Is a POEM the Requiem for Heller’s Myotomy?

Matthew G. Hartwig, MD, MHS, FACS
Associate Professor Surgery
Director, Minimally Invasive Thoracic Surgery Fellowship
Duke University Health System
Disclosure Slide

• Consultant for Medtronic, Mallincrodt, and Quark Pharmaceuticals unrelated to this talk.

• Research funding from Torax for the treatment of GERD.
The Essence of the Matter

• …because as we know, there are *known knowns*; there are things we know we know. We also know there are *known unknowns*; that is to say we know there are some things we do not know. But there are also *unknown unknowns*-the ones we don’t know we don’t know…it is the latter category that tend to be the difficult ones.

-Donald Rumsfeld
Secretary of Defense
News briefing February 12th, 2002
Known, Knowns…

Case Presentation
- 63 y/o female referred by PCP for GERD.
- History of BrCa s/p lumpectomy and chemo/XRT, depression, chronic pain
- Complaining of substernal and epigastric pain, heartburn, food getting stuck and regurgitation worsening over many years.
Known, Knowns...

Case Presentation

• 24-hour pH study—off her PPI’s

Interpretation / Findings
Distal Esophageal Acid Exposure (contact time reported as % total time)
- Total .5% (Normal < 4.2%);  Upright .4% (Normal < 6.3%);  Supine .7% (Normal < 1.2%)

Number of reflux episodes:
The total number of reflux episodes for the entire study was 17 (Normal < 73).
Known, Knowns…

Case Presentation

- Manometry:

<table>
<thead>
<tr>
<th>LES Pressures</th>
<th>esSleeve e, IRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal (respiratory min) (mmHg)</td>
<td>41.0</td>
</tr>
<tr>
<td>Basal (respiratory mean) (mmHg)</td>
<td>49.2</td>
</tr>
<tr>
<td>Residual (mean) (mmHg)</td>
<td>15.9</td>
</tr>
<tr>
<td>Residual (highest) (mmHg)</td>
<td>29.6</td>
</tr>
<tr>
<td>Percent relaxation (%)</td>
<td>60</td>
</tr>
</tbody>
</table>

**Esophageal Motility**

<table>
<thead>
<tr>
<th>Number of swallows evaluated</th>
<th>Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluated @ 3.0 - 11.0 above LES</td>
<td>10</td>
</tr>
<tr>
<td>Peristaltic (velocity ≤ 6.25 cm/s) (%)</td>
<td>90</td>
</tr>
<tr>
<td>Simultaneous (vel. ≥ 6.25 cm/s) (%)</td>
<td>0</td>
</tr>
<tr>
<td>Failed (%)</td>
<td>10</td>
</tr>
</tbody>
</table>

These findings are most consistent with EGJ Outflow Obstruction as can be seen in the setting of mechanical obstruction, primary or secondary motility disorders, or an achalasia variant. Recommend correlation with clinical symptoms. A well done barium swallow, EGD and possible EUS or CT chest would be helpful here.
Disorders of EGJOO

Chicago Classification v3.0

Fig. 1. Diagnosis of disorders of EGJOO according to CC ver3.0 (adapted from Collman et al. [3]). Disorders of EGJOO are classified into EGJOO and achalasia (types I, II and III), with or without esophageal body peristalsis, respectively. PEP = Panesophageal pressurization.

Digestion 2017;95:29–35
Disorders of EGJOO: Clinical Evaluation

- Hi Res Manometry
- EGD/EUS
- Endoflip
- Barium Swallow
- CT scan
- Botox

Known, Knowns...

Case Presentation

• EGD

The examined esophagus was normal. Six biopsies were obtained with cold forceps for histology in the proximal esophagus, in the mid esophagus and in the distal esophagus.

A small hiatal hernia was present.
Disorders of EGJOO: Clinical Evaluation

- Hi Res Manometry
- EGD/EUS
- Endoflip
- Barium Swallow
- CT scan
- Botox

*World J Gastroenterol* 2017 February 21; 23(7): 1289-1297
Known, Knowns...

Case Presentation

• EGD Endoflip

After completion of the exam and under direct endoscopic visualization, the EndoFLIP balloon catheter was advanced into the stomach, inflated to 20cc and withdrawn across the LES/GEJ. The balloon was inflated and diagnostic measurements were obtained. At 20cc the DI was 1.4 and the diameter was 5. At 30cc the DI was 1.2 and the diameter was 5.2. At 40cc the DI was 2.0 and the diameter was 7.5.

- EndoFLIP measurements as above. These are equivocal for intrinsic dysmotility and not diagnostic of achalasia.
Disorders of EGJOO: Clinical Evaluation

- Hi Res Manometry
- EGD/EUS
- Endoflip
- Barium Swallow
- CT scan
- Botox
Known, Knowns...

Case Presentation

- BaSw

Findings:
Normal pharyngeal morphology and function. Esophagus is negative for stricture, ulceration, filling defects, or diverticula. Moderate esophageal dysmotility. No hiatal hernia is seen.

There is no spontaneous or inducible gastroesophageal reflux.

Examination of the stomach demonstrated normal rugal folds. The stomach and duodenal bulb appear normal without evidence of ulceration or mass. Normal gastric emptying is observed.

Fluoroscopic examination of the duodenum demonstrates normal motility and morphology without evidence of ulceration or mass lesion.

Impression:
1. Moderate esophageal dysmotility.
Disorders of EGJOO: Clinical Evaluation

- Hi Res Manometry
- EGD/EUS
- Endoflip
- Barium Swallow
- CT scan
- Botox
Known, Knowns…

Case Presentation

- CT Chest: normal esophagus

Impression:

1. Indeterminate scattered subcentimeter pulmonary nodules measuring up to 4 mm. Comparison with older outside studies will be helpful.

2. Reticulation in the periphery of the left lung consistent with sequelae of radiation therapy.
Disorders of EGJOO: Clinical Evaluation

- Hi Res Manometry
- EGD/EUS
- Endoflip
- Barium Swallow
- CT scan
- Botox

Use of botulinum toxin as a diagnostic/therapeutic trial to help clarify an indication for definitive therapy in patients with achalasia

David A Katzka MD & Donald O Castell MD

Received: 06 July 1998
Accepted: 07 October 1998
Known, Knowns…

Case Presentation

• EGD Botox injection
  – 100 units into GEJ

• Patient reports improvement in dysphagia. Still with some substernal chest pain/pressure

• Requests intervention for dysphagia
Known, Knowns…

- April 14, 1913, at the University of Leipzig
  Ernst Heller performed a transabdominal extramucosal cardioplasty
  - Anterior and posterior walls of the cardia
  - 8 cm in length
  - F/u for 8 years with good results

Known, Knowns…

• J. H. Zaaier from Leiden, along with other surgeons from Holland demonstrated only one (anterior) myotomy was required.

• J. Dor from Marseille, France described in 1962 a modification that included a 10cm myotomy (5cm on to the stomach) and an anterior fundoplication
Known, Knowns…

- Ancona and colleagues demonstrated equal efficacy of laparoscopic to open transabdominal myotomy with fundoplication, but with decreased pain, LOS, and scarring.

- Over the last 20+ years laparoscopic heller myotomy has become the gold-standard therapy for achalasia.

Known, Unknowns…

• How long should the myotomy be?
  – Wright et al compared 1-2 cm gastric portion of myotomy with Dor to 3 cm gastric myotomy with Toupet.
  – ”Extended” myotomy better and more in line with original description by Heller

Known, Knowns…

- GERD after myotomy leads to worse long-term outcomes and the incidence of GERD after LHM is VERY high at nearly 50%...if you don’t do a fundoplication.

Heller Myotomy Versus Heller Myotomy With Dor Fundoplication for Achalasia

A Prospective Randomized Double-Blind Clinical Trial

William O. Richards, MD, * Alfonso Torquati, MD, MSCI,* Michael D. Holzman, MD, MPH,* Leena Khaitan, MD, MPH,* Daniel Byrne, MS, † Rami Lutfi, MD,* and Kenneth W. Sharp, MD*

Known, Knowns…

• BUT, the incidence of GERD after LHM is VERY low at 8% when a fundoplication is performed.

Known, Unknowns…

• What fundoplication is best?
  – Rawlings et al compared Dor to a Toupet after myotomy and found no significant difference.
Known, Knowns…

• What fundoplication is best?
  – Rebecchi et al in an RCT compared Heller/Dor to Heller/Floppy Nissen and found > 5x dysphagia rate for Nissen (2.8% v 15%) with equal reflux control.

Known, Knowns…

• Durability of symptom relief 90%+ for LHM at 2 years based on level 1 evidence.

"Pneumatic Dilation versus Laparoscopic Heller's Myotomy for Idiopathic Achalasia"

Known, Knowns…

- Even at 10-15 years success after LHM is over 80%

Four Hundred Laparoscopic Myotomies for Esophageal Achalasia

A Single Centre Experience

Giovanni Zaninotto, MD, FACS,* Mario Costantini, MD,† Christian Rizzetto, MD,‡ Lisa Zanatta, MD,† Emanuela Guirroli, MD,† Giuseppe Portale, MD,† Loredana Nicoletti,† Francesco Cavallin, PhD,‡ Giorgio Battaglia, MD,† Alberto Ruol, MD, FACS,† and Ermanno Ancona, MD, FACS†

Could robotics be a better option?
- 0% vs 16% perforation rate, about 60 patients per arm.

Robotic-Assisted Heller Myotomy Versus Laparoscopic Heller Myotomy for the Treatment of Esophageal Achalasia: Multicenter Study

Santiago Horgan, M.D., Carlos Galvani, M.D., Maria V. Gorodner, M.D., Pablo Omelanczuck, M.D., Fernando Elli, M.D., Federico Moser, M.D., Luis Durand, M.D., Miguel Caracoche, M.D., Jorge Nefa, M.D., Sergio Bustos, M.D., Phillip Donahue, M.D., Pedro Ferraina, M.D.
Per-oral Endoscopic or Esophageal Myotomy (POEM)

• First procedure: Harujiru Inoue, Japan, 2008

• First publication of results in 17 patients by Dr. Inoue in 2010

Inoue et al. Endoscopy 2010
POEM: TECHNIQUE
POEM: TECHNIQUE
POEM: TECHNIQUE

Tunnel and myotomy 2-3 cm distal to GEJ
POEM: TECHNIQUE
POEM: TECHNIQUE
POEM

Long-Term Outcomes of an Endoscopic Myotomy for Achalasia

The POEM Procedure

Lee L. Swanstrom, MD,*† Ashwin Kurian, MD,*† Christy M. Dunst, MD,*† Ahmed Sharata, MD,* Neil Bhayani, MD,*† and Erwin Rieder, MD*

– 18 pts, F/U 11 months
– Myotomy length 9 cm
– LOS 1 dy, return to normal activity in 3 days
– Eckardt score 6 to 1
– 28% of patients had esophagitis
– pH monitoring: 46% had pathologic reflux

Known, Knowns…

- Clinical recurrences over 2x as high for POEM compared to LHM at 2 years in uncontrolled, non-randomized studies.
Known, Unknowns…

• 10 year results: Is there anyone 10 years out from POEM?
POEM: LONGER TERM OUTCOMES

Clinical outcomes five years after POEM for treatment of primary esophageal motility disorders

Ezra N. Teitelbaum¹ · Christy M. Dunst¹² · Kevin M. Reavis¹² · Ahmed M. Sharata² · Marc A. Ward¹ · Steven R. DeMeester¹² · Lee L. Swanström¹²³

• Only 27 patients, of 36 had f/u
• Symptomatic success at 5 years: 83%, but 10% of followed patients required reintervention less than 5 years, and another 20% were being evaluated for reintervention.
• Significant continued reduction in Eckardt score (6.4 pre-POEM vs 1.7 current; p<0.001)

POEM: LONGER TERM OUTCOMES

Clinical outcomes five years after POEM for treatment of primary esophageal motility disorders

As you would expect, the incidence of GERD after POEM is VERY high because there is no fundoplication.

Peroral Endoscopic Myotomy for the Treatment of Achalasia: An International Prospective Multicenter Study

Daniel von Renteln,1 Karl-Hermann Fuchs,2 Paul Fockens,3 Peter Bauerfeind,2 Melina C. Vassiliou,5 Yuki B. Werner,6 Gerald Fried,5 Wolfram Breithaupt,2 Henriette Heinrich,4 Albert J. Bredenoord,3 Jan F. Kersten,7 Tessa Verlaan,5 Michael Trevisonno,5 and Thomas Rosch1

- 70 pts, 5 centers in Europe and North America
- Myotomy length 13 cm
- Symptom relief: 12 months 82% (51 pts)
- 42% had esophagitis on EGD. (all managed with PPI)
Known, Knowns...

- As you would expect, the incidence of GERD after POEM is VERY high because there is no fundoplication.
  - GERD evidenced by pH monitoring (OR 4.30, 95% CI 2.96–6.27, P<0.0001). On average (48% for POEM)
  - GERD evidenced by erosive esophagitis (OR 9.31, 95% CI 4.71–18.85, P<0.0001) (23% for POEM)
Known, Knowns…

• POEM may NOT be that less invasive or more cost effective
  – Typically done under general anesthesia
  – Same operative time as LHM
  – POEM has LONGER LOS by over a day

Laparoscopic Heller Myotomy Versus Peroral Endoscopic Myotomy (POEM) for Achalasia
A Systematic Review and Meta-analysis

Francisco Schlottmann, MD,* Daniel J. Luckett, BS,† Jason Fine, ScD,† Nicholas J. Shaheen, MD, MPH,‡ and Marco G. Patti, MD*
Known, Unknowns…

• What about the type of motility disorder?
  – POEM could be better for Type III achalasia?

<table>
<thead>
<tr>
<th></th>
<th>POEM n=49</th>
<th>LHM n=26</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median length of myotomy (cm)</td>
<td>16 (7 – 26)</td>
<td>8 (6 – 10)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Median procedure time (min)</td>
<td>102 (43 – 345)</td>
<td>264 (189 – 331)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Adverse events, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>2 (4)</td>
<td>1 (4)</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (2)</td>
<td>6 (23)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Total</td>
<td>3 (6)</td>
<td>7 (27)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Mean length of stay, days (SD)</td>
<td>3.3 (1.9)</td>
<td>3.2 (2.3)</td>
<td>0.68</td>
</tr>
<tr>
<td>PPI therapy, n (%)</td>
<td>19 (38.8)</td>
<td>12 (46.1)</td>
<td>0.7</td>
</tr>
<tr>
<td>Eckardt stage II or III, n (%)</td>
<td>1 (2.0)</td>
<td>5 (19.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Need for subsequent therapy, n (%)</td>
<td>0</td>
<td>2 (7.7)</td>
<td>0.11</td>
</tr>
<tr>
<td>Clinical response, n (%)</td>
<td>48 (98)</td>
<td>21 (80.8)</td>
<td>0.01</td>
</tr>
<tr>
<td>Duration of follow-up, months (SD)</td>
<td>8.6 (1.7)</td>
<td>21.5 (3.9)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Known, Unknowns…

• What about the type of motility disorder?
  – POEM could be better for Type III achalasia?

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<thead>
<tr>
<th></th>
<th>POEM</th>
<th>LHM</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD)</strong></td>
<td>58.3 (18.8)</td>
<td>51.6 (17.9)</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Female, n (%)</strong></td>
<td>20 (40.8)</td>
<td>13 (50.0)</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>Prior therapy, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>30 (61.2)</td>
<td>7 (26.9)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Endoscopic therapies</td>
<td>15 (30.6)</td>
<td>19 (73.1)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>LHM</td>
<td>4 (8.2)</td>
<td>0</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Eckardt stage, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1 (2.0)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>I</td>
<td>2 (4.1)</td>
<td>0</td>
<td>0.25</td>
</tr>
<tr>
<td>II</td>
<td>24 (49.0)</td>
<td>4 (15.4)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>III</td>
<td>22 (44.9)</td>
<td>22.0 (84.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>Mean residual pressure, mmHg (SD)</strong></td>
<td>34.4 (15.5)</td>
<td>36.2 (13.9)</td>
<td>0.79</td>
</tr>
</tbody>
</table>
Conclusions

- **KNOWN, KNOWNs**
  - LHM remains the gold standard therapy for achalasia, but POEM’s short term results demonstrate equal efficacy at relieving dysphagia.
  - LHM creates minimal amounts of GERD when done concomitantly with a fundoplication
  - GERD sequelae following POEM are significant

- **KNOWN, UNKNOWNs**
  - POEM may be superior in subsets of achalasia
  - POEM as it evolves will likely replace current procedures