UNITED EUROPEAN GASTROENTEROLOGY ueg journal

Original Article

United European Gastroenterology Journal
2016, Vol. 4(6) 770–777

DOI: 10.1177/2050640615626051
ueg.sagepub.com
SAGE

Endoscopic management of patients with post-surgical leaks involving the gastrointestinal tract: A large case series

Raffaele Manta[1], Angelo Caruso[2], Carlo Cellini[2], Mariano Sica[2], Angelo Zullo[3], Vincenzo Giorgio Mirante[2], Helga Bertani[2], Marzio Frazzoni[4], Massimiliano Mutignani[1], Giuseppe Galloro[5] and Rita Conigliaro[2]

Abstract

Background: Post-surgical anastomotic leaks often require a re-intervention, are associated with a definite morbidity and mortality, and with relevant costs. We described a large series of patients with different post-surgical leaks involving the gastrointestinal tract managed with endoscopy as initial approach.

Methods: This was a retrospective analysis of prospectively collected cases with anastomotic leaks managed with different endoscopic approaches (with surgical or radiological drainage when needed) in two endoscopic centres during 5 years. Interventions included: (1) over-the-scope clip (OTSC) positioning; (2) placement of a covered self-expanding metal stent (SEMS); (3) fibrin glue injection (Tissucol); and (4) endo-sponge application, according to both the endoscopic feature and patient's status.

Results: A total of 76 patients underwent endoscopic treatment for a leak either in the upper (47 cases) or lower (29 cases) gastrointestinal tract, and the approach was successful in 39 (83%) and 22 (75.9%) patients, respectively, accounting for an overall 80.3% success rate. Leak closure was achieved in 84.9% and 78.3% of patients managed by using a single or a combination of endoscopic devices. Overall, leak closure failed in 15 (19.7%) patients, and the surgical approach was successful in all 14 patients who underwent re-intervention, whilst one patient died due to sepsis at 7 days.

Conclusions: Our data suggest that an endoscopic approach, with surgical or radiological drainage when needed, is successful and safe in the majority of patients with anastomotic gastrointestinal leaks. Therefore, an endoscopic treatment could be attempted before resorting to more invasive, costly and risky re-intervention.

Keywords

Anastomotic leak, fistula, endoscopy, treatment, OTSC, SEMS, fibrin glue

Received: 4 August 2015; accepted: 13 December 2015

Introduction

Among potential post-surgical complications involving the gastrointestinal tract (GI), anastomotic leak onset is surely a dreadful event.[1] Indeed, a fistula often requires a re-intervention, is associated with a definite morbidity and mortality, and with relevant costs.[2–4] An early post-surgical fistula – i.e. occurring in the first week following the operation – is generally managed with a surgical approach, which is mandatory when peritonitis, mediastinitis, or severe generalized sepsis are present.[5,6] A fistula occurring later in the post-operative period often presents with a subtle clinical

[1]Surgical Digestive Diagnostic and Interventional Endoscopy, "Niguarda-Cà Granda" Hospital, Milan, Italy
[2]Gastroenterology and Endoscopy Unit, "Nuovo S. Agostino" Hospital, Modena, Italy
[3]Gastroenterology and Digestive Endoscopy, "Nuovo Regina Margherita" Hospital, Rome, Italy
[4]Digestive Physiopathology Unit, Baggiovara Hospital, Modena, Italy
[5]Department of Clinical Medicine and Surgery, Unit of Surgical Digestive Endoscopy, Federico II University of Naples, Naples, Italy

Corresponding author:
Raffaele Manta, MD, Endoscopy Unit Niguarda Ca-Granda Hospital, Piazza dell'Ospedale Maggiore 3, 20162, Milano, Italy.
Email: r.manta@libero.it

manifestation, and no definite consensus exists on the most appropriate therapeutic approach in this setting. Different devices, including endoclips, stents, endoscopic suturing devices, fibrin glue injection, and endo-luminal vacuum devices have been introduced in recent decades.[7,8] These allowed an endoscopic approach to be performed in patients with post-surgical leakage, so that such a complication could be treated conservatively in selected cases without a re-intervention. We previously described a series of patients with post-surgical leakage, in either upper or lower GI tract, in whom the endoscopic positioning of over-the-scope clip (OTSC) was successful in 11 out of 12 cases.[9] Hereby, we report the endoscopic management in a large series of patients with different post-surgical leaks involving the GI tract.

Patients and methods

Data for all patients with a post-surgical leak involving the GI tract, irrespective of the previous surgical intervention type, who were referred to two Endoscopic Units to be treated with an endoscopic approach, were prospectively collected in a dedicated database. In detail, our case series included only those patients with a post-surgical leak referred by the surgeon for an initial endoscopic attempt in order to avoid re-intervention. Information on the previous surgical approach (laparoscopic or open), indication for surgery (malignant or benign disease), time of fistula occurrence (early or delayed), site of leak (upper or lower GI tract), diameter of leak, the endoscopic device used, technical endoscopic success, post-endoscopic complications, the need for an additional approach for purulent content drainage (surgical or radiological), the hospital stay, and the clinical outcome was collected. The fistula was defined as 'early' when occurring in the week following surgery, or 'delayed' when later. A complete leakage closure was verified at endoscopic and/or radiological assessment. The endoscopic treatments included: (1) OTSC positioning; (2) placement of a covered self-expanding metal stent (SEMS); (3) fibrin glue injection (Tissucol); and (4) endo-sponge application, according to both the endoscopic feature and the patient's status. Briefly, the first attempt was to apply one or more OTSC. Fibrin glue was used as an adjunctive treatment to close the gap between two OTSCs, when needed. A SEMS was applied when the closure was considered incomplete at endoscopy. When dehiscence characteristics (diameter, site, edge, etc.) were not fitting for OTSC positioning, a SEMS was directly used. We employed either 'partially covered' or 'full-covered' SEMSs. In the upper GI, we used 'partially covered' SEMSs from April 2009 to September 2013, and thereafter a 'fully covered' SEMS (Taewoong Medical, Seoul, Korea). For colon SEMS, we used only 'partially covered' SEMSs. The SEMSs were changed after 1 month if leak closure was not achieved. Endo-sponge was the first approach when an abscess cavity was present beyond the anastomotic leak. For the latter approach, an open-pored polyurethane sponge was installed transanally by using an endoscope after examination and rinsing of the abscess cavity with saline solution. The endo-sponge was periodically changed, in an out-patient setting, until fistula closure was achieved, according to the procedure reported elsewhere.[10] The initial endo-sponge positioning was performed in hospital, and the changing as out-patient until closure. Single or multiple endoscopic devices were used, based on site of leak and the therapeutic outcome. In those patients with a fluid collection in the abdominal cavity, drainage by either a radiological or surgical approach was performed, beyond the endoscopic treatment. In addition, all patients received broad-spectrum antibiotics, and parenteral nutrition until an adequate oral food intake was possible. Before endoscopic procedures, written informed consent was obtained by each patient.

Results

Overall, 76 patients with a post-surgical leak involving the GI tract were treated with an endoscopic approach from April 2009 to September 2014. There were 36 males, and the mean age was 63 years (range: 23–88). The surgery was performed for a neoplastic disease in 52 (68.4%) patients, and for a benign disease in the remaining 24 cases. An open or laparoscopic surgical approach was performed in 43 (56.6%) and 34 patients, respectively. The series included five leaks developed after gastric-oesophageal anastomosis, 10 following bariatric surgery, 22 gastric resections, five pancreatic surgeries, five small intestine resections, 24 colorectal, and five urologic surgical interventions. The intestinal leak was classified as early in 36 (47.4%) cases, and delayed in 40 patients. Overall, 47 and 29 patients were managed with only endoscopic treatment for either upper or lower GI leak, respectively; outcomes are provided in Tables 1 and 2.

As shown, in the upper tract the endoscopic treatment was successful 39 (83%) patients. In three out of 47 patients SEMS placement was complicated by stent migration, requiring another SEMS larger in diameter in order to treat the leak. No complications were observed in OTSC positioning procedure. A laparoscopic repair was needed in five cases (one unsuccessful: oesophagectomy), and total gastrectomy in two patients, whilst one patient with a total gastrectomy died from sepsis at 7 days (Table 1). A case leak closure following OTSC placement is provided in Figure 1.

Table 1.Please insert end period Patients with anastomotic leaks involving the upper intestinal tract

N	Surgery(type)	Fistula type	Diameter (mm)	Endoscopic therapy	Success(Yes/Not)	Other therapy	Final outcome	Hospitalstay (days)
1	Heller's myotomy	Early	40	SEMS (3)*	Not	Laparoscopic suturing	Oesophagectomy	180
2	Oesophagectomy	Early	40	OTSC (2)* + SEMS (2)	Yes	Not	Closure	60
3	Oesophagectomy	Delayed	8	SEMS (1)	Yes	Not	Closure	20
4	Nissen's funduplication	Early	15	OTSC (1) + SEMS (2)	Yes	Not	Closure	23
5	Nissen's funduplication	Delayed	55	OTSC (4) + Tissucol*	Not	Laparoscopic suturing	Closure	100
6	Sleeve gastrectomy	Delayed	40	OTSC (2) + SEMS (1)	Not	Laparoscopic suturing	Closure	37
7	Sleeve gastrectomy	Early	12	SEMS (2)	Not	Laparoscopic suturing	Closure	92
8	Sleeve gastrectomy	Early	30	SEMS (1)	Yes	Not	Closure	67
9	Sleeve gastrectomy	Delayed	30	SEMS (2)	Yes	Not	Closure	78
10	Sleeve gastrectomy	Delayed	40	OTSC (2) + SEMS (1)	Not	Open re-intervention	Gastrectomy	78
11	Sleeve gastrectomy	Early	25	OTSC (2) + SEMS (1)	Yes	Surgical drainage	Closure	90
12	Gastric by-pass	Delayed	12	OTSC (1) + SEMS (1)	Yes	Radiological drainage	Closure	21
13	Gastric by-pass	Delayed	25	OTSC (2) + Tissucol	Yes	Radiological drainage	Closure	120
14	Gastric banding removal	Early	8	OTSC (1)	Yes	Not	Closure	15
15	Gastric banding removal	Delayed	10	OTSC (1)	Yes	Not	Closure	21
16	Total gastrectomy	Delayed	15	OTSC (1) + SEMS (1)	Yes	Not	Closure	24
17	Total gastrectomy	Early	10	OTSC (1)	Yes	Not	Closure	10
18	Total gastrectomy	Delayed	15	OTSC + SEMS (2)	Yes	Not	Closure	45
19	Total gastrectomy	Delayed	30	SEMS (2)	Yes	Not	Closure	50
20	Total gastrectomy	Early	25	OTSC (1)	Yes	Not	Closure	30
21	Total gastrectomy	Early	5	OTSC (1)	Yes	Not	Closure	10
22	Total gastrectomy	Early	5	OTSC (1)	Yes	Not	Closure	5
23	Total gastrectomy	Early	5	OTSC (1)	Yes	Not	Closure	5
24	Total gastrectomy	Delayed	15	OTSC (1) + SEMS (1)	Yes	Not	Closure	18
25	Total gastrectomy	Delayed	15	OTSC (1) + SEMS (1)	Yes	Not	Closure	22

(continued)

Table 1. Continued

N	Surgery(type)	Fistula type	Diameter (mm)	Endoscopic therapy	Success(Yes/Not)	Other therapy	Final outcome	Hospitalstay (days)
26	Total gastrectomy	Early	40	OTSC (2) + SEMS (1)	Yes	Surgical drainage	Closure	21
27	Total gastrectomy	Early	40	OTSC (2) + SEMS (2)	Yes	Surgical drainage	Closure	88
28	Total gastrectomy	Early	40	OTSC (2) + SEMS (2)	Not	Radiological drainage	Dead	7
29	Total gastrectomy	Early	50	OTSC (3) + SEMS (1)	Yes	Surgical drainage	Closure	60
30	Total gastrectomy	Early	5	OTSC (1)	Yes	Radiological drainage	Closure	5
31	Total gastrectomy	Early	30	OTSC (1) + SEMS (2)	Yes	Radiological drainage	Closure	45
32	Partial gastrectomy	Early	5	OTSC (1)	Yes	Not	Closure	5
33	Partial gastrectomy	Delayed	10	OTSC (1)	Yes	Radiological drainage	Closure	7
34	Partial gastrectomy	Early	10	OTSC (1)	Yes	Not	Closure	7
35	Partial gastrectomy	Delayed	40	OTSC (2) + Tissucol	Not	Open re-intervention	Gastrectomy	28
36	Partial gastrectomy	Delayed	5	OTSC (1)	Yes	Not	Closure	5
37	Partial gastrectomy	Delayed	7	OTSC (1)	Yes	Not	Closure	10
38	Whipple's intervention	Delayed	8	OTSC (1)	Yes	Not	Closure	14
39	Whipple's intervention	Delayed	5	OTSC (1)	Yes	Not	Closure	21
40	Whipple's intervention	Delayed	5	OTSC (1)	Yes	Not	Closure	12
41	Whipple's intervention	Early	5	OTSC (1)	Yes	Surgical drainage	Closure	14
42	Whipple's intervention	Delayed	10	OTSC (1)	Yes	Surgical drainage	Closure	15
43	Duodenal resection	Early	10	OTSC (1)	Yes	Not	Closure	7
44	Duodenal resection	Delayed	5	OTSC (1)	Yes	Not	Closure	5
45	Jejunal resection	Delayed	10	OTSC (1)	Yes	Not	Closure	7
46	Ileal resection	Early	20	OTSC (1) + SEMS (1)	Not	Laparoscopic suturing	Closure	21
47	Ileal resection	Early	8	OTSC (1)	Yes	Not	Closure	7

*SEMS: Self-expandable metallic stent (number of device used); OTSC: over-the-scope clip; Tissucol: fibrin glue injection.

Table 2. Patients with anastomotic leaks involving the colon

N	Surgery	Fistula type	Diameter (mm)	Endoscopic therapy*	Success (yes/not)	Other therapy	Final outcome	Hospital stay (days)
1	Anterior rectal resection	Early	10	OTSC (1)	Yes	Not	Closure	15
2	Anterior rectal resection	Delayed	5	OTSC (1)	Yes	Not	Closure	5
3	Anterior rectal resection	Delayed	30	Endo-sponge	Yes	Not	Closure	Out-patient
4	Anterior rectal resection	Delayed	30	Endo-sponge	Yes	Not	Closure	Out-patient
5	Anterior rectal resection	Delayed	6	OTSC (1)	Yes	Not	Closure	7
6	Anterior rectal resection	Early	50	OTSC (2) + SEMS (1)	Not	Open re-intevention	Miles' resection	64
7	Anterior rectal resection	Early	50	OTSC (2) + SEMS (1)	Not	Open re-intevention	Miles' resection	55
8	Anterior rectal resection	Delayed	15	Endo-sponge	Yes	Not	Closure	Out-patient
9	Anterior rectal resection	Early	10	OTSC (1)	Yes	Not	Closure	7
10	Anterior rectal resection	Early	5	OTSC (1)	Yes	Not	Closure	6
11	Anterior rectal resection	Early	5	OTSC (1)	Yes	Not	Closure	5
12	Anterior rectal resection	Delayed	30	Endo-sponge	Yes	Not	Closure	Out-patient
13	Anterior rectal resection	Early	20	OTSC (2) + SEMS (1)	Yes	Radiological drainage	Closure	34
14	Anterior rectal resection	Early	10	OTSC (2)	Yes	Radiological drainage	Closure	15
15	Left colectomy	Delayed	20	Endo-sponge	Yes	Not	Closure	Out-patient
16	Left colectomy	Early	50	Endo-sponge	Yes	Not	Closure	Out-patient
17	Left colectomy	Early	20	OTSC (1) + SEMS (1)	Yes	Not	Closure	41
18	Left colectomy	Early	20	OTSC (2)	Not	Radiological drainage	Open re-invention	48
19	Right colectomy	Delayed	10	OTSC (1)	Yes	Not	Closure	7
20	Right colectomy	Delayed	30	OTSC (2)	Not	Radiological drainage	Open re-invention	30
21	Right colectomy	Delayed	15	OTSC (1)	Not	Laparoscopic suturing	Closure	28
22	Total colectomy	Delayed	30	Endo-sponge	Yes	Not	Closure	Out-patient
23	Total colectomy	Delayed	25	OTSC (2)	Not	Radiological drainage	Open re-invention	32
24	Hartmann's resection	Delayed	5	OTSC (1)	Yes	Not	Closure	7
25	Prostatectomy	Delayed	10	OTSC (1)	Yes	Not	Closure	5
26	Prostatectomy	Early	5	OTSC (1)	Yes	Not	Closure	7
27	Prostatectomy	Delayed	5	OTSC (1)	Yes	Not	Closure	7
28	Cystectomy	Delayed	7	OTSC (1)	Yes	Not	Closure	5
29	Cystectomy	Delayed	15	OTSC (2)	Not	Open re-intervention	Nephrostomy	31

*SEMS: Self-expandable metallic stent (number of device used); OTSC: over-the-scope clip; Endo-sponge: open-pored polyurethane sponge.

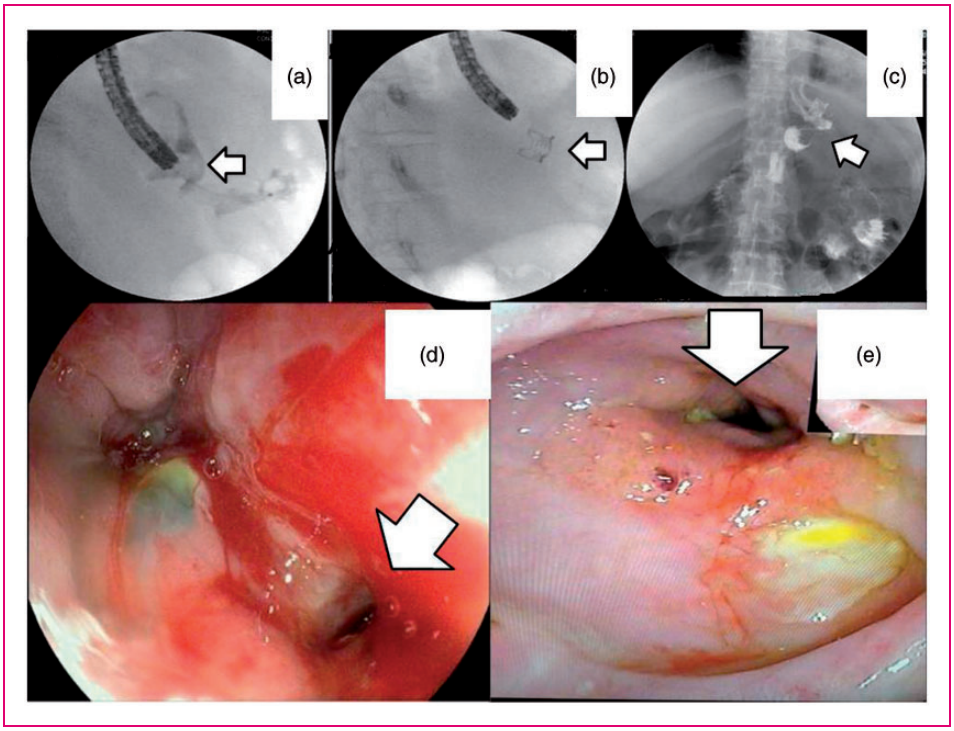

Figure 1. Patient with a <10 mm post-surgical leak following oesophageal-jejunal anastomosis. Radiological pictures: anastomotic leak (a), OTSC placement (b), and leak closure (c). Endoscopic pictures: anastomotic leak (d, arrow), and complete leak closure (e; arrow indicates the anastomotic lumen).

Table 3. Outcome of fistula treatment according to devices used

Device used	Patients treated	Fistula closure (%)
OTSC	39	33 (84.6)
SEMS	7	5 (71.4)
Endo-sponge	7	7 (100)
OTSC + SEMS	21	17 (80.9)
OTSC + Tissucol	1	0
SEMS + Tissucol	1	1

In the colon, leak closure following the endoscopic approach was achieved in 22 (75.9%) patients. No complications regarding either SEMS or OTSC positioning were recorded in these patients. In failure cases, Miles' resection was needed in two patients, open re-intervention in three, laparoscopic repair in one case, and cutaneous nephrostomy in another patient (Table 2). Therefore, following an endoscopic approach the anastomotic leak was successfully closed in 61 (80.3%) out of 76 treated patients. Overall, the median of hospital stay was 16 days (range: 5–180 days), being <1 month in 49 (71%) out of 69 cases treated as inpatients (Tables 1 and 2). Leak closure was achieved in 45 (84.9%) out of 53 patients managed by using only one type of device, and in 18 (78.3%) out of 23 cases following a combination of endoscopic devices, without a statistically significant difference (Table 3). Finally, a similar success rate was achieved in patients with early (29/36; 80.6%) and those with a delayed (32/40; 80%) fistula.

Discussion

Post-surgical leak in the GI tract is potentially associated with devastating consequences.[1–6] In the past, a conservative approach was generally performed, but re-intervention was frequently needed, with relevant post-surgical morbidity and a definite mortality. Therefore, to attempt less invasive therapeutic approaches for treating these – generally debilitated – patients is surely an advantage. In recent decades novel endoscopic closure techniques have been introduced, allowing the successful treatment of selected patients with a GI fistula.[1,7,8] Therefore, the management of patients with a post-surgical leak involving the GI tract has dramatically changed. However, based on the heterogeneity of patients, the different anatomic sites involved, diverse leakage type and devices used, no codified approach for all cases exists. Therefore, reporting large cases series in the literature is of paramount importance to increase knowledge about the potential

applications and outcomes of different endoscopic approaches. Analysis of our prospectively collected data showed that selected patients with a post-surgical GI leakage may be successfully managed in the majority of cases with a conservative, endoscopic treatment. In detail, the OTSC and the OTSC plus SEMS were the most frequently used devices in our experience, and leak closure was achieved in as many as 81–85% of cases treated with these approaches.

For treatment of colon leaks, we commonly used OTCS (16 cases), whilst a SEMS was positioned in only four of these patients. Although a recent series found the SEMS application was successful in 86% of 22 cases with leakage following colorectal resection,[11] stent migration has been reported to occur in as many as 25% of patients, particularly in the lower GI tract where the increased motility causes stent migration both distally and proximally.[1] Moreover, the majority of patients complained of faecal incontinence following SEMS placement, which regressed only some weeks later (average: 14 wks), affecting quality of life.[11] All these inconveniences are lacking when using one or more OTSC.

Endo-sponge application to manage patients with anastomotic leakage following colorectal surgery was introduced more recently. A recent systematic review of literature reported data from 174 patients treated with endo-sponge in 13 different case series, with a success rate >94%.[12] In our experience, treatment with endo-sponge was successful in all seven patients with colorectal anastomotic leakages, all managed as outpatients, without complications or recurrence.

A novel finding coming from our series is that endoscopic repair of a rectal leak is possible even following urologic interventions. Indeed, by positioning an OTSC we achieved the closure in four out of five patients following cystectomy or prostatectomy, suggesting that this approach could be implemented in clinical practice.

Overall, in our case series, the endoscopic approach for leak closure failed in 15 (19.7%) patients, including eight cases in the upper GI tract and seven cases in the colon. A surgical re-intervention was successful in all 14 retreated patients, whilst one patient died from a generalized sepsis at 7 days following total gastrectomy for cancer, despite positioning of two OTSC and two SEMS, and radiological drainage.

Possible limitations of our study are the retrospective design and heterogeneity of patients, preventing a direct comparison among different groups. Moreover, we collected only those patients referred by the surgeon for an endoscopic attempt in order to initially avoid re-intervention. Therefore, the prevalence of different conditions we treated did not reflect the absolute prevalence of post-surgical complications. However, our comprehensive, large case series provides relevant information in different clinical scenarios for the management of patients with post-surgical leakage.

In conclusion, our data found that an endoscopic approach is successful and safe in the majority of patients with GI leakage suitable for such treatment when performed by skilled endoscopist. However, an interdisciplinary collaboration among the gastroenterologist, surgeon, radiologist and nutritional staff is required to correctly manage these patients. Therefore, an endoscopic treatment – with appropriate radiological or surgical drainage when required – could be attempted to close post-surgical leaks before resorting to more invasive, costly and risky re-intervention. Further prospective, randomized studies comparing surgery and endoscopy in such a setting are urged.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

None declared.

References

1. Willingham FF and Buscaglia JM. Endoscopic management of gastrointestinal leaks and fistulae. *Clin Gastroenterol Hepatol* 2015; 13: 1714–1721.
2. Lang H, Piso P, Stukenborg C, et al. Management and results of proximal anastomotic leak in a series of 1114 total gastrectomies for gastric cancer. *Eur J Surg Oncol* 2000; 26: 168–171.
3. Rutegard M, Lagergren P, Pouvelas I, et al. Intrathoracic anastomotic leakage and mortality after esophageal cancer resection: A population based study. *Ann Surg Oncol* 2012; 19: 99–103.
4. Lee WS, Yun SH, Roh YN, et al. Risk factors and clinical outcome for anastomotic leakage after total mesorectal excision for rectal cancer. *World J Surgery* 2008; 32: 1124–1129.
5. Hyman NH. Managing anastomotic leaks from intestinal anastomoses. *Surgeon* 2009; 7: 31–35.
6. Mileski WJ, Joehl RJ, Rege RV, et al. Treatment of anastomotic leakage following low anterior colon resection. *Arch Surg* 1998; 123: 968–971.
7. Manta R, Magno L, Conigliaro R, et al. Endoscopic repair of post-surgical gastrointestinal complications. *Dig Liver Dis* 2013; 45: 879–885.
8. Mennigen R, Senninger N and Laukoetter MG. Novel treatment options for perforations of the upper gastrointestinal tract: Endoscopic vacuum therapy and over-the-scope clips. *World J Gastroenterol* 2014; 20: 7767–7776.
9. Manta R, Manno M, Bertani H, et al. Endoscopic treatment of gastrointestinal fistulas using an over-the-scope clip (OTSC) device: Case series from a tertiary referral center. *Endoscopy* 2011; 43: 545–548.

10. Bemelman WA. Vacuum assisted closure in coloproctology. *Tech Coloproctol* 2009; 13: 261–263.
11. Lamazza A, Sterpetti AV, De Cesare A, et al. Endoscopic placement of self-expanding stents in patients with symptomatic anastomotic leakage after colorectal resection for cancer: Long-term results. *Endoscopy* 2015; 47: 270–272.
12. Strangio G, Zullo A, Ferrara EC, et al. Endo-sponge therapy for management of anastomotic leakages after colorectal surgery: A case series and review of literature. *Dig Liver Dis* 2015; 47: 465–469.