Management of reflux after peroral endoscopic myotomy

Zachary M. Callahan, Bailey Su, Michael Ujiki

Department of Surgery, NorthShore University HealthSystem, Evanston, IL, USA

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Correspondence to: Zachary M. Callahan, MD. General Surgery Resident, Department of Surgery, Northshore University HealthSystem, 2650 Ridge Ave, Evanston, IL 60201, USA. Email: zmcallahan@gmail.com.

Abstract: Peroral endoscopic myotomy (POEM) has emerged as an attractive treatment option for patients suffering from achalasia. The endoscopic nature of the procedure prevents an accompanying fundoplication to decrease post-procedure gastroesophageal reflux (GER). A large amount of literature exists reporting incidence of post-POEM GER but differences in the metric used to report GER, short follow-up and infrequent objective measuring creates wide variation in this data. Moderately sized multi-institutional trials and meta-analysis that use the most sensitive metric of GER suggest the incidence is close to 50%, which is significantly higher than traditional Heller myotomy with fundoplication. Although chronic GER has serious risks and implications in this patient population, many studies report complete subjective and objective resolution with anti-reflux medications. Novel endoscopic fundoplication technologies are emerging but their role in post-POEM GER is yet to be determined.

Keywords: Peroral endoscopic myotomy (POEM); reflux; myotomy; Heller

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Introduction

Heller myotomy has long been established as effective surgical treatment for achalasia. Soon after the procedure’s adoption, reports of postoperative pathologic gastroesophageal reflux (GER) created controversy among surgeons; some surgeons attributed reflux to an overzealous myotomy while others insisted that it was an unavoidable result of the procedure (1–4). Reflux after myotomy makes physiologic sense because although obliterating the lower esophageal sphincter allows passage of food and resolution of dysphagia, it also weakens the anatomic mechanism that protects the distal esophagus from caustic gastric contents. The controversy was ultimately settled after numerous studies demonstrated the necessity of an accompanied fundoplication during myotomy; fundoplication effectively reduced post-operative GER without affecting dysphagia scores or recurrence (5–10).

Interestingly, the impressive technologic and technical advent of the peroral endoscopic myotomy (POEM), an incisionless procedure that boasts a comparable success and complication rate as Heller myotomy (11–13), has resurfaced the problem encountered by the first esophagomyotomy surgeons twenty years earlier. The endoscopic nature of the procedure prevents a concomitant anti-reflux procedure. Additionally, some argue that this approach does not necessarily warrant an anti-reflux procedure, as the spared longitudinal muscles fibers, intact phrenoesophageal ligament, and preserved nervous complex of the gastroesophageal (GE) junction protect against significant reflux (14–18). This review will discuss the definition, incidence, diagnosis, implications, and treatment of post-POEM GER.

Definition

Before discussing the incidence of post-POEM GER, it is important to acknowledge the variation in how GER is measured across studies and recognize that this may account
for the wide range of incidence reported in the literature. Assessments may include symptom questionnaires, proton
pump inhibitor (PPI) use, endoscopic evidence of reflux
esophagitis, or 24-hour pH abnormalities. Thus, it is no
surprise that large meta-analyses differ depending on which
metric is used (19). In fact, the most objective measure of
GER, abnormal pH levels, tends to be the least reported
outcome metric after POEM (13,20). Additionally, some
selection bias where only symptomatic patients undergo
testing, may further obscure the data. Lastly, the relative
novelty of POEM prevents a fair long-term comparison
to laparoscopic Heller myotomy (LHM) and long-term
incidence of GER after POEM remains unknown.

### Incidence and diagnosis of reflux

#### Symptoms

The greatest amount of literature on post-POEM GER
uses symptoms as a marker of reflux (Table 1). Most studies
use clinical symptoms such as regurgitation, heartburn, and
retrosternal pain, though some have adopted standardized
reflux score such as GERDQ, GERSS, and GERD-HRQL.
Interestingly, many patients experience these symptoms
pre-operatively as a result of achalasia and it is unclear how
this affects the true rate of reflux. In the current literature,
post-POEM GER ranges from 6% to 37%. Studies with
the largest sample sizes (n>100) place the incidence between
16–22% (17,21-25). A true conclusion from this data should
be drawn carefully, as the majority of POEM studies have
less than 1-year follow-up. Additionally, some but not all
patients are discharged on varying lengths and doses of PPI
prophylaxis, which may alter symptomatology. Recently, a
large meta-analysis using 2,142 patients with an average of
7.6 months of follow-up after POEM, found the incidence
of symptomatic GER to be lower, at 8.8% (20). This
discrepancy may be partially explained by the predominantly
Asian populations in many of these studies; Asian countries

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study type</th>
<th>Region</th>
<th>Patients evaluated (n)</th>
<th>GER rate</th>
<th>Follow-up (months)</th>
<th>Definition</th>
<th>Discharge on PPI</th>
</tr>
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<td>RC, SI</td>
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<td>von Renteln</td>
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<td>PC, 5 centers</td>
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<td>70</td>
<td>33%</td>
<td>3</td>
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<td>–</td>
</tr>
<tr>
<td></td>
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<td>China</td>
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<td>Median 11.5</td>
<td>Clinical symptoms</td>
<td>8 weeks, regular dose</td>
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<tr>
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<td>PC, SI</td>
<td>China</td>
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<td>10.3%</td>
<td>Mean 14.4</td>
<td>Clinical symptoms</td>
<td>2 weeks, regular dose</td>
</tr>
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<td>81</td>
<td>9%</td>
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<td>12 to 24</td>
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<td></td>
<td>61</td>
<td>36</td>
<td>Clinical symptoms</td>
<td>–</td>
</tr>
<tr>
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<td>China</td>
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<td>6.0%</td>
<td>12</td>
<td>Clinical symptoms</td>
<td>2 weeks, regular dose</td>
</tr>
<tr>
<td>Shiwaku</td>
<td>2016</td>
<td>PC, SI</td>
<td>Japan</td>
<td>70</td>
<td>7.1%</td>
<td>3</td>
<td>Clinical symptoms</td>
<td>4 weeks, regular dose</td>
</tr>
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<td>Familiari</td>
<td>2016</td>
<td>PC, SI</td>
<td>Italy</td>
<td>103</td>
<td>18.4%</td>
<td>Mean 7.6</td>
<td>GERDQ &gt;7</td>
<td>–</td>
</tr>
<tr>
<td>Ramchandani</td>
<td>2016</td>
<td>RC, SI</td>
<td>India</td>
<td>102</td>
<td>21.6%</td>
<td>Mean 13.4</td>
<td>Clinical symptoms</td>
<td>–</td>
</tr>
<tr>
<td>Hungness</td>
<td>2016</td>
<td>PC, SI</td>
<td>USA</td>
<td>111</td>
<td>28%</td>
<td>Mean 24</td>
<td>GERDQ &gt;7</td>
<td>6 months, regular dose</td>
</tr>
<tr>
<td>Werner</td>
<td>2016</td>
<td>RC, 3 centers</td>
<td>USA, Europe</td>
<td>79</td>
<td>24.1%</td>
<td>3 to 6</td>
<td>Clinical symptoms</td>
<td>2 weeks, double dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>12 to 18</td>
<td>Clinical symptoms</td>
<td>2 weeks, double dose</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>80</td>
<td>37%</td>
<td>Clinical symptoms</td>
<td>2 weeks, double dose</td>
</tr>
<tr>
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<td>2017</td>
<td>PC, SI</td>
<td>India</td>
<td>261</td>
<td>16.8%</td>
<td>12</td>
<td>Clinical symptoms</td>
<td>–</td>
</tr>
</tbody>
</table>

PC, prospective cohort; RC, retrospective cohort; SI, single institution; POEM, peroral endoscopic myotomy.
have lower prevalence of GER and less GER-pathogenetic factors such as different lifestyles and eating habits (32).

Even if symptomatic GER after POEM is as low as 8.8%, it is important to recognize that the correlation between symptomatic and pathologic GER, evidenced by esophagogastroduodenoscopy (EGD) or pH monitoring, is questionable. Jones et al. (33) tested for correlation between GERSS/GERD-HRQL surveys and pH testing in 43 patients after POEM. They found poor correlation with either survey; most alarming was that asymptomatic patients comprised 50% of those with pathologic acid reflux. Multiple other studies demonstrated similar findings (23,34-38). The variation in methods of measuring symptoms as well as poor correlation of symptoms to pathologic GER suggests that the best measure of post-POEM GER is not subjective, but objective.

**Esophagitis**

Esophagitis diagnosed on endoscopy works nicely as an objective measure of pathologic GER. In POEM literature, esophagitis is most commonly measured with the Los Angeles (LA) classification during endoscopy (Table 2). The classification groups the degree of esophageal erosion into mild (A, B) and more severe (C, D). In large studies that impose universal post-POEM endoscopy, the rate of esophagitis ranges from 6 to 64.7% (Table 3). It is important to note that although all these studies required post-procedure EGD regardless of symptoms, not all had 100% compliance and thus some bias affects this data; a patient who is having symptoms of reflux is more likely to be willing to undergo endoscopy than a patient who is asymptomatic. Regardless, the rate of esophagitis is quite high across these studies but the majority of patients exhibited only mild esophagitis (class A or B). The meta-analysis by Akintoye et al. again seems to settle a bit lower than the rest of the literature. They found the average incidence of esophagitis in 1,762 patients to be 13% with 8.4-month follow-up. Using esophagitis on EGD as a marker for GER is imperfect as the grading is somewhat subjective and it requires an invasive procedure with inherent risks. Additionally, one could argue that esophagitis is actually the consequence of reflux and thus not the most sensitive marker; the most sensitive marker would objectively detect reflux in real-time.

**pH monitoring**

Schlottman et al., in a large meta-analysis, reminds physicians that POEM is a new technology and thus should be evaluated with the most sensitive and accurate test (13). Exposure of the esophagus to gastric contents is most accurately measured by pH probe studies. The invention of wireless probes that can collect up to 96 hours of data has allowed an increasing amount of post-POEM pH data to emerge. Most post-POEM studies use a DeMeester score of greater than 14.7 or an esophageal pH of less than 4 for greater than 5% of the study period to classify as abnormal acid exposure, which is consistent with non-POEM-related GER literature. Incidence of abnormal pH studies in POEM patients ranges from 15–88% (Table 4). This parameter, more so than symptoms of esophagitis, is affected by smaller sample size (n=23–103) and short follow-up (only two studies with a mean follow up of greater than 10 months). The Akintoye meta-analysis estimates abnormal acid exposure of 47% in 336 patients at an average follow-up for 8.6 months. It should be emphasized that the most objective, sensitive test for post-POEM GER not only demonstrates an alarmingly high rate of GER but that both symptomatic and endoscopic markers seem to drastically underestimate it.

**Rate of GER in LHM; how does POEM compare?**

Despite the seemingly high rate of GER after POEM, it is important to remember that myotomy even with fundoplication has a fairly high rate of post-procedure GER as well. Studies examining GER after LHM suffer from
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study type</th>
<th>Region</th>
<th>Total patients (n)</th>
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<th>Esophagitis rate</th>
<th>Follow-up (months)</th>
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<td>Mean 10.5</td>
<td>“A or B”</td>
</tr>
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<td>PC, 5 centers</td>
<td>USA, Europe</td>
<td>70</td>
<td>70</td>
<td>42%</td>
<td>3</td>
<td>A [21], B [9], C [0], D [0]</td>
</tr>
<tr>
<td>Cai</td>
<td>2014</td>
<td>RCT, SI</td>
<td>China</td>
<td>100</td>
<td>100</td>
<td>10%</td>
<td>3 to 6</td>
<td>–</td>
</tr>
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<td>Sharata</td>
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<td>USA</td>
<td>100</td>
<td>73</td>
<td>27.4%</td>
<td>6</td>
<td>A [15], B [3], C [2], D [0]</td>
</tr>
<tr>
<td>Inoue</td>
<td>2015</td>
<td>PC, SI</td>
<td>Japan</td>
<td>500</td>
<td>414</td>
<td>64.7%</td>
<td>2</td>
<td>A [140], B [107], C [20], D [1]</td>
</tr>
<tr>
<td>Ramchandani</td>
<td>2016</td>
<td>RC, SI</td>
<td>India</td>
<td>220</td>
<td>84</td>
<td>16.8%</td>
<td>Mean 13.4</td>
<td>A [10], B [4], C [0], D [0]</td>
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<td>103</td>
<td>103</td>
<td>20.4%</td>
<td>Mean 7.6</td>
<td>A [9], B [6], C [5], D [1]</td>
</tr>
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<td>USA, Europe</td>
<td>85</td>
<td>68</td>
<td>36.8%</td>
<td>3 to 6</td>
<td>A [14], B [11], C [0], D [0]</td>
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<tr>
<td>Shiwaku</td>
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<td>Japan</td>
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<td>6%</td>
<td>3</td>
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<td>Nabi</td>
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<td>India</td>
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<td>227</td>
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<td>12</td>
<td>A [26], B [11], C [3], D [1]</td>
</tr>
<tr>
<td>Kumbhari</td>
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<td>RCC, 7 centers</td>
<td>USA, Europe, Asia</td>
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<td>233</td>
<td>23.2%</td>
<td>Median 12</td>
<td>A [27], B [14], C [9], D [4]</td>
</tr>
</tbody>
</table>

RC, retrospective cohort; PC, prospective cohort; RCT, randomized control trial; RCC, retrospective case-control; SI, single institution; LA, Los Angeles; POEM, peroral endoscopic myotomy; EGD, esophagogastroduodenoscopy.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study type</th>
<th>Region</th>
<th>Total patients (n)</th>
<th>Patients with pH testing (n)</th>
<th>Abnormal pH</th>
<th>Follow-up (months)</th>
<th>Abnormal pH definition</th>
</tr>
</thead>
<tbody>
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<td>Chan</td>
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<td>RC, SI</td>
<td>China</td>
<td>56</td>
<td>34</td>
<td>15%</td>
<td>6</td>
<td>&gt;14.7 DeMeester</td>
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<tr>
<td>Nabi</td>
<td>2017</td>
<td>PC, SI</td>
<td>India</td>
<td>408</td>
<td>92</td>
<td>28.3%</td>
<td>3</td>
<td>&gt;14.7 DeMeester</td>
</tr>
<tr>
<td>Filicori</td>
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<td>USA</td>
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<td>26</td>
<td>38%</td>
<td>6</td>
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<tr>
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<td>PC, SI</td>
<td>USA</td>
<td>100</td>
<td>68</td>
<td>38.2%</td>
<td>6</td>
<td>&gt;14.7 DeMeester</td>
</tr>
<tr>
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<td>PC, SI</td>
<td>USA</td>
<td>101</td>
<td>23</td>
<td>39%</td>
<td>Median 6.8</td>
<td>&gt;14.7 DeMeester</td>
</tr>
<tr>
<td>Wang</td>
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<td>RC, SI</td>
<td>China</td>
<td>56</td>
<td>32</td>
<td>40.6%</td>
<td>Mean 39.3</td>
<td>Esophageal pH &lt;4 for &gt;5% of the 24-h period</td>
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<td>PC, SI</td>
<td>Italy</td>
<td>103</td>
<td>103</td>
<td>50.5%</td>
<td>Mean 7.6</td>
<td>Esophageal pH &lt;4 for &gt;5% of the 24-h period</td>
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<tr>
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<td>RCC, 7 centers</td>
<td>USA, Europe, Asia</td>
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<td>57.8%</td>
<td>Median 12</td>
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<td>6</td>
<td>&gt;14.7 DeMeester</td>
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<td>Khashab</td>
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<td>USA</td>
<td>60</td>
<td>25</td>
<td>88%</td>
<td>Mean 3.9</td>
<td>Abnormal acid exposure</td>
</tr>
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</table>

RC, retrospective cohort; PC, prospective cohort; RCC, retrospective case-control; SI, single institution; POEM, peroral endoscopic myotomy.
the same pitfalls that afflict post-POEM studies. Multi-institutional studies that use abnormal pH as a marker for GER place the true incidence of GER after LHM as high as 21–42% (43-45). A well-executed retrospective review of prospectively collected data by Bhayani et al. (40) demonstrated similar incidence of GER after LHM and POEM as assessed by 24-hour pH studies (32% LHM vs. 39% POEM; P=0.7) and other studies corroborate these findings (11,12,46).

Despite this, the two largest and most recent meta-analyses designed to address this question suggest that the rate of post-POEM GER is significantly higher than for LHM, as many surgeons originally suspected (13,47). Table 5 summarizes the results from Repici et al., which demonstrated significantly higher rates of GER across subjective and objective markers for POEM patients when compared to LHM. Analysis from Schlottman et al. (13) tells a similar story. POEM was found to have significantly higher rates of esophagitis on EGD (22.4% POEM vs. 11.5% LHM) and abnormal acid exposure in pH studies (47.5% in POEM vs. 11.1% in LHM). Both analyses include thousands of patients and likely represent the most accurate estimate of post-POEM GER in comparison to LHM.

### Treatment of post-POEM GER

In almost all studies where post-POEM GER was diagnosed, patients were treated with PPIs. Numerous studies conclude that GER was easily controlled in this manner with symptom resolution in all patients (16,20,21,27,28,38,49-53). Additionally, a handful of studies documented objective evidence of GER resolution with PPI treatment, usually by repeat EGD (23,35,36,54). These studies varied in terms of PPI dosing and length of therapy but most used double dose PPI for 6 weeks if endoscopic esophagitis was found.

With such a high efficacy of PPIs in post-POEM GER, a logical conclusion might be to universally prescribe PPIs for POEM patients. Lifelong PPI therapy has

### Table 5 GERD after per-oral endoscopic myotomy as compared with Heller myotomy with fundoplication: a systematic review with meta-analysis by Repici et al. 2018 (47)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Symptomatic GER</th>
<th>Esophagitis on EGD</th>
<th>Abnormal pH</th>
</tr>
</thead>
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<tr>
<td>POEM</td>
<td>19.0%</td>
<td>29.4%</td>
<td>39.0%</td>
</tr>
<tr>
<td>Studies</td>
<td>17</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Total patients (n)</td>
<td>1,275</td>
<td>1,056</td>
<td>289</td>
</tr>
<tr>
<td>Follow up (months)</td>
<td>Not stated</td>
<td>9.3</td>
<td>Not stated</td>
</tr>
<tr>
<td>LHM</td>
<td>8.8%</td>
<td>7.6%</td>
<td>16.8%</td>
</tr>
<tr>
<td>Studies</td>
<td>20</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Total patients (n)</td>
<td>1,136</td>
<td>752</td>
<td>1,022</td>
</tr>
<tr>
<td>Follow up (months)</td>
<td>Not stated</td>
<td>26.6</td>
<td>22.8</td>
</tr>
</tbody>
</table>

GERD, gastroesophageal reflux disease; GER, gastroesophageal reflux; EGD, esophagogastroduodenoscopy; POEM, peroral endoscopic myotomy; LHM, laparoscopic Heller myotomy.

Implications of post-POEM GER

Regardless of variation in the reported incidence of post-POEM GER, it is undeniable that reflux after POEM affects a sizeable number of patients and the clinical implications of this are yet to be determined. This is particularly important as most long-term failures after treatment of achalasia are related to complications of reflux (36). Perhaps the more concerning risk is that of Barrett’s esophagus and progression to esophageal adenocarcinoma. Leeuwenburgh et al. examined a cohort of achalasia patients treated with pneumatic dilation at an impressive 8.9 years of average follow-up. They found that 8.4% of their cohort developed Barrett’s esophagus and 7% of that group developed esophageal adenocarcinoma (48). Studies looking specifically at rates of Barrett’s esophagus after POEM are sparse but early results seem to suggest that this is more than just a theoretical risk (26). In fact, the implications of post-POEM GER are so great that a recent publication in *Endoscopy* asked if reflux has the potential to “kill POEM” and warned surgeons to monitor these patients carefully (19).
drawbacks however. Firstly, patient compliance is a major issue especially because the majority of these patients are asymptomatic. Additionally, there are increasing concerns for serious side effects with long-term PPI use secondary to vitamin deficiencies, bone fractures, kidney disease, community acquired pneumonia, and increasing rates of Clostridium difficile infections (55-59).

The barriers to medical treatment of post-POEM GER might make surgical treatment a reasonable option. If a patient’s reflux is severe and refractory, one could certainly offer a laparoscopic fundoplication; this has been demonstrated to be a safe and successful treatment method in a handful of patients (60,61). Obviously, requiring a laparoscopic procedure after POEM is not ideal and obviates the endoscopic benefit of the initial procedure.

An endoscopic fundoplication would be most ideal and the relatively novel transoral incisionless fundoplication (TIF) is an attractive option (Esophyx; EndoGastric Solutions, Redmond, WA, USA). This fully endoscopic procedure creates an anti-reflux barrier through creation of a valve 2 to 4 cm in length with a 270 degree or greater circumferential wrap (62). A 2013 systematic review of 551 patients with GER who underwent TIF demonstrated a PPI discontinuation rate of 67% and a 72% patient satisfaction rate. Unfortunately, pH metrics failed to show normalization in this group (63). Notwithstanding, using TIF to treat post-POEM GER has been published in a small case series. Tyberg et al. demonstrated 100% PPI discontinuation in five patients that underwent TIF after POEM. At 3-month EGD, all patients had resolution of esophagitis. Unfortunately, pH metrics after TIF were not measured (64).

Other endoscopic options for GER management exist and could theoretically be used to treat post-POEM GER. The Stretta system (Restech Mederi-RF, Houston, TX, USA) uses radiofrequency ablation to create thermal effect below the mucosa at the GE junction and restore the reflux barrier (65). In non-POEM patients, this technology has been fairly well studied. A recent meta-analysis by Fass et al., containing 2,468 patients (4 randomized controlled trials, 23 cohort studies, and 1 international registry) showed that Stretta improved GERD-HRQL score by 14.6 points (P<0.001) and 51% of patients discontinued PPIs (P<0.001). In a smaller subset of patients, Stretta lowered the incidence of esophagitis by 24% (P<0.001) and DeMeester score by 13.79 (P<0.001) (66). Data looking at Stretta specifically for post-POEM GER has yet to be published.

The Anti-Reflux Mucosectomy (ARMS) involves endoscopic resection of gastric and esophageal mucosa in crescentic fashion which causes remodeling of the gastric cardia flap valve (67). There is little literature on outcomes but the pilot study is encouraging, showing significant improvement in abnormal acid exposure as documented by pH monitoring. Other therapies involving electrical stimulation and magnets are emerging in animal models as well (68,69). It is important to remember that the goal of treating post-POEM GER is objective improvement in reflux because subjective markers in achalasia patients are inconsistent and inaccurate. None of the endoscopic therapies presented above have demonstrated efficacy to this regard leading some to argue that none of them are indicated after POEM until more data become available. To this same end, no endoscopic GER therapy, except for a small case series of TIF patients, has been used in post-POEM GER specifically, and thus the safety and efficacy in this patient population remains unknown.

Recommendations

The post-POEM GER literature suffers from wide variation in methods of measuring GER and thus the true incidence of reflux in these patients is unknown. However, in summating large multicenter studies and current meta-analyses, a significant proportion, possibly more than half of POEM patients, will have pathologic reflux as documented by the most sensitive marker, pH monitoring. This incidence is likely higher than that seen in the current standard, LHM. Thus, the authors conclude that all patients who undergo POEM should be discharged on daily PPI for 6 to 12 months followed by a 96-hour pH study. If the study is positive, then the standard of care is to continue PPI or undergo a laparoscopic anti-reflux procedure in addition to screening EGD every 5 years. If the pH test is negative, the PPI is stopped and repeat testing is only done for patients who develop symptoms. This group should also undergo EGD every 5 years. Similar standards are being adopted by many major medical centers across the world and has the potential to prevent serious complications of uncontrolled post-POEM GER (26,33,34,36,39,41,47).

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None.
Footnote

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References


