

# Creation of a third space endoscopy program at a tertiary academic US medical center

## Abstract

Third space endoscopy (TSE) is a rapidly evolving and advancing area in the field of gastroenterology allowing for new minimally invasive treatment options for various gastrointestinal diseases including achalasia, refractory gastroparesis, subepithelial tumors and esophageal strictures. Given the positive impact TSE can have on patients as well as the healthcare system with potentially fewer complications and long-term cost savings, more TSE training opportunities and endoscopy programs are needed. In this article, we discuss the different aspects of third space endoscopy training as well as steps and considerations that need to be addressed prior to starting a TSE program. Our hope is that an overview of our experiences creating a TSE program at our own institution, including both our successes as well as the difficulties we faced, will help inspire and guide others in the future.

**Keywords:** coagulation forceps, submucosal injections, third space endoscopy, per oral endoscopic myotomy, endoscopic submucosal dissection, endoscopic retrograde cholangiopancreatotomy, endoscopic mucosal resection, current procedural terminology

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**Abbreviations:** TSE, third space endoscopy; ERCP, endoscopic retrograde cholangiopancreatotomy; EMR, endoscopic mucosal resection; ESD, endoscopic submucosal dissection; AMA, American Medical Association; CMS, Centers for Medicare and Medicaid; ASGE, American Society for Gastroenterology Endoscopy; CPT, Current Procedural Terminology; RUC, Relative Value Scale Update Committee

## Introduction

Third space endoscopy is a rapidly evolving and advancing area in the field of gastroenterology. This unique technique involves accessing the submucosa, referred to as “the third space” with subsequent submucosal tunneling in order to perform a host of diagnostic and therapeutic interventions through less invasive methods. The “third space” is a potential space located between the muscularis mucosa and the muscularis propria, which consists of flimsy areolar tissue and traversed with longitudinal and horizontal blood vessels.<sup>1,2</sup> The technique of accessing the third space through endoscopic tunneling was first described by Sumiyama and colleagues in order to intervene upon Barrett’s esophagus, laterally spreading mucosal polyps, noninvasive early cancers and submucosal tumors.<sup>3</sup> This technique was also utilized for esophageal myotomy by Pasricha and colleagues in swine models and then applied to patients with achalasia by Inoue and colleagues in what is now known as a POEM (per oral endoscopic myotomy) procedure.<sup>1,4,5</sup>

Advances in third space endoscopy have revealed new and exciting opportunities to treat various gastrointestinal diseases including achalasia, refractory gastroparesis, subepithelial tumors and esophageal strictures. However, utilization of these techniques in tertiary US medical centers is limited. Reasons for this include the extensive training and the high technical demands required to perform these procedures as well as the challenges these procedures pose from an institutional perspective.<sup>6</sup>

With the advances in third space endoscopy, patients are being provided with the option to undergo minimally invasive endoscopic

procedures as an alternative to surgery which has large implications on patients as well as the healthcare system with potentially fewer complications and long-term cost savings. Therefore there is a need for more third space training opportunities and endoscopy programs in United States (US) medical centers.

In this paper, we will discuss the different aspects of third space endoscopy training as well as steps and considerations that need to be addressed prior to starting third space endoscopy programs at tertiary US medical centers. Our hope is that an overview of our experience creating a third space endoscopy program at our own institution, including our successes as well as the difficulties we faced, will help inspire and guide others in the future.

## Training

### Overview

With the clear need for development of third space endoscopy at US medical centers, organized and comprehensive strategies to achieve training in third space procedures are necessary. Currently, third space endoscopy training is not an integral component of advanced endoscopy fellowship programs across the United States. Therefore, endoscopists interested in learning third space endoscopy must find alternate pathways to acquiring these techniques.<sup>7</sup>

### Step-up approach to training

First described in Japan, a step-up approach to training has become the most accepted and successful method for third space endoscopy training. This approach involves observation, animal training and procedures on human patients under direct expert supervision prior to independent procedures.<sup>8</sup> Through self-study, endoscopists acquire in depth knowledge of instrumentation and electrosurgical equipment along with a thorough knowledge of the evaluation, techniques, and limitation of the procedures. However, this must be followed by robust supervised practice on explant animal models and hands on practice sessions with ex vivo models at regional and national conferences

and sessions.<sup>9</sup> Having an animal training workshop is a vital step in the training process. Although the animal model stomach, most commonly swine, is far from the reality of the human stomach, there are many similarities which allow for rapid repetition and practice.<sup>10</sup> While experience with ex vivo models is helpful, live animal models should also be integrated into training. Practice on live animals allows the trainee to learn how to treat intra-procedural bleeding and deal with complications more efficiently.

There is considerable variation regarding the dissection technique experience required prior to transition from animal models to human patients. The European Society of Gastrointestinal Endoscopy recommends performing at least 20 ESD procedures in animal and/or ex vivo models before human practice, with the goal of at least eight en-bloc complete resections in the last 10 training cases with no perforation.<sup>11–13</sup> In Asia where ESD has gained widespread use, skills are acquired over a period of years through a mentor-apprentice model.<sup>7</sup> However, in the US, this time-honored model is not easily adapted into the current training structure especially considering the lack of experts and volume of cases to support such an approach. To circumvent these issues, several endoscopists interested in learning third space endoscopy have traveled to Japan in order to observe experts in the field. However, this method of training is not sustainable or possible for all advanced endoscopists interested in acquiring these skills. This form of training has been challenged in regards to whether it is substantial enough training prior to proceeding with human cases.<sup>7</sup> While it is clear that several different types of exposure to third space endoscopy is needed, it is also suggested that an important part of beginning third space endoscopy in humans, specifically ESD, is to carefully select which lesions to remove. Given the higher incidence of colorectal cancer in the US compared to gastric cancer in Japan, appropriate rectal lesions are more viable ESD for beginners in the US. Traditionally it has been proposed that smaller, 2–3cm rectal laterally spreading tumors provide a good starting point for endoscopists starting ESD.<sup>7</sup>

### Fellowship training

For gastroenterology fellows interested in third space endoscopy, it is important to consider an advanced endoscopy fellowship that incorporates third space endoscopy experience. Advance endoscopy fellowship historically focused on skills such as endoscopic retrograde cholangiopancreatotomy (ERCP) and endoscopic ultrasound (EUS). More recently, training regarding large polyp endoscopic mucosal resection (EMR), endoscopic suturing as well as endoscopic submucosal dissection (ESD) and POEM have been incorporated into select advanced endoscopy fellowship training and have been pushing the boundaries for trainees.

When a gastroenterology fellow is considering an advanced endoscopy fellowship especially for training in third space endoscopy, many priorities and factors must be considered. While finding a well-established program with a high volume of diverse cases is important, having the opportunity to work with highly skilled and experienced endoscopists in order to gain guidance and mentorship is of the utmost importance. Observation of an experienced endoscopist is imperative given that third space endoscopy has historically been taught in a master-apprentice model.<sup>7</sup> However, adequate hands-on experience is also essential in third space endoscopy training. While many advanced endoscopy fellowships encompass third space endoscopy training, several programs are limited to didactics and animal labs. This is due to the fact that not every medical center that has an advanced endoscopy fellowship performs ESD, POEM or other third space

endoscopy procedures. Furthermore, the programs that do perform these procedures may limit hands-on trainee involvement given the significant risks associated with these procedures. While many of the initial steps for learning third space endoscopy can be acquired with observation, hands on experience with human cases are important in order to master these skills.

### Important factors to consider when choosing advanced endoscopy fellowship

- i. Choose an advance endoscopy fellowship at a program that is actively performing third space endoscopy.
- ii. Pick a program that is a high volume center in order to have as much opportunity to observe complex cases as well as to ensure repetition of more common procedures.
- iii. Identify experts in the field for observation as well as potential mentors for career planning and guidance.
- iv. Ensure the program provides supplemental educational opportunities such as didactics, literature reviews and attendance at regional and national conferences and courses.
- v. Discuss potential research opportunities that focus on diseases associated with third space endoscopy such as achalasia, Barrett's esophagus, squamous cell carcinoma of the esophagus, gastroparesis, early gastric cancers, submucosal lesions, colorectal lesions amenable to ESD. Also consider research on post procedural sequela and outcomes.
- vi. Be sure to not overlook the potential limitations of each program such as lack of experience, mentorship and opportunities for hands-on training.

## Establishing a third space endoscopy program

### Overview

Third space endoscopy procedures are being performed more commonly in the US. ESD specifically has gained support and interest due to its ability to perform en-block resections of large lesions and superior curative resection rates when compared to EMR.<sup>14</sup> However widespread adoption of ESD has been limited for several reasons including long procedure durations, the high technical demands required of the endoscopist, increased risk of adverse events and lack of reimbursement.<sup>15</sup> These limitations hinder the amount of available training opportunities available to endoscopists and create an uphill battle for those desiring to start a third space endoscopy program at their institution. Here we will outline some of the important considerations to take when embarking on establishing a third space endoscopy program.

### Institution, division and endoscopy support

To establish a well-designed and high-functioning third space endoscopy program, gaining the support of the health care institution, gastroenterology division and endoscopy suite leadership is paramount. Several steps and hurdles are involved in starting a program and backing from all levels of hospital leadership can make the growing pains more manageable. From an institutional standpoint, it is important to provide evidence regarding the considerably long term gain an upfront investment can produce. An example of this can be seen in the treatment of achalasia. A cost comparison study by Miller et al.<sup>17</sup> showed that while cost of a single pneumatic dilation of the lower esophageal sphincter may be less than that of a POEM,

the long term costs of pneumatic dilation exceed that of POEM due to the need for recurrent dilations and hospitalizations for uncontrolled symptoms.<sup>16,17</sup> Understanding of this long-term gain by institutional leadership is imperative in order to receive funding for equipment as well as colleague and staff support. Mutual respect, understanding and support from surgical subspecialties is needed given that third space endoscopy procedures are able to treat diseases historically treated with surgery. Education regarding these procedures and their potential complications needs to be provided to not only gastroenterologists and surgeons but also to radiologists and pathologists. Radiologists need to be aware of the procedures and devices utilized in third space endoscopy in order to correctly interpret post-procedure radiographic findings accurately as well as to identify possible complications, an example being pneumomediastinum/pneumoperitoneum status post POEM. These radiographic findings are expected procedural insufflation outcomes for a normal procedure and do not warrant emergent intervention. Pathologists also need to be aware of the ability for en-bloc resection, how the specimens will be delivered to pathology and the important components to include in the report such as margin depth, as well as vascular and lymphatic invasion to assist in R0 assessment for curative resection evaluation.

Strong support from division leadership is necessary in order to begin a robust and sustained referral basis. Gastroenterologists including gastroenterology fellows need to be educated regarding this rapidly evolving and growing field and the endoscopic procedures now available to treat conditions such as large colon or gastric polyps as well as achalasia and gastroparesis. Historically, patients with these conditions that failed medical or basic endoscopic management were referred to surgery. However with the advent of third space endoscopy, new endoscopic procedures exist that provide less invasive options for treatment. Support and referral by gastroenterology colleagues as well as referring doctors in the community and surgical colleagues is how a third space endoscopy program can begin to build volume and recognition.

Endoscopy leadership support is also extremely vital to the development and success of a third space endoscopy program. It is important for endoscopy leadership to encourage culture change and manage expectations of the endoscopy anesthesiology colleagues, nurse anesthetists, nurses and technicians. The endoscopy staff needs to understand the differences between third space procedures and the more common endoscopic procedures such as colonoscopy, EGD and ERCP. The third space endoscopy procedures tend to be of longer duration and require the use of devices and techniques that require specific training. Time and investment spent training endoscopy nurses and technicians in these skills will have long-term positive effects as it will allow for more efficient procedures with less delays and complications.

## Equipment

Third space endoscopy is an innovative field that requires new technology to perform these complex procedures. It is vital to have the necessary equipment and adequate supplies when establishing a third space endoscopy program. Below is a list of the commonly used equipment and accessories for third space endoscopy.<sup>18,19</sup>

- a. A dedicated cart to store the devices and equipment (labeled and organized for proper inventory)
- b. Endoscopes (Olympus GIF-HQ 190, 1T, 2T, pediatric colonoscope)
- c. Distal Cap
- d. Electrosurgical generators (ERBE VIO 300D or Olympus ESG-300)
- e. Carbon dioxide insufflators
- f. Adjustable insufflation with ultra low, low, medium and high flow rates (Olympus MAJ-1742 or Olympus MAJ-1816)
- g. Endoscopic flushing pumps (Olympus OFP-2, ERBE JET 2)
- h. Electrosurgical knives (Dual J Olympus, T and I type Hybrid ERBE)
- i. Coagulation forceps (Coagrasper, Olympus FD-410/411UR/412LR)
- j. Apollo overstitch
- k. Endoclips
- l. Methylene blue for submucosal injections, lifting agents/solutions
- m. Lugol's solution
- n. Cork, pins, large pathology containers
- o. Procedure reporting documents for: diagnosis, anatomy of site, and procedure times (start, stop, tunnel, myotomy, close)

## Billing and documentation

In addition to the support from the institution, division and endoscopy unit, a new third space endoscopy program requires a well-designed and established system for billing and coding. Physician reimbursement is a complex process that involves many key stakeholders such as Centers for Medicare and Medicaid (CMS), the American Medical Association (AMA), industry and specialty societies such as American Society for Gastroenterology Endoscopy (ASGE), American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA). Currently third space endoscopy procedures are coded as unlisted procedures which leads to inconsistent or no reimbursement to the endoscopist. A recent editorial published in *Gastrointestinal Endoscopy* discussed this issue and outlined the steps needed in order to obtain Category I Current Procedural Terminology (CPT) codes for third space endoscopy procedures in order to create more consistent reimbursement. A key component to achieving a Category I CPT code is to have necessary medical evidence in the form of clinical trials that demonstrate safety and clinical efficacy. However, even if this evidence is demonstrated to the highest degree with systemic reviews of randomized controlled trials, other components such as clinical efficacy, diseases prevalence and estimated use by providers are considered by the CPT Editorial Panel prior to creation of a Category I CPT code.<sup>20</sup>

Once a Category I CPT code is created, the Relative Value Scale Update Committee (RUC) determines the work and practice expense values that ultimately determine associated payment. However, the RVUs are based on survey data from providers actively performing the procedures which historically has required at least 300 practicing providers to participate. This poses a problem for third space endoscopy which is not yet widely practiced in the US and therefore would likely translate to poor survey response. These points to the need to establish more training programs and opportunities for endoscopists interested in learning third space endoscopy. The process required to obtain a

Category I CPT code also shows the important need for third space endoscopists to work together in a proactive and collaborative fashion to carry out well-designed studies and provide the medical evidence required.<sup>20</sup> However, since a standardized form of payment for third space endoscopy has not yet occurred, it is important for a new third space endoscopy program to educate and communicate well with the billing department. Billers need to understand what these procedures are and how to correctly document and bill accordingly. Appeal letters to insurance companies are also important to have formatted and ready to use in an effort to get reimbursement despite lack of CPT codes. An additional prewritten patient letter for appeals to insurance companies is also recommended and should be signed by the patient.

Additional documentation including procedural consent forms and templates for clinic and procedure notes need to be created as does information to provide to patients. Having concise and clear information to provide to patients is crucial given these procedures are new and complex. Creation of handouts that include easy-to-understand descriptions of the procedures as well as pictures and diagrams is extremely helpful for patients. The electronic medical record can also be helpful in regards to pre-made order sets with required medications as well as pre-procedure checklists to ensure all potentially needed equipment is available. Standardized post-procedure order sets are also useful to ensure consistent and accurate care. For example, post POEM, it is helpful to have a standard order set that includes the appropriate dietary restrictions, correct medications including antibiotics, proton pump inhibitors and pain medications, and imaging studies (upper GI series) to assess for defects.

## Conclusions

This is an exciting time in gastroenterology given the rapidly expanding field of third space endoscopy. The ability to provide effective and less invasive procedures for common conditions previously managed with surgery has very positive long-term effects on both patients and the health care system. In order to overcome the challenges that exist with establishing a third space endoscopy program, creation of more robust training opportunities and integration into advanced endoscopy fellowships is imperative. With mentorship, institutional support and collaborative efforts from exiting third space endoscopy programs, together we can bring about the changes needed to advance this field and push the boundaries of endoscopic innovation.

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## Conflicts of interest

The authors declare that they have no conflicts of interest to disclose.

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None.

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