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Historical notes: The road to peroral endoscopic myotomy☆

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ABSTRACT

Submucosal endoscopy with saftey valve mucosal flap was developed in the animal laboratory of the Mayo Clinic Developmental Endoscopy Unit. This concept, and ultimately clinical technique, was an outgrowth of earlier efforts to improve endoscopic excision of mucosal disease by manipulating the submucosa. The ability of the mucosa to readily separate from the submucosa (delaminate) was the critical observation that was refined into a method transforming the submucosa into a working space while allowing the overlying mucosal flap to serve as a protective barrier.

1. Introduction

This chapter takes the reader through the evolution of a revolutionary concept that directs diagnostic and therapeutic activities within the layers of the gut wall. Currently, the most well-known clinical application of submucosal endoscopy is the peroral endoscopic myotomy (POEM) procedure.

2. Prelude to submucosal endoscopy

In 1998, the Developmental Endoscopy Unit of the Mayo Clinic began an intensive effort to solve the riddle of safe and easy en bloc resection. At that time, endoscopic submucosal dissection was being performed in Japan but had obvious drawbacks (risk, training, limited expertise, and primitive technique) which remain prevalent despite growth in this procedure. Cap-based endoscopic mucosal resection (EMR) was an available solution to en bloc resection of targeted areas up to 20 mm in diameter, but provided less than satisfactory results with piecemeal resection of larger mucosal lesions. Our initial efforts involved two-handed dissection using a fixed or mounted endoscope, a grasper, and needle knife, including the earliest versions of the insulated-tip needle knife. Although this method had appeal within a broader growth in flexible endoscopic technology (Figure 1), the lack of triangulation frustrated this intended application. An important observation made during this effort was the ready delamination of the mucosa from the submucosa, as evidenced by the ability to create giant submucosal fluid cushions (SFC). We learned that in the esophagus, large strips of mucosa could literally be peeled off from the SFC at any length desired. This observation then lead to the concept of widespread EMR (WEMR), directed chiefly at the potential excision of a Barrett segment. WEMR was proposed to the original Apollo group as one of their inaugural research efforts. A special endoscope, proposed by Robert Hawes, was built to provide both up-down and right-left deflectors. This later became recognized as the R scope (Olympus, Japan), but it did not enable WEMR. Specialized cutting caps finally enabled WEMR in the esophagus. The caps had cutting wires permitting longitudinal and horizontal cutting to be performed while the edge of the cap skidded between the mucosa and SFC [1]. WEMR as a concept was attractive, but in this iteration, it was less than ideal, requiring piecemeal stripping.

The basis of endoscopic interventions is a mechanical activity, invariably directed from the lumen toward the serosa. It is within the deeper layers of the gut wall and beyond the serosa where risk and danger lurk—bleeding and contamination of sterile spaces. Intrigued with delamination and the value of the SFC, we redirected efforts to alter the submucosa by transforming the submucosa into a protective barrier. The most successful outcome of this effort was the discovery of hydroxypropyl methylcellulose as a cheaper and more readily available alternative to hyaluronic acid as an SFC [2]. If an impenetrable SFC could be created, then excising any mucosal disease could be made infinitely safer and perhaps easier. We then began to experiment with the delivery of paraffin into the submucosa. This had many challenges, one of which was diffusing the paraffin within the submucosa. If the submucosa could be transformed into a space, this would facilitate distributing the paraffin. This led to the discovery of submucosal gas dissection, using short pulses of highly pressurized CO_2 delivered via a standard needle catheter into the submucosa. Clinicians were already familiar with incidental submucosal gas dissection with argon gas when using an argon plasma coagulator.

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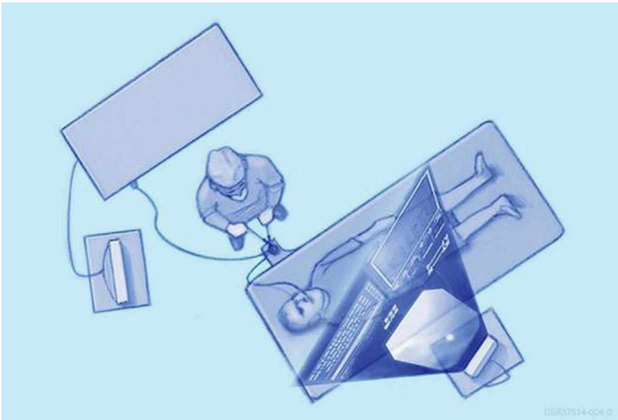

Fig. 1. Conceptual illustration of performing endoscopic intervention by mounting the endoscope and allowing the endoscopist to use both hands. In this concept, the forward video display provides the endoscope image along with data displays. The smaller side monitor is a touch-screen display.

3. Submucosal endoscopy

As our experience with manipulating the submucosa by gas dissection grew along with our appreciation for the safety of this method, in 2004, the Submucosal Inside Out Project (SIOP) program was conceptualized and initiated (Figure 2). The SIOP concept was based on gas dissection, and most importantly, the phenomenon of mucosal "delamination." This effect was most pronounced in the esophagus and stomach. Surgeons for years have used intramural and submucosal tunneling for the placement of feeding tubes. SIOP began to explore the possibility of converting the submucosa into an open or free working space within which an endoscope and endoscopic devices could be passed. The original goal for SIOP was to continue the effort to find a safer and more expedient method to perform en bloc resection of mucosal disease, as a replacement for traditional endoscopic submucosal dissection [3]. Working from "inside" the gut wall toward the gut lumen to excise tissue should theoretically be safer. The technique, directed "outside," toward the deeper layers of the gut wall, should enable safe sampling of the muscle layer to better characterize and study motility disorders which our motility specialists were pressing for [4,5]. With the advent of natural orifice translumenal endoscopic surgery (NOTES), the same method of converting the submucosa into a free space might also provide an offset access to the peritoneal cavity, allowing the overlying mucosal "flap" to serve as a protective barrier and sealant against soiling and contamination. This theoretical approach to viscerotomy was proposed during the inaugural natural orifice surgery consortium for assessment and research (NOSCAR) meeting in 2005 and incorporated in the first white paper [6]. The enthusiasm for NOTES diverted SIOP away from mucosal resection and into tunneled offset viscerotomy. We were able to perform readily and successfully this in the stomach to direct an endoscope to the gall bladder and demonstrate successful cholecystectomy using this method [7].

The esophagus had greater appeal as a novel and ideal application for this offset tunneling technique to gain access to the mediastinum, ideally to gain access to the external esophagus and esophagogastric junction, heart, great vessels, and lymph nodes [8]. To accomplish this, a myotomy was mandated. Our initial experience with the technique was published and reported as the Submucosal Endoscopy with safety valve Mucosal Flap (SEMF) method [9,10]. The myotomy with this inaugural method was full thickness (Figure 3). It was immediately apparent to us that SEMF with myotomy offered an alternative option for the surgical management of achalasia. In our animal laboratory,

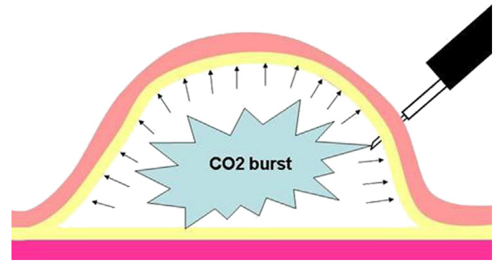

Fig. 2. Illustration of submucosal CO_2 gas dissection. This is accomplished using a needle injection catheter and a pressurized CO_2 capsule. (Color version of figure is available online.)

myotomies of various lengths across the esophagogastric junction could readily be performed and safely so, because of the undisturbed overlying protective mucosal flap. The excitement from the SEMF experience was shared with the Apollo Group at a meeting in Baltimore. One of the Apollo members, Jay Pasricha, with an established career interest in achalasia was knighted to move ahead with a formal animal study directed at this application of SEMF. This experience demonstrated the value of the SEMF technique combined with myotomy of the circular muscle layer only as an effective option in the treatment of achalasia [11].

4. The SEMF method

The first step to the SEMF method is gaining access to the submucosa, which is accomplished by the creation of an SFC followed by opening the mucosa just enough to allow balloon catheter insertion. SEMF in the animal laboratory (and currently in our clinical practice) is based on blunt dissection using small endoscopic retrograde cholangiopancreatography stone retrieval balloons to create the submucosal space or tunnel (Figure 4). Once the first few centimeter length of submucosal space is initiated by inflation of the 11.5-mm balloon, the fully inflated balloon is pulled through the mucosal insertion site to fracture it open sufficiently enough to place the tip of the endoscope into this new space. Repeating the steps of advancing the deflated balloon catheter several centimeters distally, inflating the balloon, and pulling the balloon back toward the endoscope tip allows

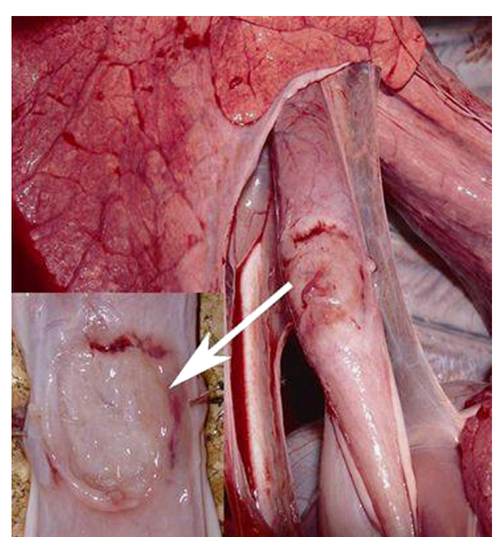

Fig. 3. Distal esophageal SEMF (2-cm diameter) full-thickness myotomy site used for access to the mediastinum. The small inset photo (white arrow pointing) demonstrates the overlying mucosal flap sealing the circular myotomy defect. (Color version of figure is available online.)