

# Novel gastrointestinal procedures

Massimiliano di Pietro

## Abstract

Over the last 20 years, a large proportion of the research in the gastrointestinal field has focused on the development of enhanced imaging modalities and minimally invasive therapy for benign and malignant conditions. Both conceptually and practically these two avenues proceed together: refinement of endoscopic and radiological imaging techniques often leads to diagnosis of diseases at early pathological stage, when surgical management with related mortality and morbidity, may not be justified. In addition, preventive medicine has triggered studies on the natural history of benign pre-neoplastic conditions with the intention of defining the boundaries for early therapeutic interventions. Similarly, in benign conditions there is pressure to develop less destructive techniques as an alternative to conventional surgical approaches, to improve outcome and patient tolerability. In this short review, novel procedures for the management of common gastrointestinal conditions are illustrated. These are at different stages of introduction into routine practice, but are likely to have a significant impact on the patient management now or in the near future.

**Keywords** Advanced endoscopic imaging; Barrett's oesophagus; colorectal adenoma; early cancer; gastro-oesophageal reflux disease; GI bleeding; oesophageal motor disorders; pancreatic cystic lesions

## Management of gastro-oesophageal reflux disease and motility disorders

Gastro-oesophageal reflux disease (GORD) is the most common gastrointestinal (GI) diagnosis in an outpatient setting.<sup>1</sup> Proton pump inhibitors (PPI) are the mainstay of GORD medical management. As many as 30% of patients have incomplete response to PPI, because PPIs do not resolve the main pathophysiological cause of GORD, the incompetence of the lower oesophageal sphincter (LOS). Laparoscopic anti-reflux surgery is traditionally indicated in these patients, as well as in those intolerant to PPIs.<sup>2</sup> There are several novel, minimally invasive procedures aimed to resolve LOS incompetence.

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## What's new?

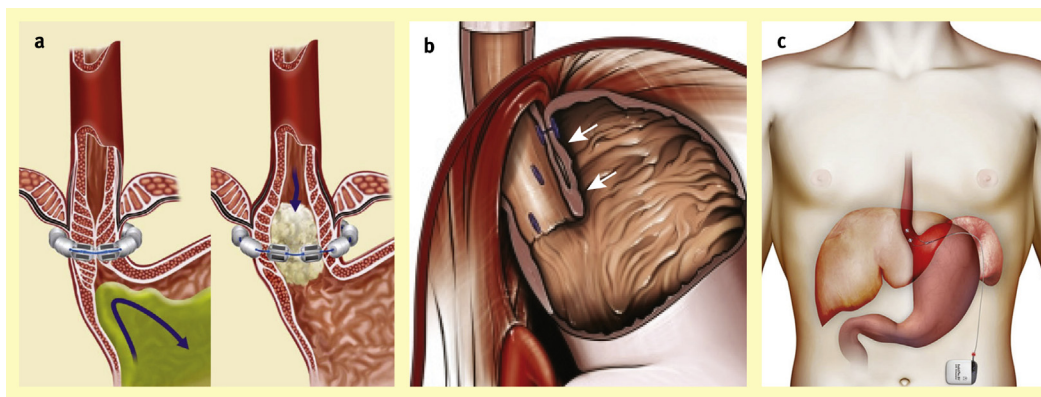
- Minimally invasive alternatives to conventional anti-reflux surgery for gastro-oesophageal reflux disease
- Improved classification and management of oesophageal motor disorders
- Hemospray<sup>®</sup>: a simple technique to manage difficult gastrointestinal (GI) bleeding
- Recent advances in lower GI imaging to enhance adenoma detection rate
- Confocal laser endomicroscopy for recognition and histopathological correlation of luminal and extra-luminal disease
- Endoscopic treatment of pre-neoplastic and early neoplastic GI lesions
- Natural orifice transluminal endoscopic surgery for staging and treatment of GI cancers and other benign conditions

The Lynx<sup>®</sup> (Torax Medical, USA) system consists of a flexible band of magnetic beads connected by small wires, which is placed laparoscopically around the LOS (Figure 1a). The Lynx<sup>®</sup> system augments the LOS, but allows the beads to separate with increased luminal pressure. In a non-randomized case series of 100 patients with GORD, Lynx<sup>®</sup> normalized the oesophageal acid exposure in 64% of individuals and significantly improved quality-of-life measures in over 90%.<sup>3</sup> The most common adverse effect is dysphagia, which may persist long-term in about 10% of patients.

Esophyx<sup>®</sup> (Endogastric Solutions, USA) is an endoscopic device that repositions the LOS in its normal anatomical site by fixing it to the fundus (Figure 1b). In a randomized controlled trial (RCT) of 63 GORD patients, comparing Esophyx<sup>®</sup> with high-dose PPI, both interventions normalized oesophageal acid exposure at 6 months in just over half of the patients, but Esophyx<sup>®</sup> was more effective in controlling symptoms (97% vs 50%,  $p = 0.006$ ).<sup>4</sup> No significant long-term adverse effects were reported.

LOS function can be regulated by electric stimulation therapy (EST), similar to the treatment of gastroparesis by gastric pacemaker. EST (Endostim<sup>®</sup>, USA/The Netherlands) is a well-tolerated system that delivers to the LOS long-term electrical impulses (Figure 1c). Case series showed that Endostim<sup>®</sup> can normalize oesophageal pH in 70–100% of patients with symptomatic benefit in over 90%.<sup>5,6</sup> EST represents an attractive intervention since it allows adjustment of the impulse to the symptomatic pattern of the patients.

Oesophageal motility disorders are a differential diagnosis for GORD symptoms in patients who have a normal endoscopy and who are complaining of non-cardiac chest pain or dysphagia. The definition and classification of motility disorders have been greatly improved since the advent of high-resolution manometry (HRM), which benefits from an increased number of pressure sensors densely spanned along the catheter. HRM generates a 3D oesophageal pressure topograph where space, time and amplitude of the contraction are represented in a single graph.<sup>7</sup> Compared to conventional manometry, advantages of HRM are its ease of use, improved tolerance by patients and the increased amount of information generated. These HRM data have led to



**Figure 1** Novel minimally invasive intervention for gastro-oesophageal reflux disease. **(a)** In the Lynx system bracelet of magnetic titanium beads is placed around the gastro-oesophageal junction, where it augments the function of the LOS. In the closed position, Lynx<sup>®</sup> acts as a barrier against reflux (left). When the luminal pressure increases, due to food bolus transit or belching/vomiting, the beads can separate allowing luminal transit (right). (Reproduced from Bonavina L et al. *Therap Adv Gastroenterol* 2013; 6(4) with kind permission from SAGE.) **(b)** The Esophyx<sup>®</sup> device repositions the LOS with a built-in vacuum invaginator and then constructs an anterior 270 degrees fundoplication by fixing the anterior and lateral wall of the distal oesophagus to the fundus by propylene fasteners (white arrows). (Adapted from Bell RC, Cadiere GB. *Surg Endosc* 2011; 25(7).) **(c)** Endostim<sup>®</sup> leads are implanted laparoscopically in the LOS and connected to a pulse generator secured in the subcutaneous layer of the abdomen. The generator is controlled by an external programmer. (Reproduced from Hoppo T et al. *Surg Endosc* 2014; 28(12) with kind permission from Springer Science and Business Media.)

the development of the new Chicago classification of the oesophageal motility disorders.<sup>7</sup> For example, HRM has allowed the identification of three different types of achalasia, all characterized by impaired LOS relaxation but with different oesophageal motor patterns and different responses to endoscopic and surgical treatment. This classification also has management implications. The effectiveness of endoscopic treatment of achalasia, such as botulinum toxin injection and pneumo-dilatation, can be limited. Surgical myotomy is traditionally considered the definitive treatment.<sup>8</sup> In 2008, Dr Inoue developed a per-oral endoscopic myotomy (POEM). POEM takes advantage of the submucosal dissection technique to perform an oesophageal submucosal tunnel which is followed by creating a longitudinal dissection of the muscle layer down to the gastro-oesophageal junction.<sup>9</sup> The mucosal entry point of the tunnel is then closed with metal clips. Several case series have showed that POEM leads to symptomatic improvement in 80–100% of patients with achalasia and can significantly reduce the LOS resting pressure, with a favourable safety profile.<sup>9</sup> Early experience showed that POEM may also be effective for treatment of other oesophageal motility disorders, such as diffuse oesophageal spasm and nutcracker oesophagus. However, RCTs are warranted before POEM can be considered a routine technique in the Western countries.

All the new procedures described in this paragraph are technically established and ready to be introduced safely into clinical practice, but RCTs with longer follow up are required to confirm their efficacy. The National Institute of Health and Care Excellence (NICE) is currently monitoring the evidence of Endostim<sup>®</sup> and POEM with the aim to issue guidance on them, whereas recommends the use of Lynx<sup>®</sup> and Esophyx<sup>®</sup> only with special arrangements for clinical governance, consent and audit or research, given the limited evidence of their efficacy.

### Endoscopic therapy of GI bleeding

Endoscopy plays a pivotal role in the diagnosis and treatment of GI bleeding. Haemostatic techniques include injectable solutions,

thermal devices or metal clips for bleeding of non-variceal origin, and band ligation or sclerotherapy with tissue adhesive for bleeding of variceal origin.<sup>10</sup> However, endoscopic therapy fails in 5–15% of cases, particularly in cases of profuse bleeding, difficult anatomical location and neoplastic bleeding. For this reason, simple haemostatic methods that are easy to deliver, such as haemostatic powders, have the potential to improve outcomes.<sup>11</sup> Hemospray<sup>®</sup> (Cook Medical, UK) is a mineral powder with proprietary formulation that can be delivered through the endoscopic channel via a spray catheter. Once in contact with water or blood the powder forms an adhesive layer that exerts a mechanical haemostatic action. In vitro data show that it can also improve platelet function. The technical advantages are that it can be applied over large surfaces, such as neoplastic lesions, and application does not require a high degree of technical expertise. In small case series with variceal and non-variceal bleeding Hemospray<sup>®</sup> controlled the acute bleeding in 81–100% of cases.<sup>11</sup> In a larger series of 63 cases of upper GI bleeding from different sources (ulcers, tumours or endotherapy site) primary and sustained haemostasis was achieved in 85% and 77% of cases, respectively.<sup>12</sup> While RCT data are awaited, haemostatic powders represent a ready-to-use tool, especially in cases with cancer-related or uncontrollable bleeding and those in a difficult anatomical position.

### Imaging of the GI tract

Detection of early cancer and prediction of histological outcome represent the two most common research endpoints in the field of endoscopic imaging. Dye chromoendoscopy using, for example, indigo carmine or methylene blue, and electronic virtual chromoendoscopic techniques, such as narrow band imaging (Olympus, Japan), iSCAN (Pentax, Japan) or FICE (Fuji, Japan), have been extensively studied in both upper and lower GI tract, but none of them has proved superior to conventional high-resolution endoscopy for detection of early cancer.<sup>13</sup> For example, for both colonic polyp detection and diagnosis of inconspicuous dysplasia in Barrett's oesophagus, there is

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