

# Evolution of the Surgical Myotomy for Achalasia

## From laparoscope to endoscope



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State-of-the-Art in Gastrointestinal Endoscopy Course

Pacific Northwest Gastroenterology Society

February 27, 2016

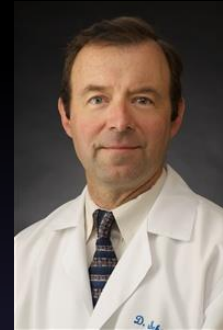
# Disclosures

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- Educational Grants
  - Olympus Corporation of America
  - Boston Scientific
  - Bard-Davol

# Swedish POEM Team

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# Objectives

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- Review the evolution of the myotomy for achalasia
- Describe the POEM technique
- Discuss a structured training program for training
- Review the outcomes of POEM

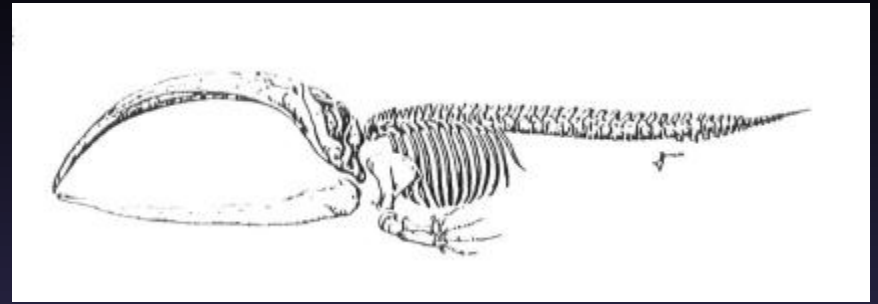
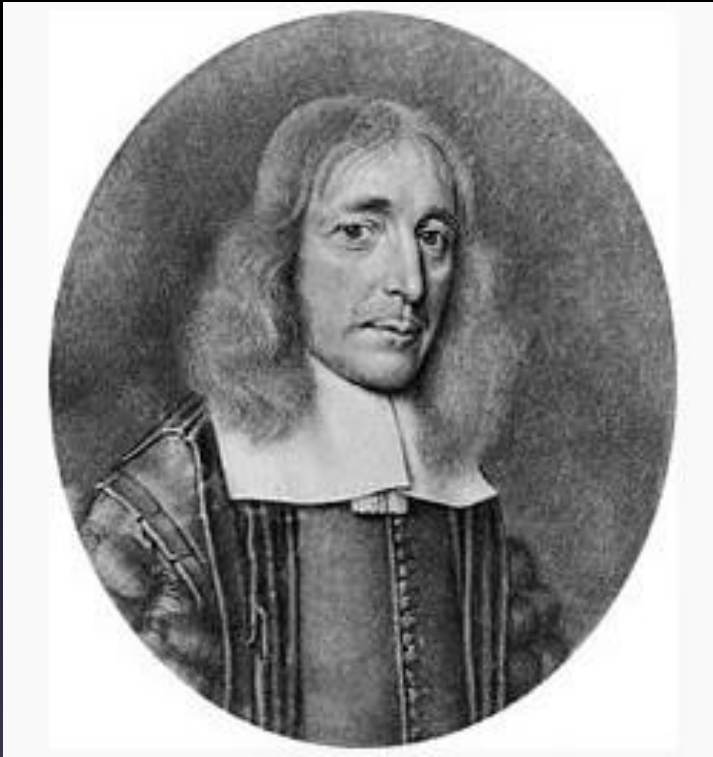
# Achalasia

- End stage motor disorder of the esophagus
- Characterized by:
  - Absent peristalsis
  - Defective LES relaxation
  - Symptoms of
    - Dysphagia
    - Regurgitation
    - Aspiration/chest pain



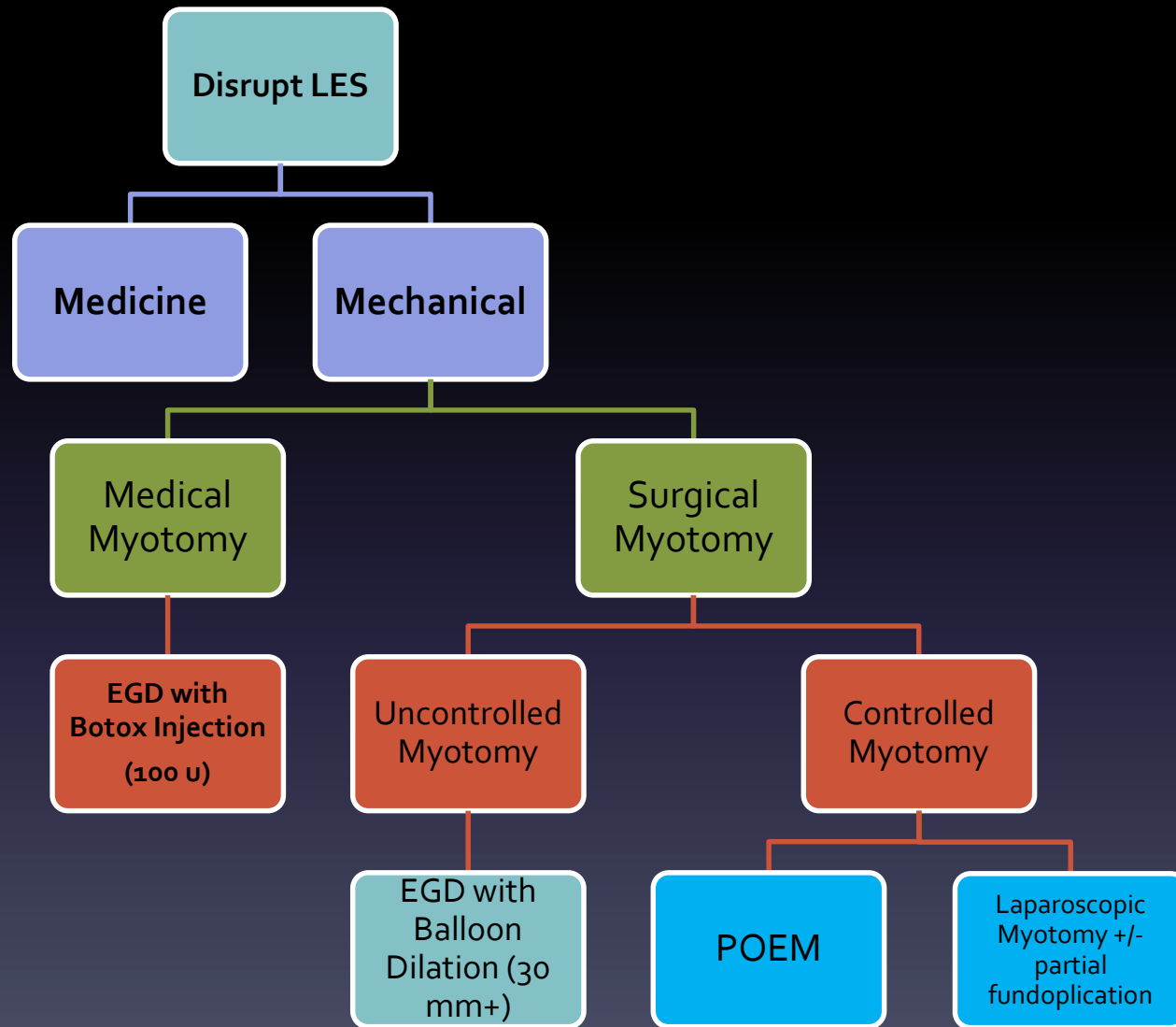
# First therapeutic intervention

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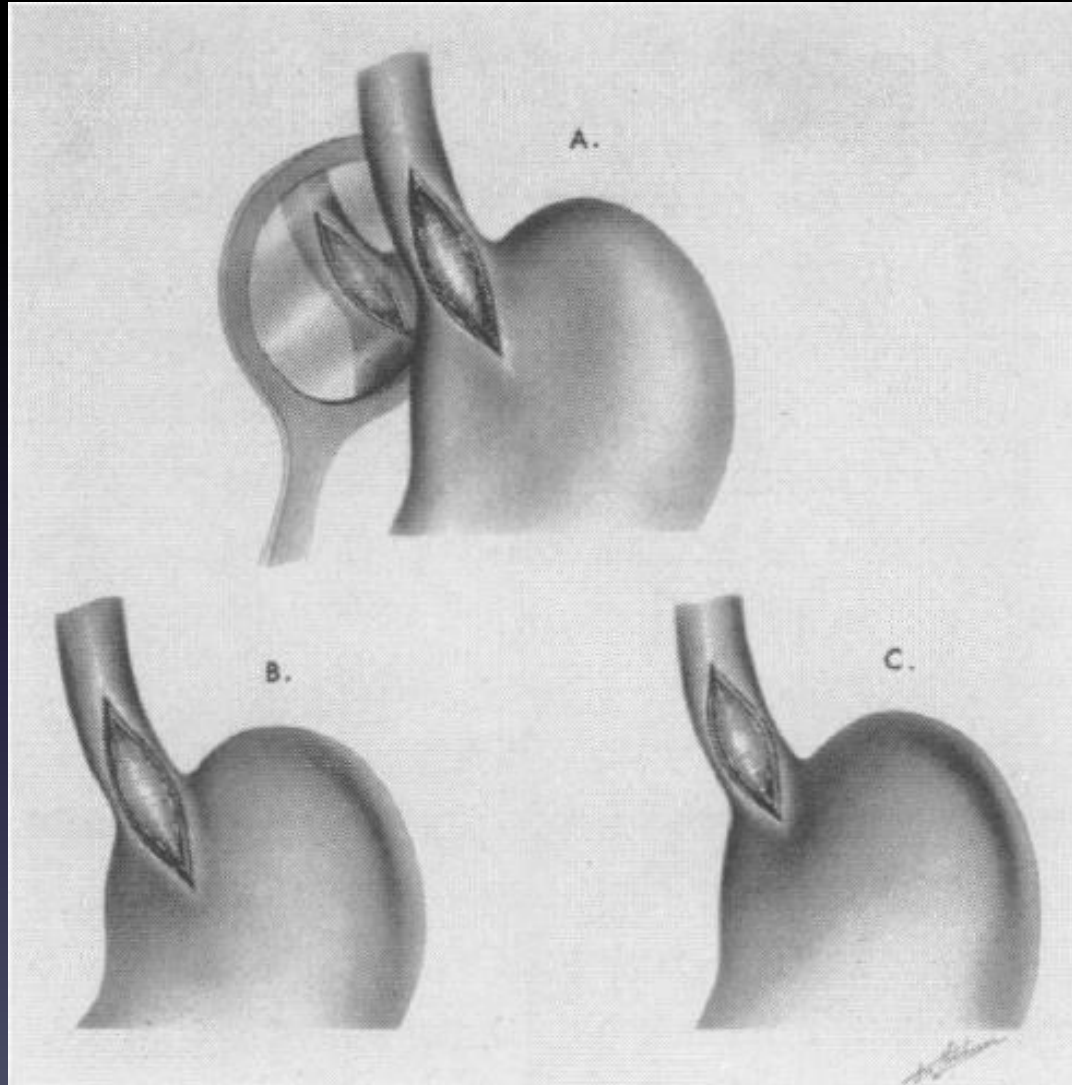
- Thomas Willis 1621 - 167

# Modern therapeutic interventions



# Heller's Myotomy

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# Modification of Heller's Myotomy

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CARDIOSPASM IN THE AGED

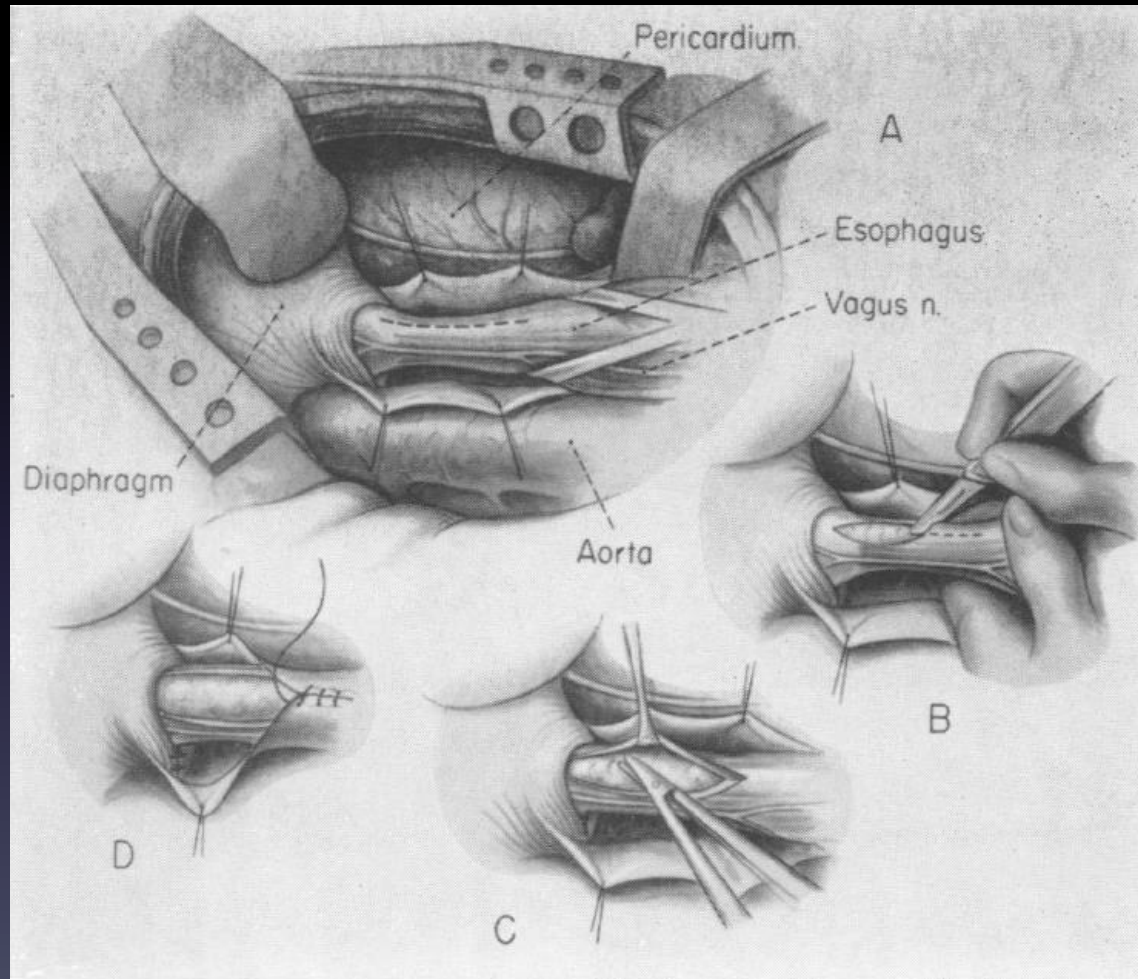
BY J. H. ZAAIJER, M.D.

OF LEIDEN, HOLLAND

PROFESSOR OF SURGERY IN THE UNIVERSITY OF LEIDEN

The results are very satisfactory, although subsequent radiologic examination show that a condition of restitutio ad integrum has not been effected. It does not appear to make any difference relative to the subsequent findings whether the incision is made on the anterior side and one on the posterior side as Heller 4 did, or one incision only on the anterior side as has been employed by de Bruine, Groeneveldt and myself.

# Trans-thoracic Modified Heller's Myotomy



# Towards a minimally invasive myotomy - VATS

## Thoracoscopic Esophagomyotomy

*Initial Experience With a New Approach for the Treatment of Achalasia*

CARLOS PELLEGRINI, M.D.,\* L. ALBERT WETTER, M.D.,\* M.  
GIL MUSSAN, M.D.,\* TOSHIYUKI MORI, M.D.,\* GEOFFREY BE

3 ics in front of PAL  
5 or 6 ics 2 inch behind PAL  
7 iCS MAL  
6 ics AAL  
+/- low to depress diaphragm



# Towards a minimally invasive myotomy - VATS

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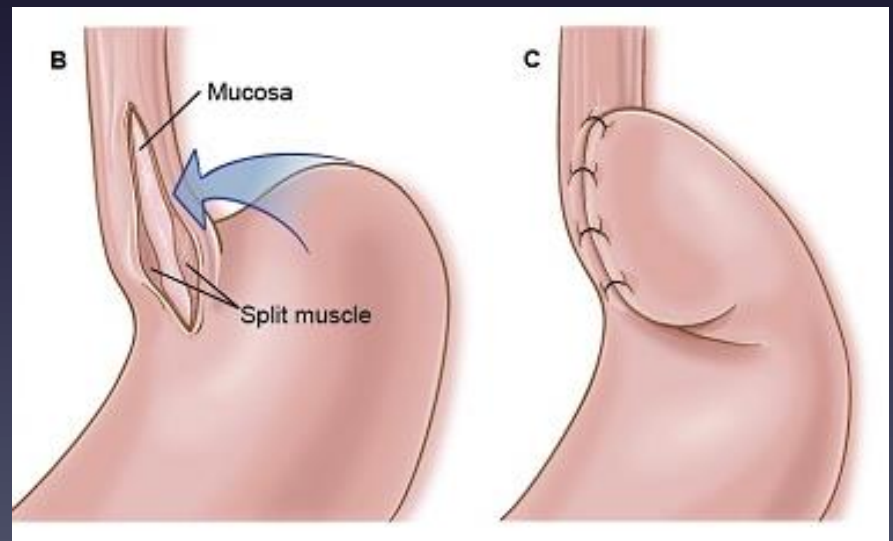
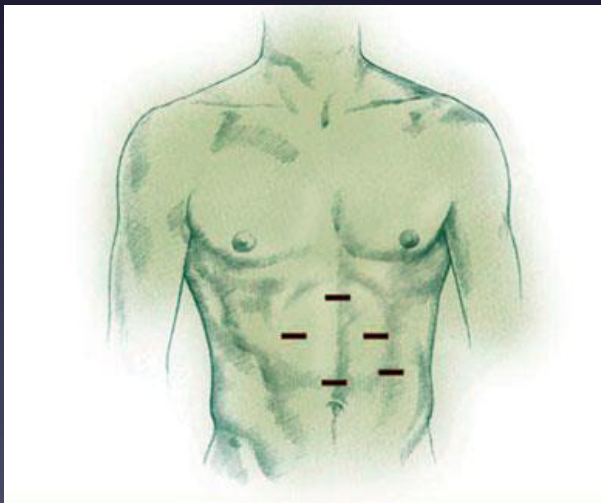
- Good relief of dysphagia
- Cumbersome with post op discomfort
- Limited exposure to GEJ
- Lack of fundoplication
- GERD developed in 60%

# Towards a minimally invasive myotomy - Laparoscopy

## Minimally Invasive Surgery for Achalasia An 8-Year Experience With 168 Patients

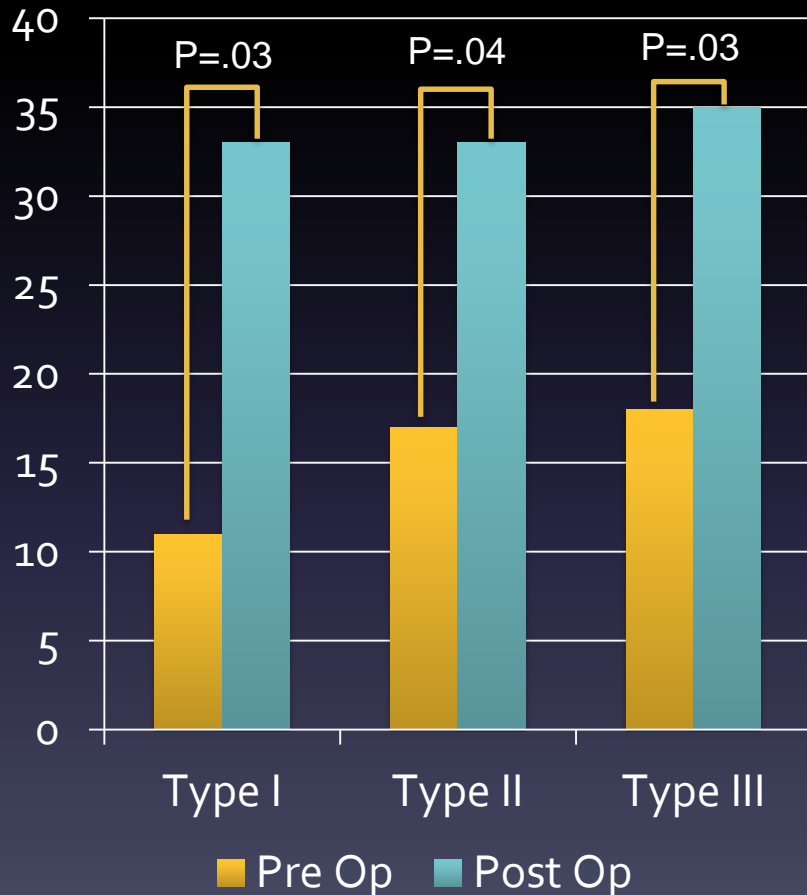
Marco G. Patti, MD,\* Carlos A. Pellegrini, MD,† Santiago Horgan, MD,† Massimo Arcerito, MD,\* Pablo Omelanczuk, MD,† Andrea Tamburini, MD,\* Urs Diener, MD,\* Thomas R. Eubanks, MD,† and Lawrence W. Way, MD\*

*From the Departments of Surgery at the \*University of California, San Francisco, California, and the †University of Washington, Seattle, Washington*

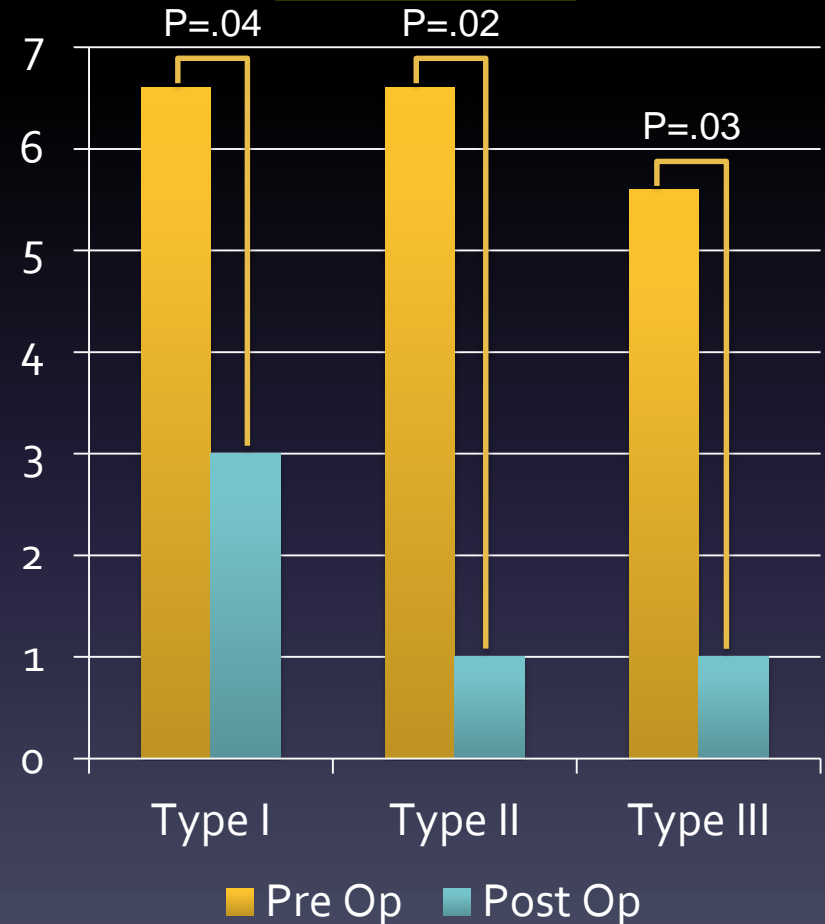


# Outcomes of Lap Myotomy/Fundo

Dysphagia Score



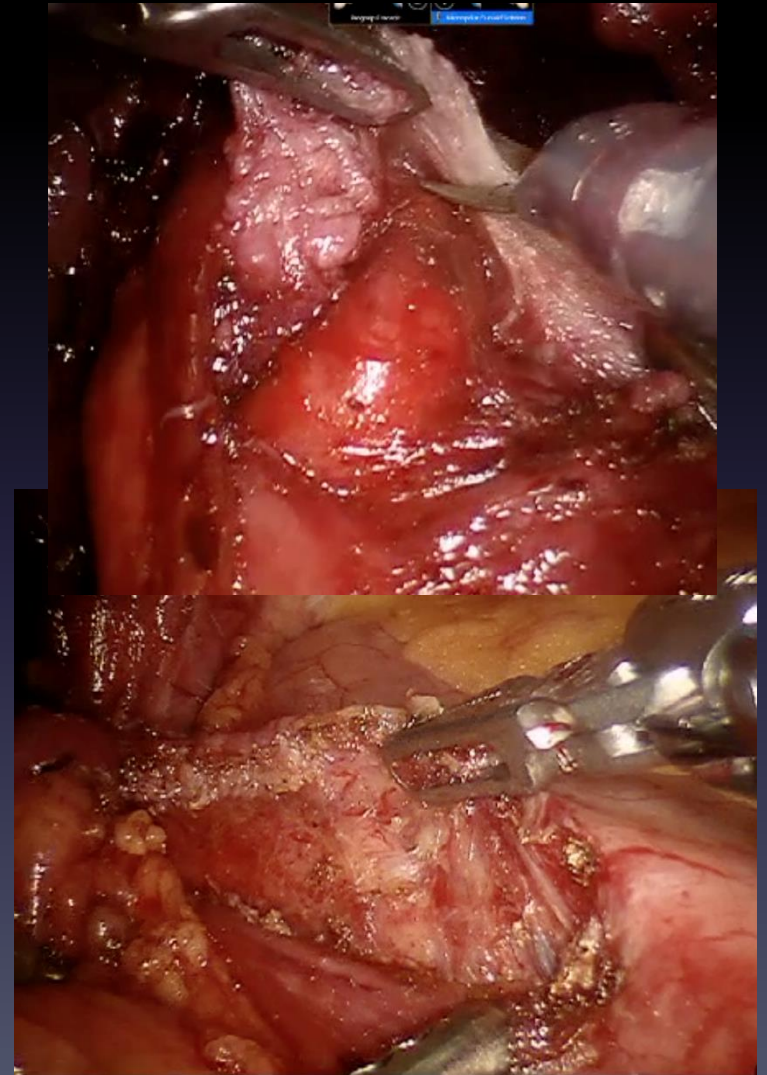
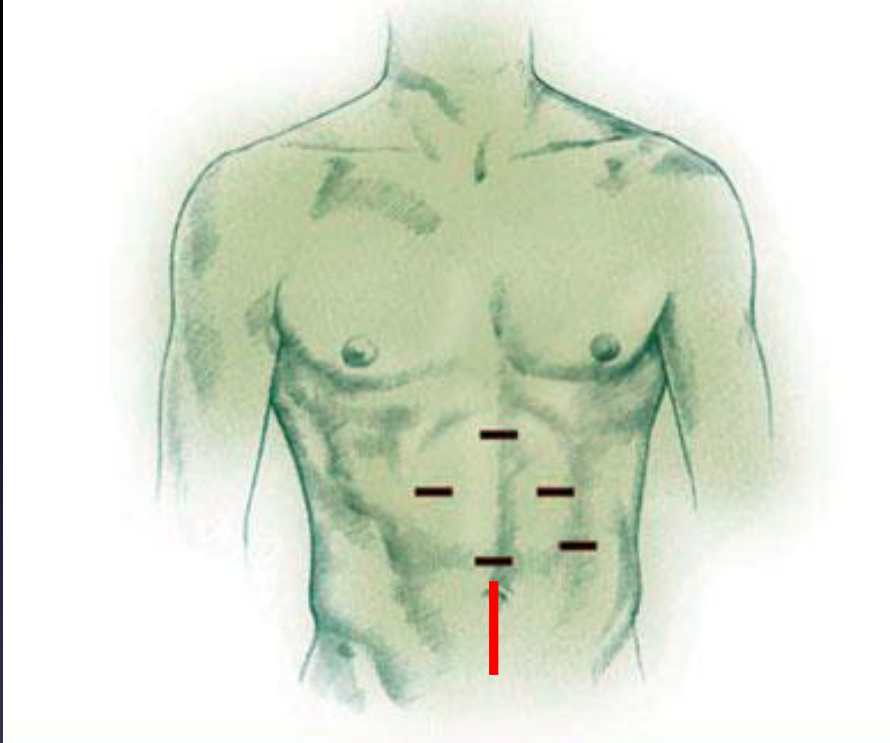
Eckardt Score





# Trend to even less invasive approaches?

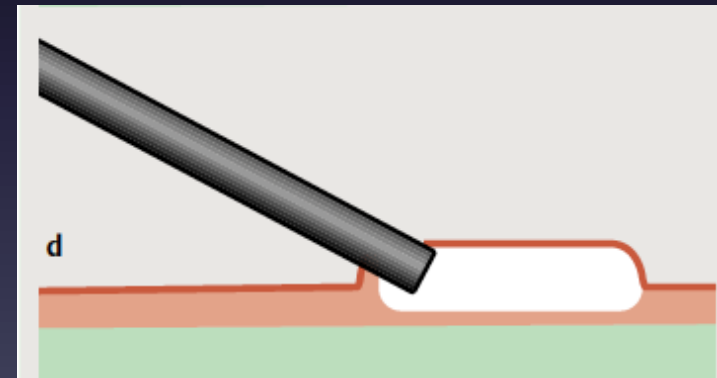
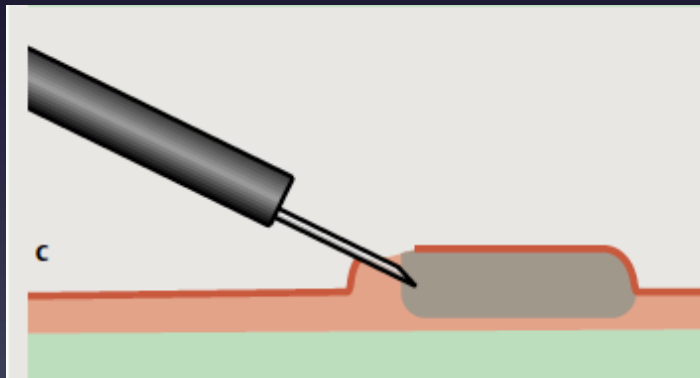
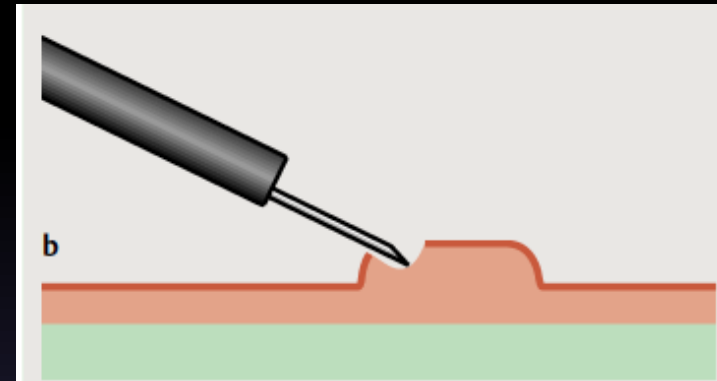
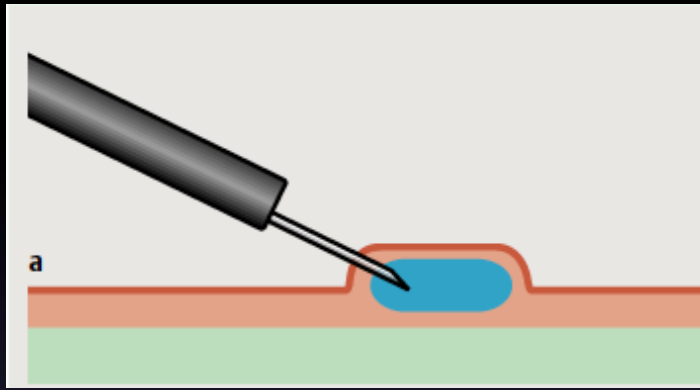
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Barry et al. Surgical Endoscopy 2011, 25:1766  
Horgan et al. J Gastrointestinal Surgery 2005, 9(8):1020  
Huffman et al. Surgery 2007, 142(4):613

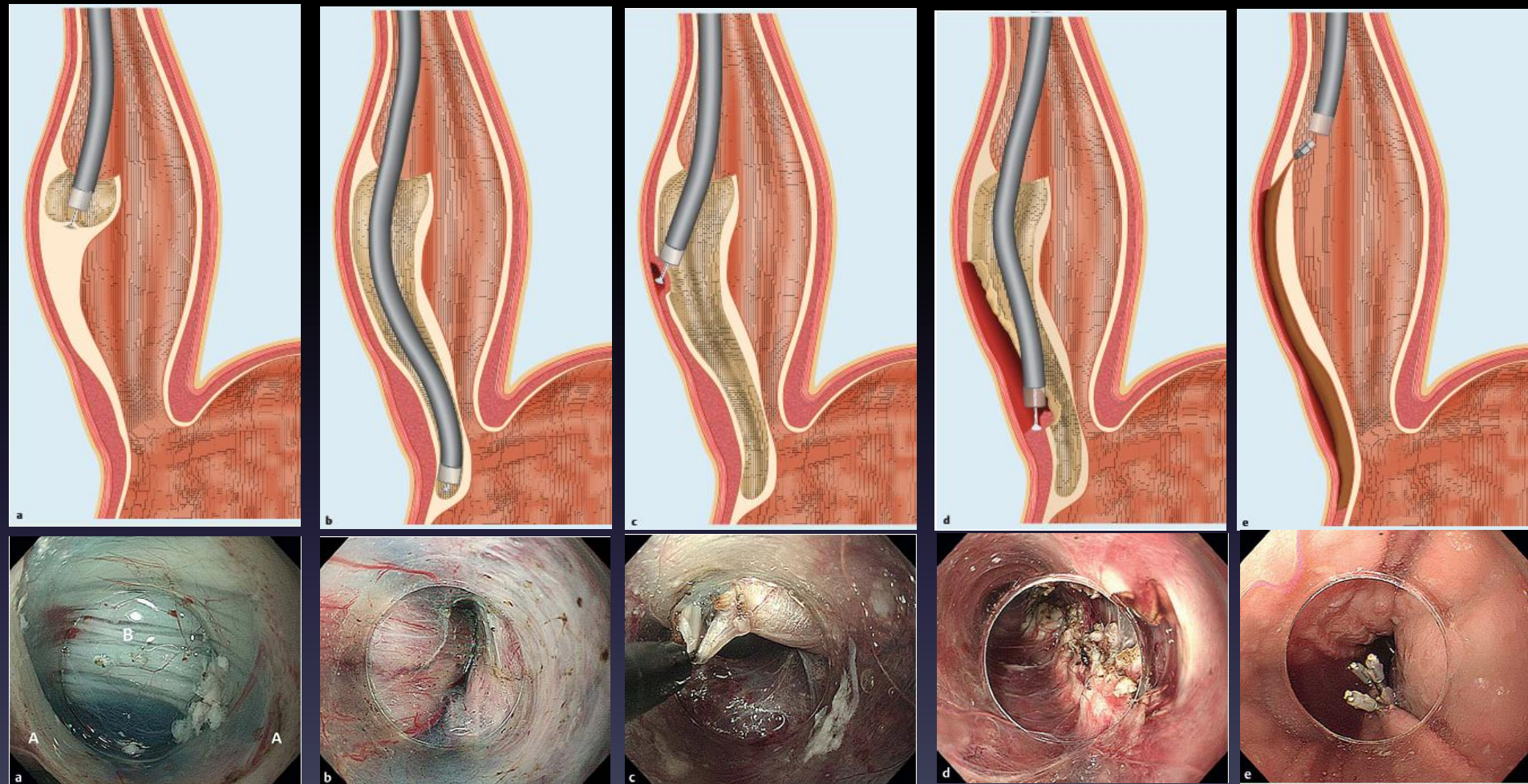
# Submucosal endoscopic myotomy

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# POEM Procedure



# POEM Procedure

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# Hands-On Training Course

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- Didactic lectures
- Porcine model (4)
- Live porcine model (4)
- Varied techniques/tools
- Case observation (3)



# POEM Team

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- Thoracic surgery (2)
- Interventional GI (1)
- Foregut fellows (2)
- Operating Room
  - Scrub techs (2)
  - Thoracic RN director (1)



The logo for OLYMPUS, featuring the word "OLYMPUS" in bold, blue, sans-serif capital letters. A thin yellow horizontal line is positioned below the text.

The logo for Boston Scientific, with the words "Boston" and "Scientific" stacked vertically in a blue, serif font.





# Team Training

- Grant funding
- Two live porcine models (8)
- 10 days prior to first cases
- Planned OR set up
- Fire drill plan
- Skills acquisition
  - Needle decompression
  - Clipping



# IRB Protocol

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## **PER ORAL ENDOSCOPIC MYOTOMY REGISTRY**

**Principal Investigator: -**

Brian Louie, MD

Swedish Cancer Institute - Thoracic and Esophageal Surgery

Director of Research and Education

Co-director, MIS Thoracic Surgery Program

# Initial POEM Procedures

- 16 animal POEMs prior
- Proctored cases (4)
  - Required
- Credentials for proctor?
- Avoid complex patient
  - Dilated esophagus
  - Prior treatments





# See one, Do one, Teach one?

DAILY MEDICAL EXAMINER



"None of you guys are students, right? 'Cause I'm not gonna sit here and play Guinea pig for some schmuck in training."

Don't worry,  
I practiced this on a  
doll once.

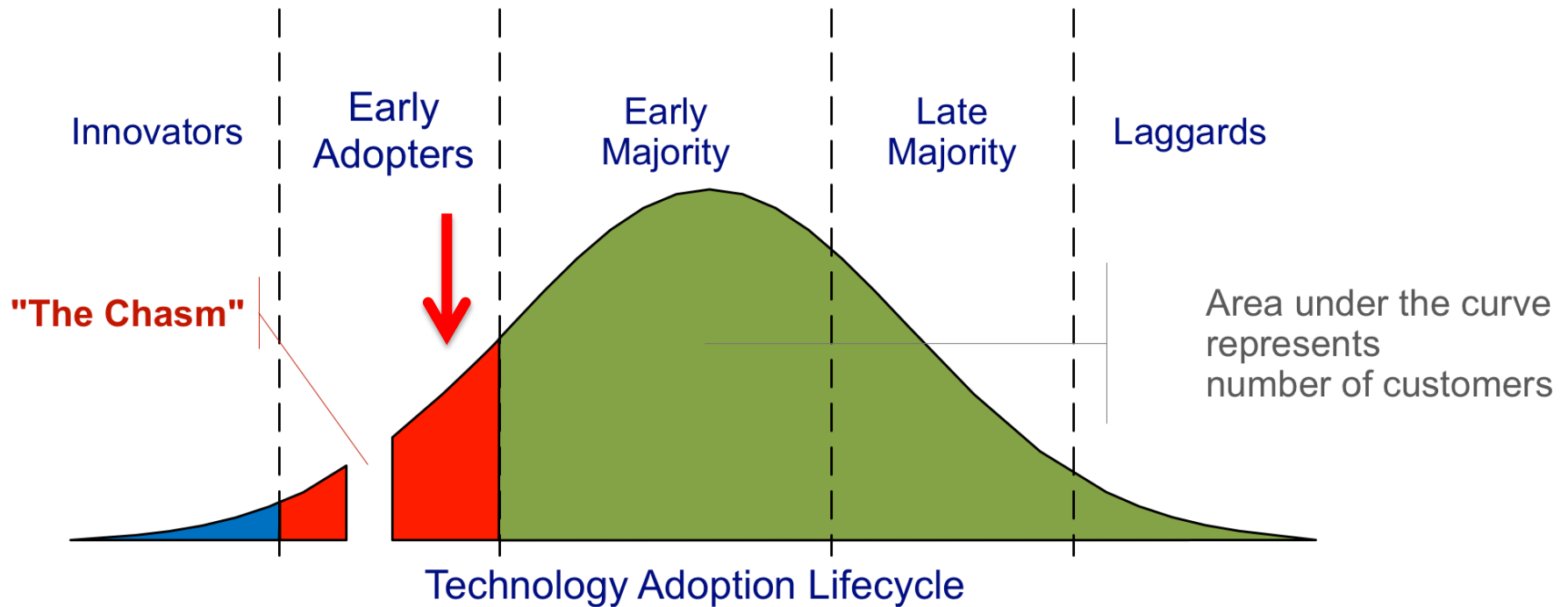
somee cards  
user card



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# Technology Adoption Lifecycle



Pashricha Inoue    Stavropoulos Swannstrom



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# Essential Components

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- Recruiting collaborators
  - GI – endoscopic techniques
  - Surgery – preparation, surgical anatomy, complications
- Proper clinical training
- Institutional support
- Institutional review board approval
- Technical/engineering/nursing support



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Desilets et al. Techniques in Gastrointestinal Endoscopy 2013  
Eleftheriadis et al. Therapeutics and Clinical Risk Management 2012

# Technology Adoption Guidelines

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- |   |   |
|---|---|
| <b>Familiarization with the device or procedure before introduction.</b>                  | ✓ |
| Cognitive training in new device or procedure. (e.g. indications, patient selection, etc) | ✓ |
| Hands-on practice on appropriate training models before use in patients                   | ✓ |
| Assessment of surgeon ability to perform safely prior to introduction.                    | ✓ |
| Full disclosure to patient.   | ✓ |
| Proctoring/preceptorship of initial cases   | ✓ |
| Meticulous recording and monitoring of surgeon outcomes with device or procedure.         | ✓ |
| Regional/national monitoring of outcomes (e.g., with the use of a database).              | ? |

# Guidelines for Innovation in GI

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# A little bit like the wild west?

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# Guidelines for Innovation in GI

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## PRESERVATION AND INCORPORATION OF VALUABLE ENDOSCOPIC INNOVATIONS



The American Society for Gastrointestinal Endoscopy PIVI  
(Preservation and Incorporation of Valuable Endoscopic  
Innovations) on peroral endoscopic myotomy

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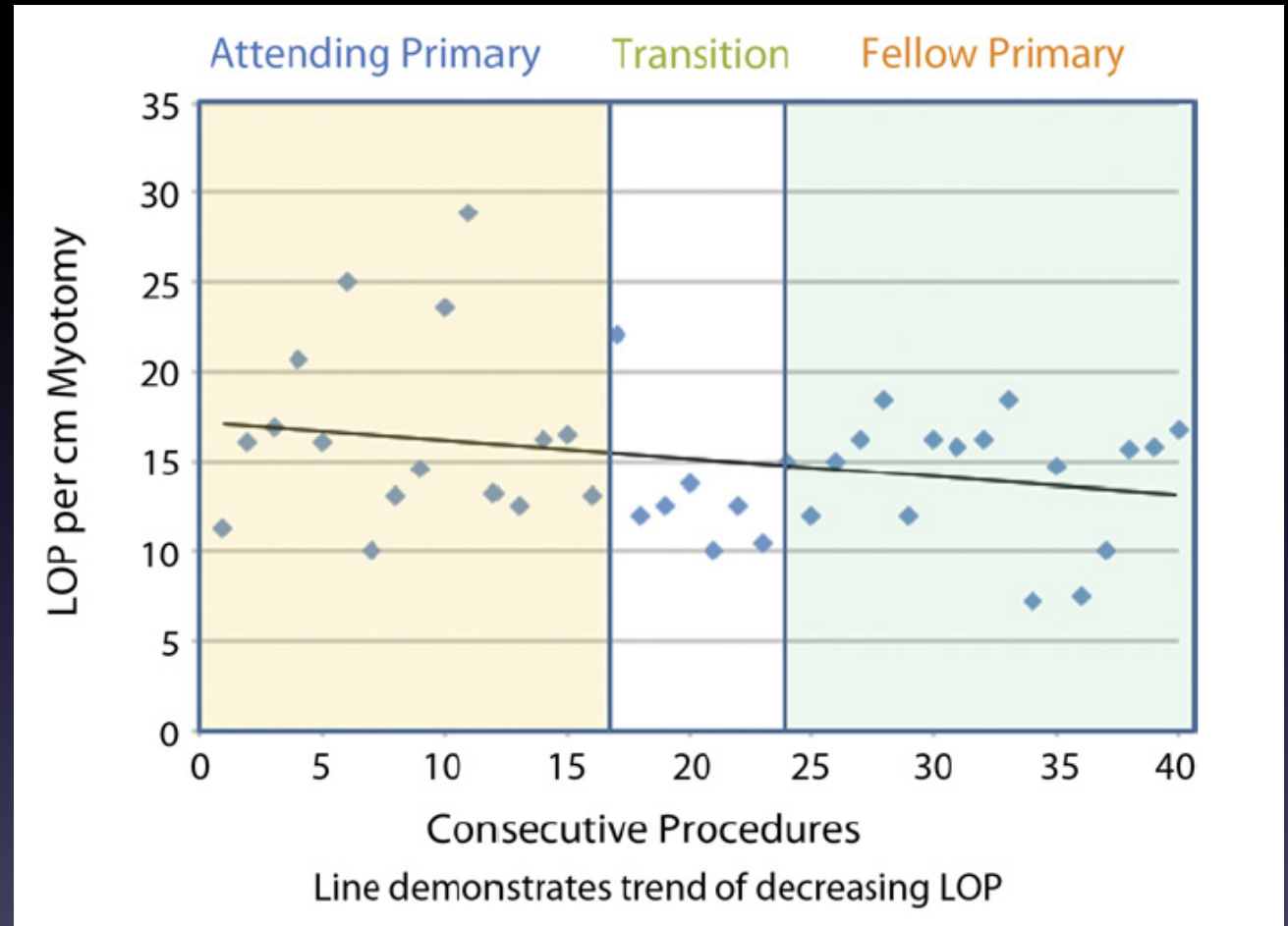
ASGE – Gastrointestinal Endoscopy May 2015

# Learning Curve for POEM

N = 20

At training = 16

Proctor = 4





# Issues of Credentialing

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## Level 1

Certifies that the learner attended a lecture or completed a lecture format course (no verification of skills).



## Level 2

Certifies the learner completed a course and was assessed via a test or other evaluation of training and was provided feedback regarding their assessment score (a better model incorporates a minimum pass rate).



## Level 3

Certifies the instructor observed the learner perform a skill and verified completion of task. Alternatively, the learner completed a course and participated in a lecture and skills lab, allowing assessment of the skills on a synthetic or tissue-based model.



## Level 4

Certifies the learner performed the procedure in a patient in a clinical setting with supervision (proctor or preceptor).



## Level 5

Certifies the learner performed a series of clinical cases, the outcomes of which have been reviewed and verified. An example of Level 5 learning may be submitting a series of video-recorded cases with outcomes to a review committee for verification.



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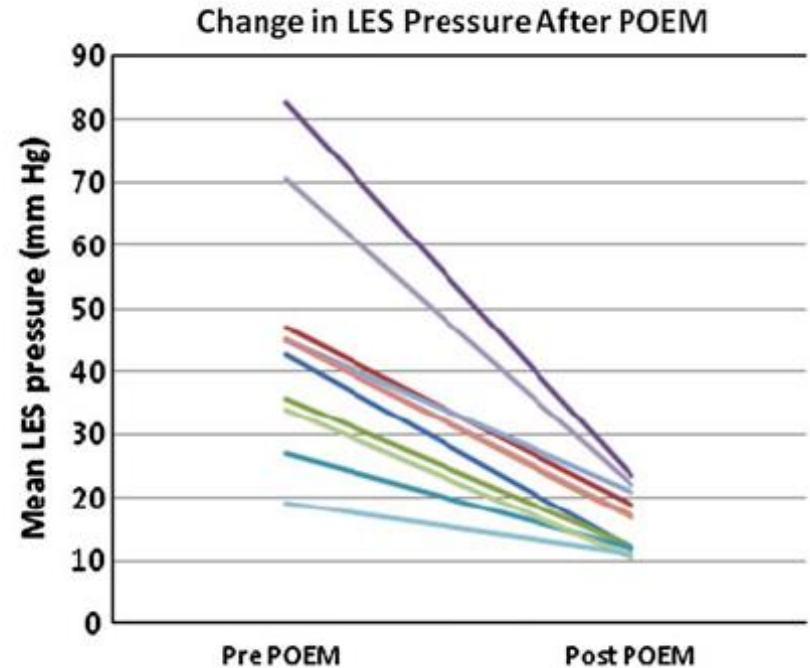
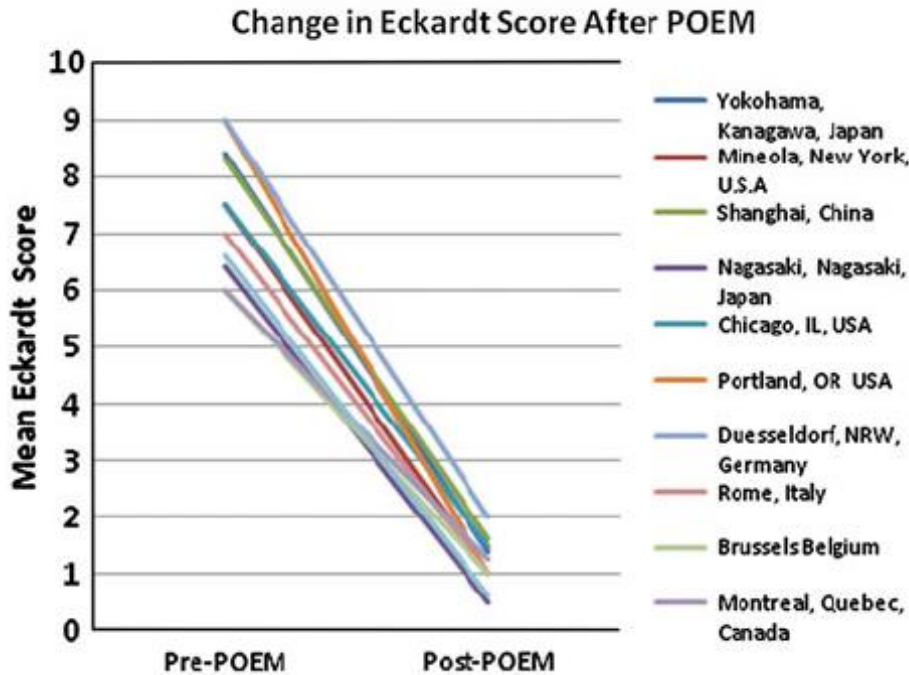
STS: Guidelines for Introduction of New Technology  
and Techniques. - DRAFT

# Objectives

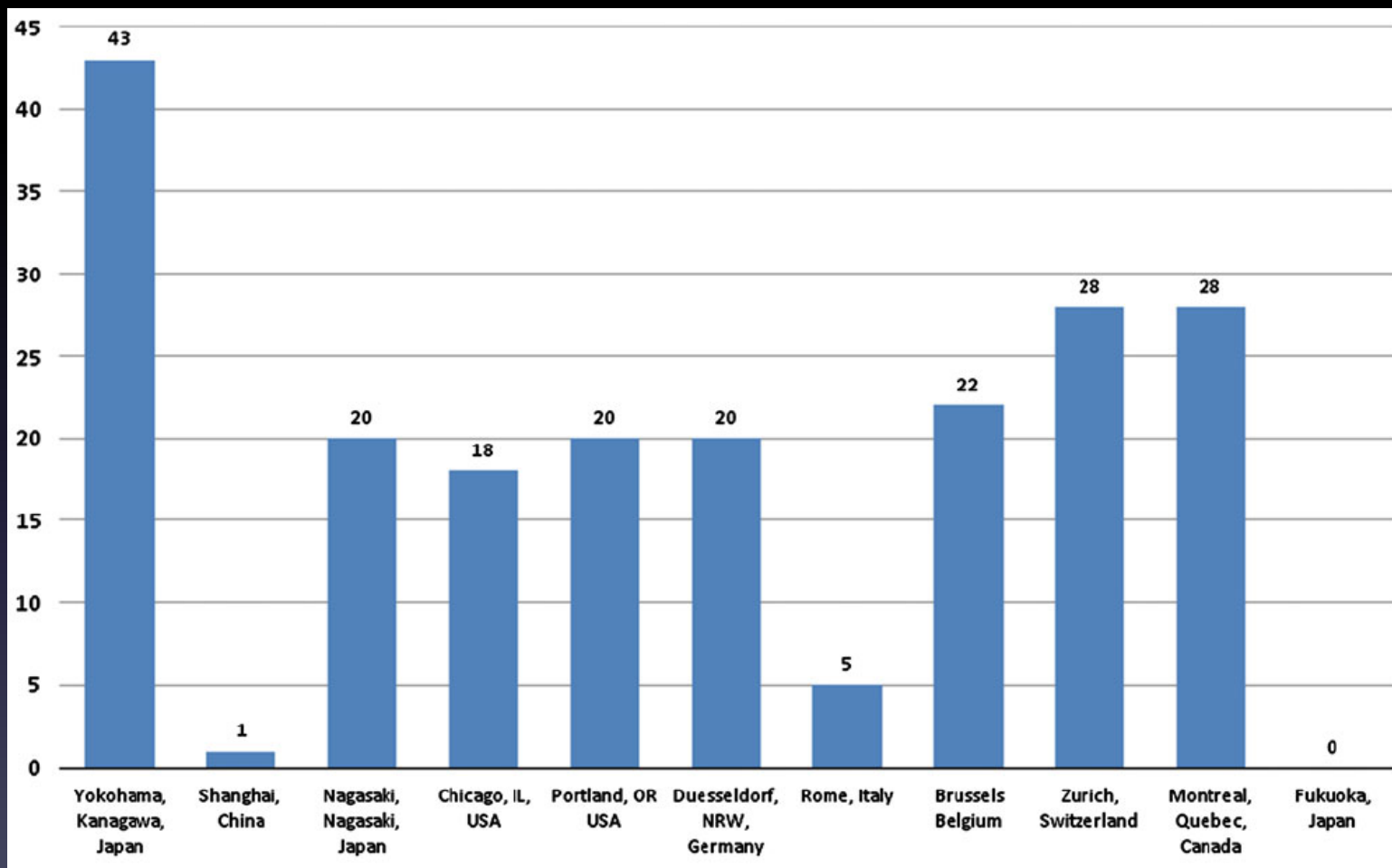
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# Outcomes of POEM



# The problem of GERD



# Swedish POEM experience

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- 37 patients underwent POEM since July 2014
- Indications:
  - Type I = 23%
  - Type II = 50%
  - Type III = 17 %
  - Other motility disorders = 10 %

# Comparison to Literature

Series	N	Number of Endoscopies	Exclusion	Prior Intervention (N,%)	Prior Myotomy (N,%)	Sigmoidal Esophagus (N,%)	Inadvertent Mucosotomy (N,%)	Mean operative time
Current Series	30	1 Attending with Fellow at case 6	None related to achalasia	11 (39.3%)	2 (7.1%)	6 (21.4%)	6 (21.4%)	141.1 mins +/- 43.3 (Sigmoid Esophagus/Redo's excluded)
Kurian et al. (2013)	40	1 Attending with Fellow at case 16	Previous esophageal surgery, BMI>40	27 (55%)	0%	N/A	10 (25%)	133 mins +/- 41
Teitelbaum et al. (2014)	36	2 Attendings	No prior interventions for the first 10 cases	4 (11%)	0%	N/A	3 (8%)	112 mins +/- 36
Patel et al. (2015)	93	1 Attending	"Contraindications to POEM"	38 (41%)	N/A	21 (23%)	24 (26%)	149.7 mins +/- 36.7 (Estimated time first 30 cases)

# Prior Interventions

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- Group 1 – non-sigmoidal, < 6 cm, no interventions
- Group 2 – non-sigmoidal, Botox, balloon dilation < 30 mm, Savary-dilation
- Group 3 – sigmoidal, > 6 cm, prior myotomy, prior surgery, dilation > 30 mm

# Early Clinical Outcomes

## Eckardt Scores

Eckardt (Mean)	Group 1 (n=11)	Group 2 (n=11)	Group 3 (n=6)
Pre	6.4 (1.96)	6.1 (2.42)	7.4 (2.79)
Post	0.8 (0.75)	1.6 (1.82)	0.5 (0.7)
P - Value	> 0.005	0.002	0.004

## GERD-HRQL

HRQL (Mean)	Group 1 (n=11)	Group 2 (n=11)	Group 3 (n=6)
Pre	16.9 (11.2)	12.7 (6.5)	22.5 (9)
Post	5 (6.3)	12.6 (13)	0 (0)
P - Value	0.02	0.99	0.015



# Operative times

Mean (Std) / Median (25 <sup>th</sup> /75 <sup>th</sup> )	Operative Time in mins	Time / cm Myotomy
Group 1	141.09 (54.87) / 130 (118-149)	24.16 (9.43) / 21 (19.7 – 23.5)
Group 2	141.18 (30.49) / 145 (123 – 161)	22.04 (6.29) / 21.9 (19.2 – 25.8)
Group 3	256.67 (74.48) / 247 (203.8 – 306)	41.38 (9.79) / 39.3 (33 -50.1)

P Value = > 0.001

# Comparative Data

DDW 2016

Table Preview - Table 1

Table 1

Subjective							
MEAN	POEM			LAP HELLER MYOTOMY			Post Operative Comparison
	Pre	Post	p-value	Pre	Post	p-value	p-value
Eckhardt Score	6.38	1.01	<0.001	6.5	1.22	<0.001	0.77
QOLRAD	4.19	6.24	<0.001	3.62	6.55	<0.001	0.36
GERD HRQL	16.06	5.95	0.002	20.68	5.62	0.003	0.9
Swallowing	13.72	30.8	<0.001	12.62	35.29	<0.001	0.27
Objective							
Mean	POEM			LAP HELLER MYOTOMY			Post Operative Comparison
	Post operative			Post Operative			p-value
DeMeester Score	23.06			16.07			0.66
Total time <4%	6.18			11.15			0.55

◀ Close Window

# Conclusions

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- Myotomy remains the choice of treatment for achalasia and can be performed via the abdomen, left chest and intramural
- But, simplicity favors a laparoscopic approach
- POEM is a promising natural orifice procedure that is rapidly gaining acceptance
- Long term results and incidence of GERD remain key issues

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