

Outcomes of temporary self-expanding plastic stents (SEPS) use for gastrointestinal leaks. A case series

Gutiérrez-Salmeán G,^{1,2} Peláez-Luna M,^{1,3} González-Galeote E,¹ Lozoya-González D,¹ Fuchs-Tarlovsky V,^{1,2} Farca-Belsaguy A.¹

1 Advanced Endoscopy Unit, ABC Medical Center.

2 Oncology Ward, Hospital General de Mexico.

3 School of Medicine, Universidad Nacional Autónoma de México (UNAM). Experimental Medicine Unit. Liver, Pancreas and Motility Laboratory (HIPAM).

Correspondence author: Mario Peláez-Luna, MD. Dr. Balmis 148. CP 06726, Mexico City, Mexico. Phone: (52) 55 5623-2673. Fax (52) 55 5623-2669. E-mail: mariopl@prodigy.net.mx

Received: April 30th, 2008 • Accepted on: April 16th, 2009

Resumen

Introducción: Las fístulas gastrointestinales pueden desarrollarse como complicación de cualquier cirugía gastrointestinal, trauma, enfermedades malignas, radioterapia o debido a problemas iatrogénicos. El uso de prótesis mecánicas autoexpandibles (SEMS), ha sido informado como un método terapéutico posible y efectivo. Las prótesis plásticas autoexpandibles (SEPS) han sido utilizadas exitosamente en el tratamiento de enfermedades malignas esofágicas, perforaciones y fístulas, pero la información en cuanto a la evolución de las SEPS en fístulas gastrointestinales es escasa.

Objetivo: Informar la evolución y complicaciones de la endoterapia con el uso de SEPS en fístulas del tracto gastrointestinal superior-posterior a cirugía gastrointestinal.

Material y métodos: Revisión retrospectiva de 5 casos de fístulas del tracto gastrointestinal superior tratadas con SEPS. Los expedientes médicos fueron revisados y se extrajo demografía, historia clínica, tipo de procedimiento endoscópico, complicaciones y seguimiento.

Resultados: Estudiamos 2 mujeres y 3 hombres con edad de 29 a 65 años. Las SEPS fueron colocadas por un periodo medio de 90 días (intervalo 30-279 días). No hubo complicaciones relacionadas

Abstract

Introduction: Gastrointestinal fistulas can develop as a complication of any gastrointestinal surgery, trauma, malignant disease, radiotherapy or because of iatrogenic procedures. The use of self expandable metallic stents (SEMS) has been reported as a feasible and effective therapeutic method. Self expandable plastic stents (SEPS) have been successfully used to treat esophageal malignancies, perforations and leaks but information regarding outcomes of SEPS in gastrointestinal leaks is scarce.

Objective: To report the outcomes and complications of endotherapy using SEPS in upper gastrointestinal tract fistulas following gastrointestinal surgery.

Material and methods: Retrospective review of 5 cases of upper gastrointestinal leaks treated with SEPS. Medical records were reviewed to obtain patients demographics, procedure success, complications and follow up.

Results: We described 2 women and 3 men with an age ranged between 29 and 65 years old. SEPS were left in place for a median period of 90 days (range: 30-279 days). There were no complications related to SEPS placement, replacement or withdrawal. Fistulas closed in 60% of the cases

a la colocación de SEPS, recolocación o retiro. Las fístulas cerraron en 60% de los casos en que se usó sólo SEPS, y en 80% de los casos cuando se utilizó SEPS y otra terapia (cianoacrilato, fibrina).

Conclusiones: La endoterapia con el uso de SEPS parece ser una opción terapéutica posible, efectiva y segura para el cierre de fístulas del tracto gastrointestinal.

Palabras clave: endoscopia gastrointestinal, fístulas, prótesis plásticas, esófago, México.

where SEPS were the only therapeutic maneuver and in more than 80% when other therapy (cyanoacrylate, fibrin) was used.

Conclusions: Endotherapy with SEPS appears as a feasible, safe and effective option for sealing gastrointestinal fistulas.

Key words: gastrointestinal endoscopy, fistula, plastics, stents, esophagus, Mexico.

Introduction

Gastrointestinal fistulas are infrequent, and can develop as a complication of any gastrointestinal surgery, trauma, malignant disease, radiotherapy or by iatrogenic mechanisms.¹⁻³ Gastrointestinal leaks or fistulas represent a feared surgical complication, since they are related to high morbidity rates⁴ and seldom improve with medical treatment,^{5,6} thus, most of the times, patients need to undergo surgery in order to fix the anatomic defect.^{5,6}

Endoscopic interventions, such as the application of tissue glue^{4,7-10} or using temporary metallic stents^{2,11,12} have been reported as a feasible and effective method to treat gastrointestinal leaks, and avoid surgical treatment.^{1,2,11,13}

The largest available series reports on the use of partially covered nitinol self-expanding metal stents (SEMS) as an effective treatment in 21 cases that developed upper gastrointestinal fistulas following laparoscopic bariatric surgery. The use of SEMS appears to be effective in sealing fistulas because they bypass the leak and act as barrier to fluids; they also develop tissue hyperplasia at both ends of the stent, preventing its migration and increasing its water proofing, however, removal of SEMS after a long period of being in place becomes difficult and requires different techniques to successfully retrieve them.¹¹

Self-expanding polyflex stents (SEPS) have been successfully used to treat different esophageal conditions including malignancies, perforations and leaks.^{14,15}

In this paper, we report the results of a case series of upper gastrointestinal fistulae following gastrointestinal surgery that were managed with SEPS.

Material and methods

Medical records of 5 patients (2 female and 3 male, ages ranging from 29 to 65 years old) referred to our endoscopy unit to treat a gastrointestinal fistula that resulted from gastrointestinal surgery were retrospectively reviewed. Cases are summarized in **Table 1**.

All patients underwent esophagogastroduodenoscopy (EGD) and SEPS placement. Fistula closure was assessed by direct endoscopic vision and radiologic examination.

Case presentation

Case 1: A 29 y/o female presented 5 years later after esophageal surgical myotomy for achalasia, with dysphagia secondary to distal esophageal stenosis. Hydrostatic dilation (CRE widewired balloon dilator; Boston Scientific, Natick MA) was attempted but was unsuccessful. The patient underwent another surgical myotomy that was complicated with a distal esophageal fistula that was recognized one week after the procedure. An EGD was performed and a polyflex stent was placed at the fistula site; the patient was able to resume oral feedings the day after the stent placement. Nine months later, the patient was asymptomatic and the fistula had closed; an abdominal X-ray showed that the stent migrated into the stomach. The stent was retrieved uneventfully using standard biopsy forceps. The patient was discharged and remains asymptomatic.

Case 2: A 65 y/o male presented with 2 months of progressive dysphagia due to upper esophageal stenosis and an esophageal leak, five years after the subsequent resection of a laryngeal cancer and radiotherapy. A PEG tube was placed for

Table 1.
Cases summary

Patients	1	2	3	4	5
Age (years)	29	65	60	42	51
Gender	Female	Male	Female	Male	Male
Prior surgery	Myotomy due to achalasia and dysphagia unresponsive to pneumatic dilation	Laryngeal cancer resection	Gastric bypass for morbid obesity	Gastric band and gastric bypass	Gastric bypass
Type of fistula	Esophageal	Esophageal	Gastrocutaneous	Gastrocutaneous	Gastrocutaneous
Stent migration	Yes (distal)	Yes (distal)	No	Yes (distal)	Yes (distal)
Outcome	Patient resumed oral feeding and was discharged. Fistula healed	After 4 months, stents were removed and no fistula evidence was observed	One month after intervention, stent was retrieved as the fistula had closed	After 4 migration episodes, the patient was discharged as the leak had closed	Patient presented with several migration episodes due to cholecistitis and huge copious meals. Fistula closed after external fibrin application
Comments	Stent retrieved using regular biopsy forceps	Stent retrieved first time using polypectomy loop and biopsy forceps second time	Stent retrieved using foreign body forceps	Cyanoacrilate and fibrin were also used	Cyanoacrilate and fibrin was also applied

nutritional support, hydrostatic dilation (CRE widened balloon dilator; Boston Scientific, Natick MA) of the stenotic portion of the esophagus was performed uneventfully and a polyflex stent was placed at the site of the fistula. Four months after the procedure, the patient had food contents oozing throughout the fistula. An EGD was performed showing distal stent migration to the stomach. The stent was removed with polypectomy loop and a new stent was placed. Four months later the stent remained in place and was removed easily using a foreign body forceps. The patient remains asymptomatic

Case 3: A 60 y/o female presented to the endoscopy unit with a gastrocutaneous fistula 3 months after undergoing gastric bypass for morbid obesity. The patient underwent an EGD that showed a fistulous tract at the anastomotic site. A self-expandable plastic stent was placed at the anastomotic site covering the fistulous orifice completely. One month after the procedure, the cutaneous site of the fistulae had closed. An EGD and x-ray showed no evidence of the fistulous tract. The plastic stent remained in place and was retired easily using a

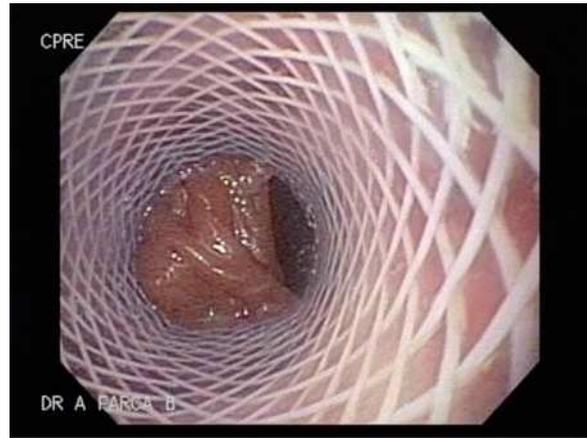
foreign body forceps. The patient remains asymptomatic.

Case 4: A 42 y/o male with nausea, postprandial vomit and a cutaneous fistulous tract was referred to the endoscopy unit 2 months after undergoing gastric bypass surgery. An EGD was performed showing a stenosis at the gastrojejunal anastomosis and a fistulous tract proximal to the anastomotic site. A hydrostatic balloon dilation (CRE widened balloon dilator; Boston Scientific, Natick MA) was performed at the anastomotic site and a plastic stent was placed covering the fistulous orifice. The patient was discharged, but one week later, the fistula output reappeared. An X ray showed stent migration to the stomach. The stent was removed with standard biopsy forceps and a new SEPS was successfully placed. Prior to stent replacement, cyanoacrilate and fibrin were applied in the fistula. Two days later, a control X ray showed that the stent migrated again into the stomach. The EGD showed that the fistulous tract persisted. The stent was removed with a polypectomy loop and it was replaced with a new stent;

Figure 1.
Fistulous opening at the anastomotic site



Figure 2.
SEPS placed and covering the fistulous opening



easily with a standard biopsy forceps. One month later, an EGD showed that the stent migrated to the efferent loop, so it was removed with a polipectomy loop and another stent was replaced; prior to the placement, fibrin was applied in the fistulous tract. One week later, there was no evidence of the cutaneous fistula orifice. An EGD was performed showing that the stent had migrated again to the stomach but there was no evidence of the fistulous tract. The stent was withdrawn easily with standard biopsy forceps and the patient was discharged. The patient is currently asymptomatic.

Case 5: A 51 y/o male developed a gastrocutaneous leak 3 months after gastric bypass. An EGD showed narrowing at the gastrojejunal anastomotic site. An EGD with hydrostatic balloon dilation (CRE widewired balloon dilator; Boston Scientific, Natick MA) was performed and a 4 mm. fistulous orifice was identified at the anastomotic site (**Figure 1**). One week later a 9 cm polyflex stent was placed due to an increased fistula output (**Figure 2**). Two weeks later, the patient developed cholecystitis and after an episode of emesis the stent migrated into the stomach. The stent was easily removed with foreign body forceps and a new stent was successfully placed (**Figure 3**). One week later, the patient had persistent nausea. An EGD showed that the stent migrated into the stomach, so it was removed by using a standard biopsy forceps and replaced. Prior to placement, cyanoacrylate was applied. The stent

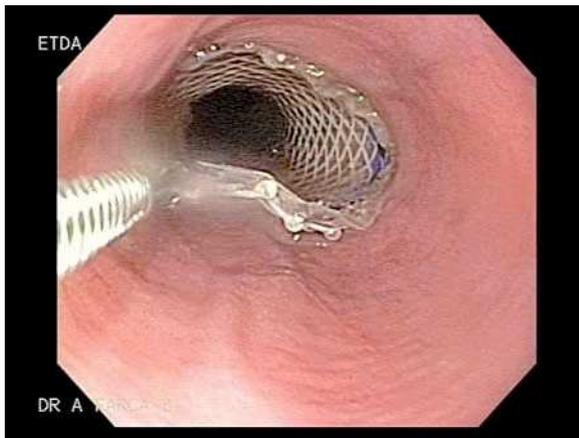
migrated 2 more times to the efferent loop and into the stomach (1 week and a month later, respectively) after copious meal intake and emesis. Each time it was retrieved and replaced successfully. After 1 week, the patient underwent surgery as the fistulous output persisted. Four months after surgery the fistula re-opened. Fibrin was applied and the leak closed.

Overall, SEPS were left in place for a median of 90 days (range: 30–279 days). The SEPS migrated in 80% of the cases, but were successfully and easily replaced. No complications related to SEPS placement, replacement or withdrawal was recorded. Fistulas closed in 60% of the cases when SEPS were the only treatment used, in 2 cases, SEPS failed to achieve fistula closure as a single therapy; thus, in one case cyanoacrylate was applied, leading to later resolution of the fistula and in other case, application of fibrin was the only therapy that closed the fistula.

Discussion

Treatment options for upper digestive tract fistulas, mainly for larger or chronic leakages have been divided into repair techniques that use clips, sealants or suturing devices and diversion techniques that use stents.^{4,9,16} The rationale for using either SEMS or SEPS in gastrointestinal fistulas is that most of the patients with this condition are weak, have numerous comorbidities and comprise a high group with surgical risk.

Figure 3.
SEPS being replaced above the fistulous opening, using
standard biopsy forceps



In this retrospective series we demonstrated that endotherapy using SEPS is a feasible, safe and effective therapeutic option, with an overall success rate of 60%, in sealing upper gastrointestinal tract fistulas, when used as single therapy; however the success rate might be overrated considering the limited number of cases in our series although similar outcomes have been previously reported.^{14,17}

A downside in our series, is that in 4 (80%) cases the SEPS migrated and needed to be replaced, something that seldom occurs with SEMS; however, the latter ones are more difficult to remove and most of the use of SEPS is needed to induce pressure necrosis of the underlying SEMS hyperplasia. It has also been reported that nearly 50% of fistulas treated with SEMS, needed to be replaced 2, to 3 times during follow-up.¹⁷

When comparing SEMS with SEPS, the latter present some practical advantages for their use: they are easily removed regardless the time they are left in place, less expensive, and although they have a higher chance to migrate, they are easily replaced. On the other hand SEMS are more expensive, and if they are left in place more than 6 weeks (something common in the treatment of gastrointestinal fistulas) they are more difficult to extract and usually need the use of SEPS to aid in their withdrawal.^{11,15,17,18}

If either SEMS or SEPS are the most effective and cost-effective ones sealing gastrointestinal

fistulas, is yet to be clarified. It is our belief that the use of either SEMS or SEPS in the management of gastrointestinal fistulas has proved to be effective and reliable. According to the available reports, SEPS seem to be better suited when fistulas are associated to strictures (since this might prevent the SEPS to migrate) meanwhile SEMS are more indicated in malignant and benign non stricture related fistulas, however we lack of clear indications for their use.

As shown in case 4 and 5, the concomitant use of synthetic seals as cyanoacrylate or fibrin with plastic stent placement could be a useful tool and surgical attempt to close gastrointestinal fistulas and which clinical scenario (i.e. location, size, output, associated stricture) including complication rates and cost effectiveness. Clear clinical indications other than personal preferences for either SEMS or SEPS use, are needed.

Although our series is small and therefore lacks of statistical power to advise change in management, the results resemble those previously reported in larger series. Comparative and larger randomized controlled studies should evaluate if endotherapy could be performed prior to any surgical attempt to close gastrointestinal fistulas and which clinical scenarios (i.e. location, size, output, stricture association of fistulas) will benefit the most from the use of SEMS or SEPS including complication rate and cost effectiveness. Clear clinical indications other than personal preferences for either SEMS or SEPS use, are needed.

References

- Pickhardt PJ, Bhalla S, Balfe DM. Acquired gastrointestinal fistulas: classification, etiologies and imaging evaluation. *Radiology* 2002; 224:9-23.
- Falcón M, Pederzoli P. The relevance of gastrointestinal fistulae in clinical practice: a review. *Gut* 2001; 49:2-10.
- González-Pinto I, Moreno-González E. Optimising the treatment of upper gastrointestinal fistulae. *Gut* 2001; 43: 21-8.
- Papavramidis S, Eleftheriadis E, Papavramidis T, Kotzampassi K, Gamvros O. Endoscopic management of gastrocutaneous fistula after bariatric surgery by using a fibrin sealant. *Gastroint Endosc*; 2004; 59: 296-300.
- Presutti J, Gorman S, Swain JM. Primary care perspective on bariatric surgery. *Mayo Clin Proc* 2004; 79: 1158-66.
- Herron DM, Bloomberg R. Complications of bariatric surgery. *Minerva Chir* 2006; 61: 125-39.
- Chung MA, Wanebo HJ. Surgical management and treatment of gastric and duodenal fistulas. [cited 2007 Nov 15]; Available at: <http://www.ptolemy.ca/members/archives/2006/Fistula/chung1996.doc>
- Gumba AA, Duffy AJ, Bell RL. Management of gastrogastric fistula after laparoscopic Roux-en-Y gastric bypass. *Surg Obes Related Dis* 2006; 2: 117-21.
- Pontieri-Lewis V. Management of gastrointestinal fistulas: a case study. *MedSurg Nursing* 2005; 14: 68-72.
- Truong S, Böhm G, Klinge U, Stumpf M, Schumpelick V. Results after endoscopic treatment of postoperative upper gastrointestinal fistulas and leaks using combined Vicryl plug and fibrin glue. *Surg Endosc* 2004; 18: 1105-8.
- Eisendrath P, Cremer M, Himpens J, Cadière GB, Le Moine O, Devière J. Endotherapy including temporary stenting of fistulas of the upper gastrointestinal tract after laparoscopic bariatric surgery. *Endosc* 2007; 39: 625-30.
- Li YD, Li MH, Han XW, Wu G, Li WB. Gastrotracheal and gastrobronchial fistulas: management with covered expandable metallic stents. *JVIR* 2006; 17: 1649-56.

13. Rots WIM, Mokoena T. Successful endoscopic closure of a benign gastrocolonic fistula using human fibrin sealant through gastroscopic approach: a case report and review of the literature. *Eur J Gastroenterol Hepatol* 2003; 15: 1351-6.
14. Ott C, Ratio N, Endlicher E, Rath HC, Gelbmann CM, Schölmerich J, et al. Self-expanding Polyflex plastic stents in esophageal disease: various indications, complications and outcomes. *Surg Endosc* 2007; 21: 889-96.
15. Radecke K, Gerken G, Treichel U. Impact of a self-expanding, plastic esophageal stent on various esophageal stenoses, fistulas and leakages: a single-center experience in 39 patients. *Gastrointes Endosc* 2005; 61: 812-8.
16. Mejía AF, Bolaños E, Chaux CF, Unigarro I. Endoscopic treatment of gastrocutaneous fistula following gastric bypass for obesity. *Obes Surg* 2007; 17: 544-6.
17. Evrard S, Le Moine O, Lazaraki G, Dormann A, El Nakadi I, Devière J. Self-expanding plastic stents for benign esophageal lesions. *Gastrointest Endosc* 2004; 60: 894-900.
18. Costamagna G, Marchese M, Iacopini F. Self expanding stents in oesophageal cancer. *Eur J Gastroenterol Hepatol* 2006; 18: 1177-80.