and efficacy of this novel technique in highly selected cases. Our study could suggest EUS-EC with LAMS as an alternative treatment to more invasive surgical procedures and to potentially less efficacious endoscopic approaches to MIO, allowing a better end-of-life period in patients with advanced malignancies. However, more data are needed before EUS-EC can be recommended as an alternative to colonic stenting.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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