

## Per-oral endoscopic myotomy white paper summary

*Achalasia is an uncommon esophageal motility disorder in which there is selective loss of inhibitory neurons resulting in loss of peristalsis and failure of adequate relaxation of the lower esophageal sphincter (LES) in response to food bolus. There is no current curative treatment that reverses the pathophysiology of achalasia. The treatment options are aimed at improving the passage of solids and liquids through the gastroesophageal junction (GEJ). The traditional treatment options include surgical myotomy and endoscopic methods that disrupt or weaken the LES, such as endoscopic balloon dilation and botulinum toxin injection (BT).*

*Per-oral endoscopic myotomy (POEM) represents a natural orifice transluminal endoscopic surgery (NOTES) approach to Heller myotomy. Preliminary data suggest that this minimally invasive endoscopic procedure may achieve clinical results similar to those of surgical myotomy. As part of the annual Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) meeting held in Chicago in July 2012, a conference was organized to collaboratively review POEM and develop a consensus document on the current status of POEM. An International POEM Survey (IPOEMS) was designed and conducted by the session moderators as part of this NOSCAR initiative to attempt to supplement the scant published literature with current data from POEM early adopters. The survey, which has now been published in detail,<sup>1</sup> included 5 Asian, 7 North American, and 4 European expert centers with a combined experience of 841 POEM procedures, including all high-volume centers (>30 cases per center) at the time of the survey in July 2012. These data span every aspect of POEM and were made available to the NOSCAR POEM panel presenters to assist them with preparation of their panel presentations that served as the basis of this white paper.*

This white paper is intended to discuss the development of POEM and outline the current state of POEM with regard to technique, indications and/or contraindications, peri-procedural evaluation and care, efficacy, safety, training, approach to starting a POEM program, and future perspectives. The sources of evidence used included: (1)

published data up to December 2013 [given the scarcity of series published in full form, we included selected abstracts with significant numbers of POEMs and adequate discussion of outcomes], (2) data from the IPOEMS, and (3) the minutes of the round-table discussion that followed the presentations by panel members of the POEM section at the annual NOSCAR meeting in Chicago in July 2012. This discussion included additional POEM operators from the United States and abroad beyond the panelists.

This document represents the shorter print version of a more detailed online white paper document.

### **PER-ORAL ENDOSCOPIC MYOTOMY FOR ACHALASIA: THE HISTORICAL AND PRECLINICAL LABORATORY EXPERIENCE**

Initial work by the Mayo Clinic Developmental Endoscopy Unit and the Apollo Group on widespread endoscopic mucosal resection, identified that with this endoscopic technique, the mucosa readily separates from the deeper layers of the gut wall, often referred to as delamination.<sup>2</sup> The 2004 Submucosal Inside Out Project began to transform the submucosa into an endoscopic working space.<sup>3-6</sup> Strategies were developed to work beneath the mucosa toward the lumen to enable en bloc excision of mucosal disease. Strategies also were developed to exit the gut wall by using a tunneled offset entry point for safe entry into body cavities, by means of a myotomy, with the overlying mucosa serving as a protective sealant flap (submucosal endoscopy with mucosal flap). Animal studies confirmed the feasibility and safety of exiting the esophagus into the mediastinum through a 2-cm myotomy.<sup>5,6</sup> It was suggested that the myotomy could be applied as an alternative therapy for achalasia. A subsequent animal study confirmed that submucosal endoscopy with mucosal flap combined with incision of the inner circular muscle layer could reduce the LES pressure in pigs.<sup>7</sup> Shortly thereafter, POEM was performed by using the submucosal endoscopy with mucosal flap principle with a technique adapted from endoscopic submucosal dissection (ESD) to create the submucosal space.<sup>8</sup> The initial work and subsequent work by other investigators involved blunt balloon dissection to create the submucosal tunnel to protect the overlying mucosa from injury and to expedite esophageal dissection.<sup>9</sup> Animal studies demonstrated that submucosal endoscopy with mucosal flap dissection deep within the gastric cardia (at least 2 cm) and cardiomyotomy are the potential defining components of a successful myotomy to treat achalasia.<sup>10</sup>

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Further, NOSCAR-supported animal studies compared circular muscle layer versus full-thickness myotomy. These studies demonstrated that the effect on LES pressure was similar with either method and that full-thickness myotomy was easier and more expeditious.<sup>11</sup>

### Indications, contraindications, and pre-procedural evaluation and preparation

POEM appears to be a safe and effective alternative for the treatment of classic achalasia.<sup>12-30</sup> However, its role and efficacy in patients with other hypertensive motor disorders, prior conventional achalasia treatments, end-stage achalasia, age extremes, and significant comorbid diseases is not clear.

#### POEM for other hypertensive motor disorders.

Preliminary data in the literature suggest POEM efficacy in motor disorders other than classic achalasia. Successful application of POEM in a small number of patients with diffuse esophageal spasm,<sup>1,16,31-33</sup> hypertensive LES,<sup>1,33,34</sup> type III spastic achalasia,<sup>1,14,17,21</sup> nutcracker esophagus,<sup>17,33</sup> and jackhammer esophagus<sup>35</sup> has been reported. It has been suggested that pain, a prominent symptom in many of these disorders, responds less well to POEM than does dysphagia, the predominant symptom in patients with typical achalasia.<sup>17</sup> In the international POEM survey, 11 of the 16 participating centers reported performing POEM for these extended manometric indications (accounting for 28% of the 841 POEMs reported in the survey).<sup>1</sup> Possibly somewhat diminished POEM efficacy was reported in patients with diffuse esophageal spasm and type III achalasia but excellent efficacy in hypertensive LES and nutcracker esophagus.<sup>1</sup> Based on the case reports in the literature and IPOEMS responses, longer esophageal myotomy is being performed for spastic disorders such as diffuse esophageal spasm that are characterized by long spastic segments of the distal esophagus.<sup>1</sup> POEM may be superior to laparoscopic Heller myotomy (LHM) in these patients because the myotomy can be extended proximally in the body of the esophagus.

**POEM after failed conventional treatments of achalasia.** Prior BI causes submucosal fibrosis which, to varying degrees, obliterates the surgical planes that adversely affect surgical myotomy and possibly POEM.<sup>36</sup> In IPOEMS, 43% of the 841 reported POEMs were performed in patients with prior failed treatments.<sup>1</sup> The general consensus among POEM operators is that the submucosal fibrosis caused by prior BI does result in a slower and more challenging dissection, but the effect is moderate and may be overcome by operator experience.<sup>1</sup> Although most POEM series have included a substantial proportion of patients, ranging from 18% to 69%,<sup>14,15,17,18</sup> with prior standard achalasia treatments, outcomes specific to these patients have not been presented until recently, when two groups attempted to examine the effect of before-POEM endoscopic treatment on POEM outcomes. During subgroup analysis of patients with or without histories of

endoscopic intervention, one group found no difference in procedure duration, intraoperative adverse events, or efficacy,<sup>37</sup> whereas the other group found prior endoscopic treatment to be a predictor of increased procedure time.<sup>38</sup> The discordant findings may be related to methodologic issues such as the very small numbers of previously treated patients included in these studies (4 and 12, respectively). POEM after failed surgical Heller myotomy is reported to be more challenging, but recent reports demonstrate excellent efficacy when POEM is performed by experienced operators.<sup>1,13,18,22,27,39,40</sup>

**POEM for end-stage achalasia.** POEM in severe sigmoid achalasia and megaesophagus was reported in only 3% and 4%, respectively, of all POEMs in IPOEMS.<sup>1</sup> Patients with severe sigmoidization and megaesophagus (end-stage achalasia) respond poorly to LHM, based on the LHM literature, and may ultimately come to esophagectomy.<sup>36</sup> Unlike LHM, POEM appears to cause minimal adhesions,<sup>19</sup> and, therefore, it should not significantly affect subsequent esophagectomy. Therefore, it could be considered as an initial treatment in these patients, with esophagectomy reserved for those with inadequate clinical response. Most published series have excluded patients with severe sigmoidization and/or megaesophagus (stage IV achalasia). One center has performed POEM in 20 stage IV patients.<sup>27</sup> POEM in such patients is more challenging than in stage I to III patients, with significantly longer procedure times (mean procedure time in 20 stage IV patients = 129 minutes compared with 100 minutes in 80 patients at other stages ( $P < .02$ , unpublished data)). No significant difference in efficacy or adverse events was noted.

**POEM in children and the elderly.** Another concern regarding POEM revolves around age extremes. There are reports of successful POEM in patients as young as 3 years and as old as 97 years, which suggests that POEM may be a feasible treatment option for appropriately selected patients, even at extremes of age.<sup>1,20,27,41-43</sup>

**POEM in patients with comorbid conditions.** The majority of IPOEMS respondents considered POEM contraindicated in patients with a history of severe pulmonary disease, cirrhosis with portal hypertension, severe coagulopathy, and prior interventions resulting in significant submucosal fibrosis such as esophageal irradiation, ablation therapy, and extensive EMR (Table 1).<sup>1</sup>

**Pre-procedural evaluation and preparation.** Pre-procedural evaluation and preparation do not differ significantly from those of LHM. IPOEMS collected detailed data on evaluation and preparation and revealed mostly minor variations among respondents.<sup>1</sup> A more detailed discussion is presented on the online full-length version of this white paper.

**POEM technique.** Many, but not all, centers perform an EGD 1 to 3 days before the POEM procedure in order to remove any solid or liquid material from the esophagus as well as to evaluate for *Candida* esophagitis or any other esophageal or gastric lesions.

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