
12TH ANNUAL
NCSCG
POST-DDW
SYMPOSIUM

Updates in Esophageal Disease

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Disclosures

- Consultant, Research Support: Medtronic

Updates in Esophageal Disease

- Barrett's Esophagus
- POEM/Achalasia
- GERD

Updates in Esophageal Disease

- Barrett's Esophagus
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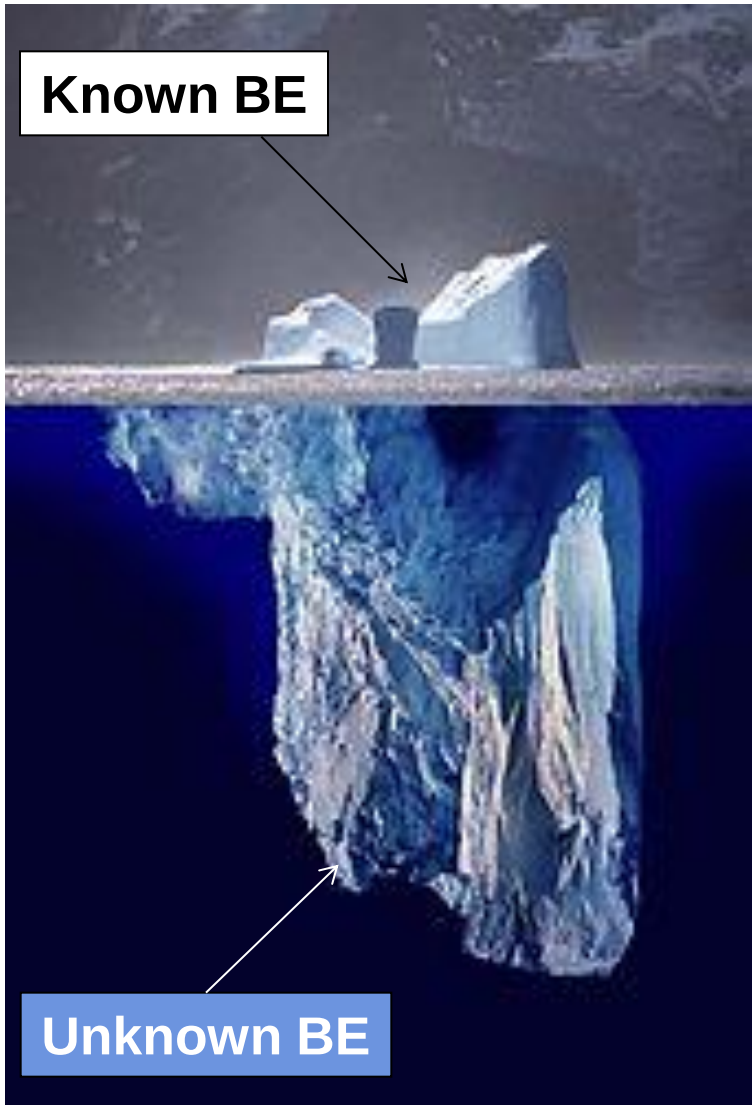
- GERD

What's New in Barrett's Esophagus

- Detection
- Surveillance/Risk of Progression
- Endoscopic Eradication Therapy (EET)
  - EMR vs. ESD
  - Issues pertaining to Ablation Therapy
- Surveillance

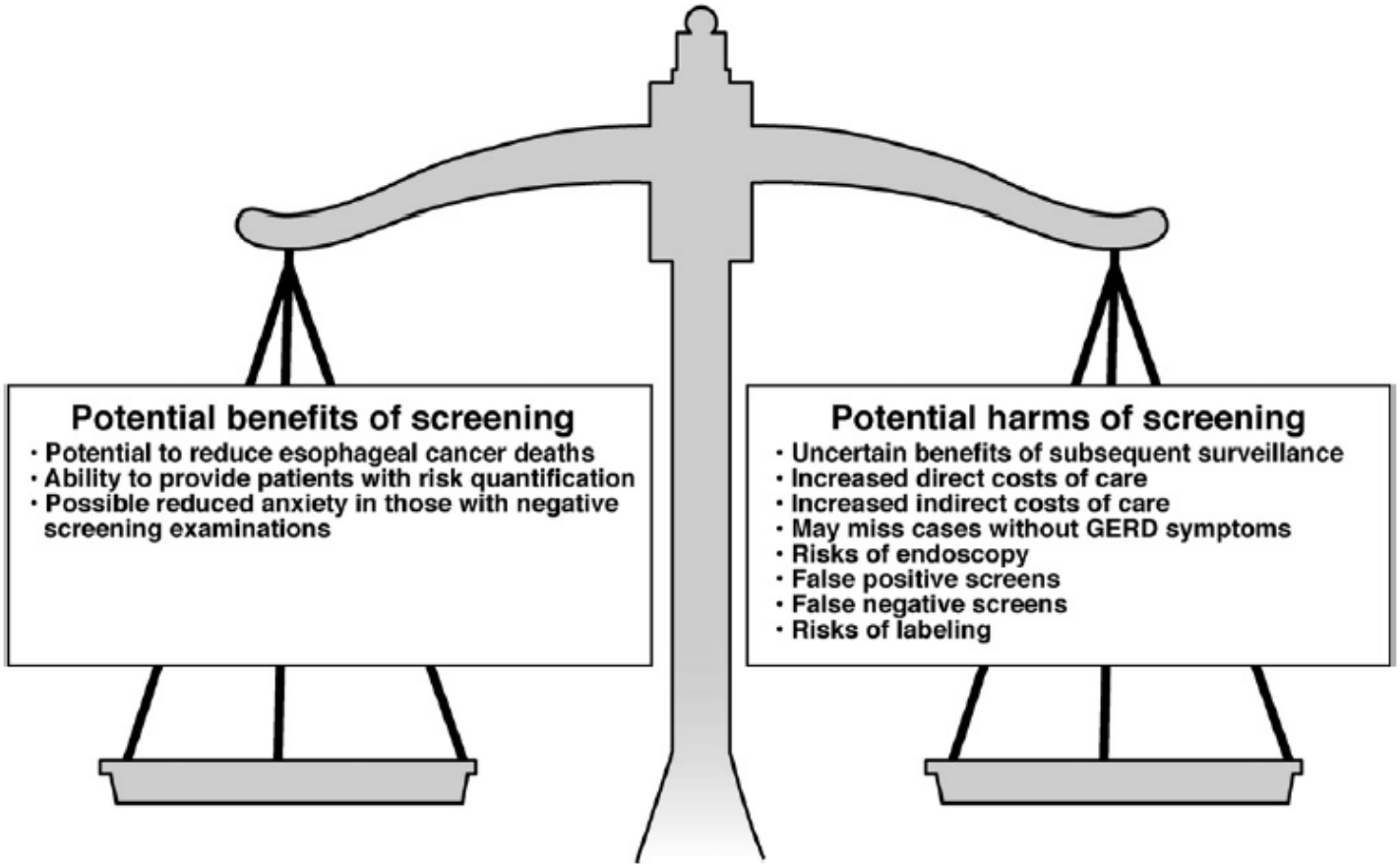
The Barrett's Iceberg



- Most Barrett's Undetected
  - Endoscopy: 22.6/100,000
  - Autopsy: 376.0/100,000
- GERD symptoms not present in 60% of Barrett's patients in population based study
- Only 23/589 pts diagnosed with EAC in Kaiser study had known BE >= 6 months

Cameron, et al. Gastroenterology 1990; 99: 918
Ronkainen et al, Gastroenterology, 2005; 129 (6): 1825-31.
Corley DA et al, Gastroenterology 2002;122(3):633-40.

Should We Screen?



Crockett SD et al, CGH, 2010, 8:7, 565-71.

Barrett's Esophagus: Detection

Table. Comparison of Guidelines on the Management of Barrett Esophagus Published by US Medical Societies & UK

	AGA,[20] 2011	ASGE,[12] 2012	ACG[a] Barrett Esophagus,[11] 2008	ACG[a] GERD,[1] 2013	SSAT,[21] 2005	ACP,[22] 2012	BSG, 2014
Who to screen for Barrett esophagus	Patients with multiple risk factors for EA[b]	Patients with multiple risk factors for EA[b,c]	Selective populations at higher risk[d]	Patients with GERD at high risk based on epidemiological profile[b]	Patients who require long-term medical therapy for GERD	Men aged >50 y with chronic GERD symptoms (>5 y) and additional risk factors for EA[b]	**Chronic GORD and multiple risk factors (>50, white, male, obese)**
Endoscopic surveillance recommended	Yes	Yes, with qualifications[e]	Yes	Yes	Yes	"May be indicated"	**Yes**
Surveillance interval for nondysplastic Barrett esophagus	3-5 y	3-5 y	3 y	"According to guidelines"	2 y	3-5 y	**2-3 yrs: length ≥3 cm 3-5 yrs: length <3 cm**
Surveillance interval for low-grade dysplasia	6-12 mo[g]	Repeat endoscopy within 6 mo to confirm, then annually[g]	Repeat endoscopy within 6 mo to confirm, then annually until no dysplasia ×2	NA	Annually	NA	**Every 6 months**
Surveillance interval for high-grade dysplasia	Surveillance every 3 mo in the absence of eradication therapy[h]	Surveillance offered only to patients unfit or unwilling to undergo operative or ablative therapy	Surveillance every 3 mo or intervention based on results and patient	NA	Intervention recommended rather than surveillance	NA	**Intervention recommended**
Preferred management for high-grade dysplasia	Endoscopic eradication therapy[i]	Endoscopic eradication therapy with endoscopic mucosal resection and/or radiofrequency ablation	Should be individualized with options of surgery, surveillance, endoscopic eradication therapy	NA	Esophageal resection[k]	NA	**Endoscopic eradication**

Spechler, JAMA, 2013 **310**(6)
Fitzgerald *et al.*, GUT, 2014 **63**(1)

Barrett's Esophagus: Detection

Abstract 54: Lao-Sirieix P et al

Evaluation of a minimally-invasive cytosponge esophageal cell collection system in patients with Barrett's esophagus

Lao-Sirieix P[1,2] , Debiram-Beecham I[1], Kerr S[4], Gadeke L[6], Alias B[1], O'Donovan M[3], Novelli M[4], Poller D[6], Kaye P[5], Zeki S[1], Bornschein J[1], di Pietro M[1], Sarmed SS[5], Haidry R[4], Ragunath K[5], Bhandari P[6], Lovat L[4], Fitzgerald RC[1]

MRC Cancer Unit, Hutchison/MRC Research Centre, University of Cambridge, Cambridge, UK
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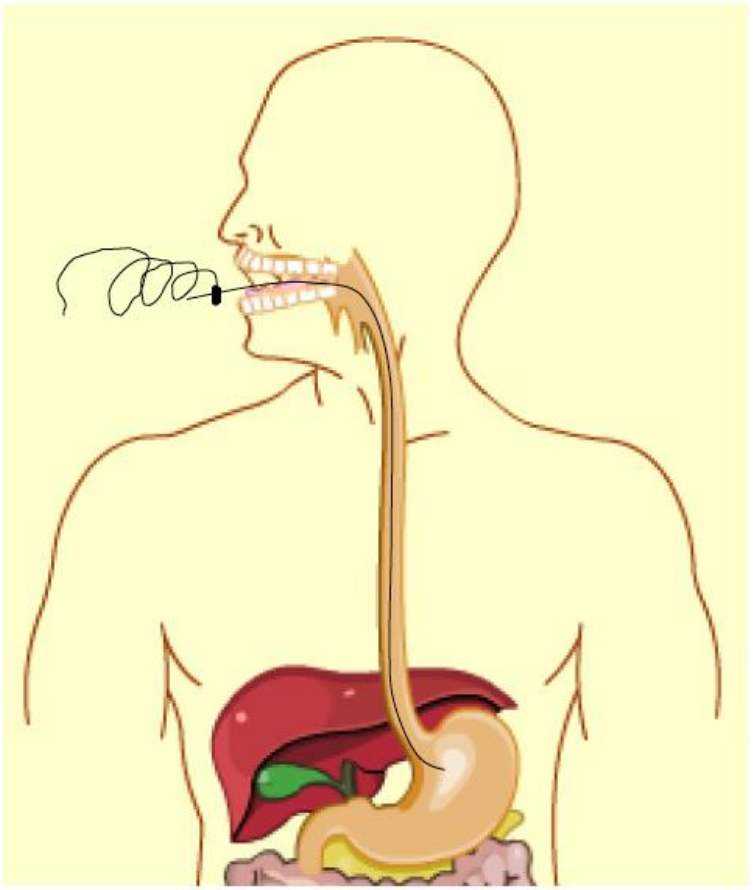
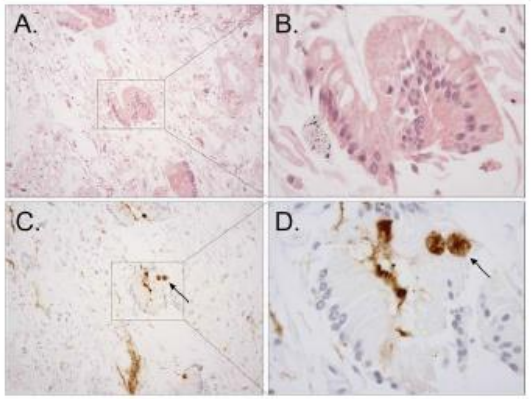
Dept. Histopathology, Addenbrooke's Hospital, Cambridge, UK
University College London Hospital, London, UK
Nottingham Queen's Medical Centre, Nottingham, UK
Queen Alexandra Hospital, Portsmouth, UK

Cytosponge-TFF3 Test

Abstract 54: Lao-Sirieix P et al





Lao-Sirieix *et al.*, Gut 2007 **56**(7); Lao-Sirieix *et al.*, Gut 2009 **58**(11)

Barrett's Esophagus: Detection

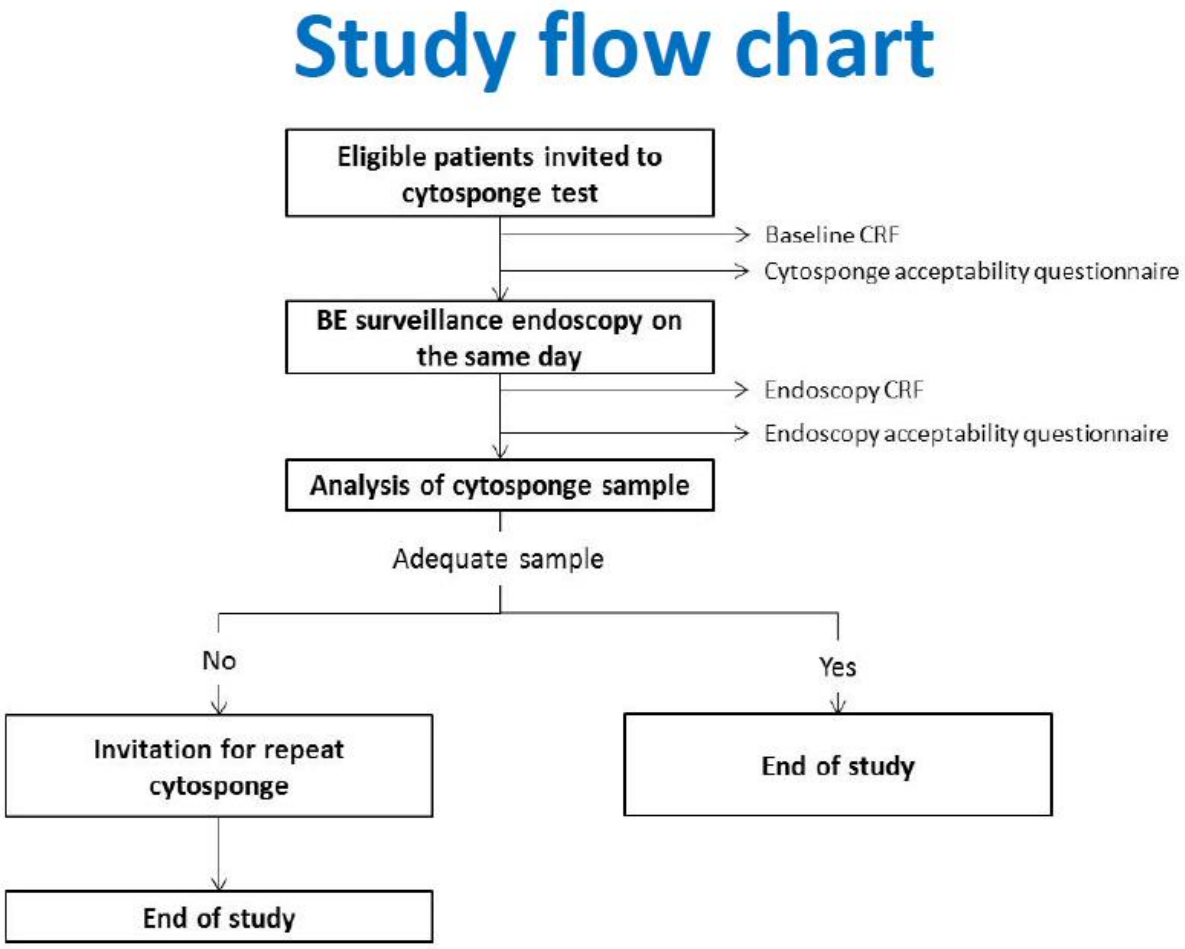
Abstract 54: Lao-Sirieix P et al

Outcome measures

- Safety
- Patient acceptability
- Sample adequacy (measured by the presence of columnar cells)
- Sensitivity of TFF3 assay for diagnosing Barrett's with a length of ≥C1 or ≥ C0M3

Protocol for Study

Abstract 54: Lao-Sirieix P et al

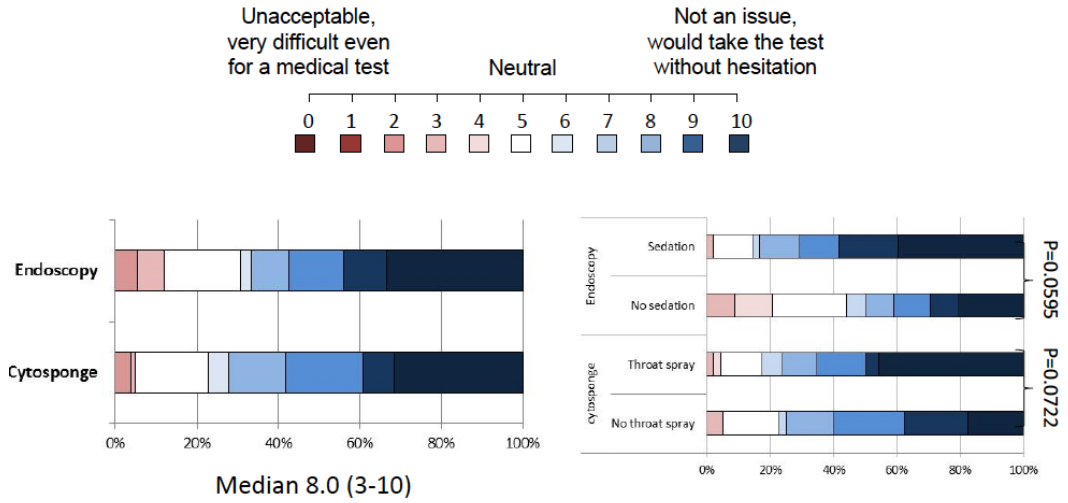


Cytosponge-TFF3 Test

Abstract 54: Lao-Sirieix P et al

RESULTS:

- 81 patients; 66 w/ pathology confirmed BE
- 98.8% swallowed Cytosponge (80/81)
- 5.9% of samples inadequate
- 95.4% sensitive (63/66) for ≥C1 or ≥C0M3
- 1 AE (Chest pain in a patient who underwent EMR x 5)



Barrett's and LGD: Effect of RFA

Surveillance *versus* Radiofrequency Ablation for Barrett's Esophagus with Confirmed Low-Grade Dysplasia: a European Multicenter Randomized Controlled Trial *(SURF)*

UZ LEUVEN · NHS Lothian · Nottingham University Hospitals NHS Trust · Cambridge University Hospitals NHS Foundation Trust · NHS Greater Glasgow and Clyde · ZIEKENHUIS RESEARCH & DEVELOPMENT ACADEMIE ST ANTONIUS · ST. JAMES'S HOSPITAL James's, St. Dublin 8. Ireland. Tel (+353-1) 410 3000 · CATHARINA-ZIEKENHUIS · HSK · amc

K.N. Phoa, F.G. van Vilsteren, R.E. Pouw, B.L. Weusten, E.J. Schoon, R. Bisschops, K. Ragunath, G. Fullarton, M. DiPietro, R. Fitzgerald, D. O'Toole, N. Ravi, O. Pech, M. Tanck, M. Visser, J. Offerhaus, C. Seldenrijk, S.L. Meijer F.J. ten Kate, J. Bergman

Research

Original Investigation

Radiofrequency Ablation vs Endoscopic Surveillance for Patients With Barrett Esophagus and Low-Grade Dysplasia A Randomized Clinical Trial

K. Nadine Phoa, MD; Frederike G. I. van Vilsteren, MD; Bas L. A. M. Weusten, MD; Raf Bisschops, MD; Erik J. Schoon, MD; Krish Ragunath, MD; Grant Fullarton, MD; Massimiliano Di Pietro, MD; Narayanasamy Ravi, MD; Mike Visser, MD; G. Johan Offerhaus, MD; Cees A. Seldenrijk, MD; Sybren L. Meijer, MD; Fiebo J. W. ten Kate, MD; Jan G. P. Tijssen, PhD; Jacques J. G. H. M. Bergman, MD, PhD

IMPORTANCE Barrett esophagus containing low-grade dysplasia is associated with an increased risk of developing esophageal adenocarcinoma, a cancer with a rapidly increasing incidence in the western world.

OBJECTIVE To investigate whether endoscopic radiofrequency ablation could decrease the rate of neoplastic progression.

DESIGN, SETTING, AND PARTICIPANTS Multicenter randomized clinical trial that enrolled 136 patients with a confirmed diagnosis of Barrett esophagus containing low-grade dysplasia at 9 European sites between June 2007 and June 2011. Patient follow-up ended May 2013.

INTERVENTIONS Eligible patients were randomly assigned in a 1:1 ratio to either endoscopic treatment with radiofrequency ablation (ablation) or endoscopic surveillance (control). Ablation was performed with the balloon device for circumferential ablation of the esophagus or the focal device for targeted ablation, with a maximum of 5 sessions allowed.

MAIN OUTCOMES AND MEASURES The primary outcome was neoplastic progression to high-grade dysplasia or adenocarcinoma during a 3-year follow-up since randomization. Secondary outcomes were complete eradication of dysplasia and intestinal metaplasia and adverse events.

RESULTS Sixty-eight patients were randomized to receive ablation and 68 to receive control. Ablation reduced the risk of progression to high-grade dysplasia or adenocarcinoma by 25.0% (1.5% for ablation vs 26.5% for control; 95% CI, 14.1%-35.9%; $P < .001$) and the risk of progression to adenocarcinoma by 7.4% (1.5% for ablation vs 8.8% for control; 95% CI, 0%-14.7%; $P = .03$). Among patients in the ablation group, complete eradication occurred in 92.6% for dysplasia and 88.2% for intestinal metaplasia compared with 27.9% for dysplasia and 0.0% for intestinal metaplasia among patients in the control group ($P < .001$). Treatment-related adverse events occurred in 19.1% of patients receiving ablation ($P < .001$). The most common adverse event was stricture, occurring in 8 patients receiving ablation (11.8%), all resolved by endoscopic dilation (median, 1 session). The data and safety monitoring board recommended early termination of the trial due to superiority of ablation for the primary outcome and the potential for patient safety issues if the trial continued.

CONCLUSIONS AND RELEVANCE In this randomized trial of patients with Barrett esophagus and a confirmed diagnosis of low-grade dysplasia, radiofrequency ablation resulted in a reduced risk of neoplastic progression over 3 years of follow-up.

TRIAL REGISTRATION trialregister.nl Identifier: NTR1198

Editorial page 1205

CME Quiz at jamanetworkcme.com and CME Questions page 1247

Author Affiliations: Author affiliations are listed at the end of this article.

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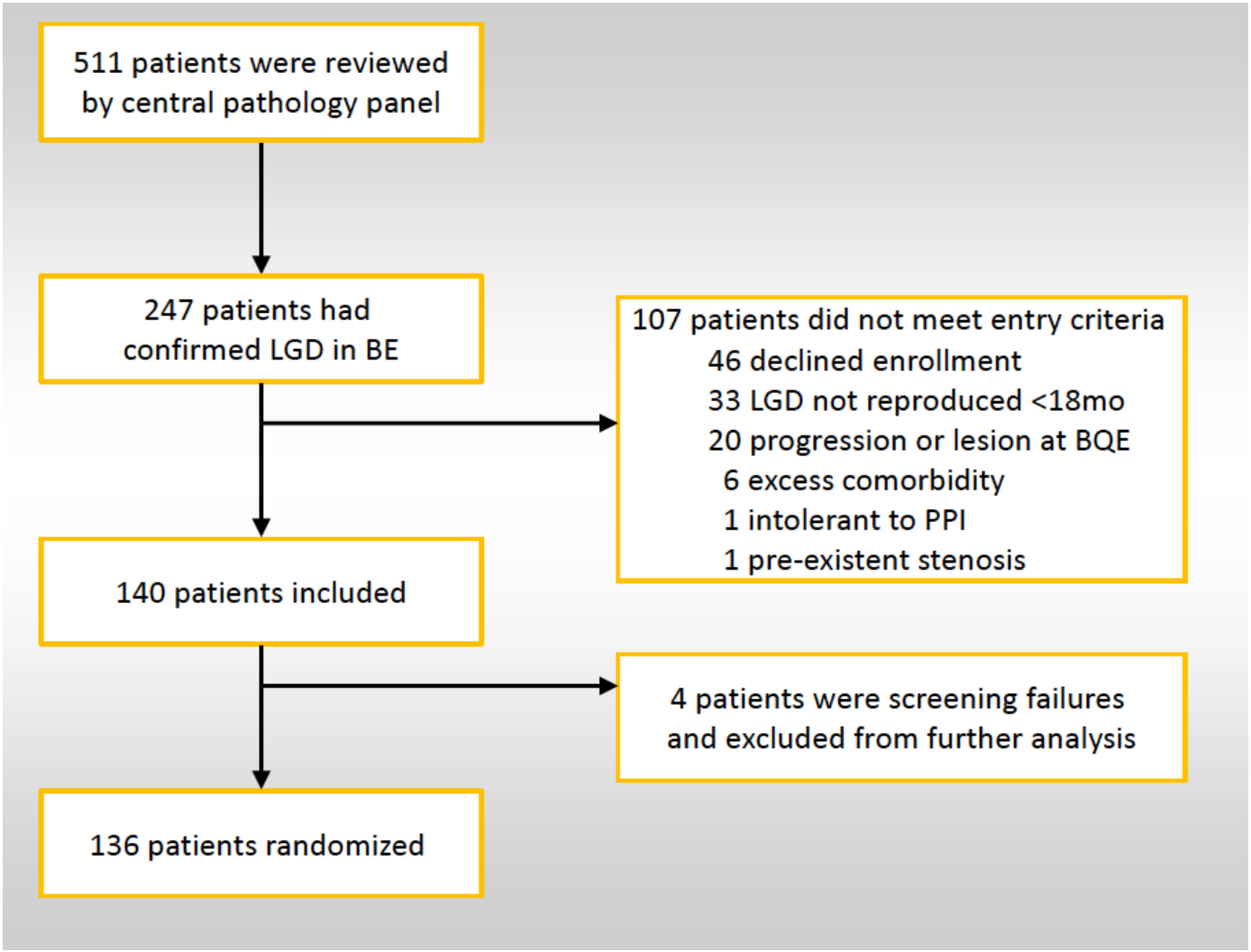
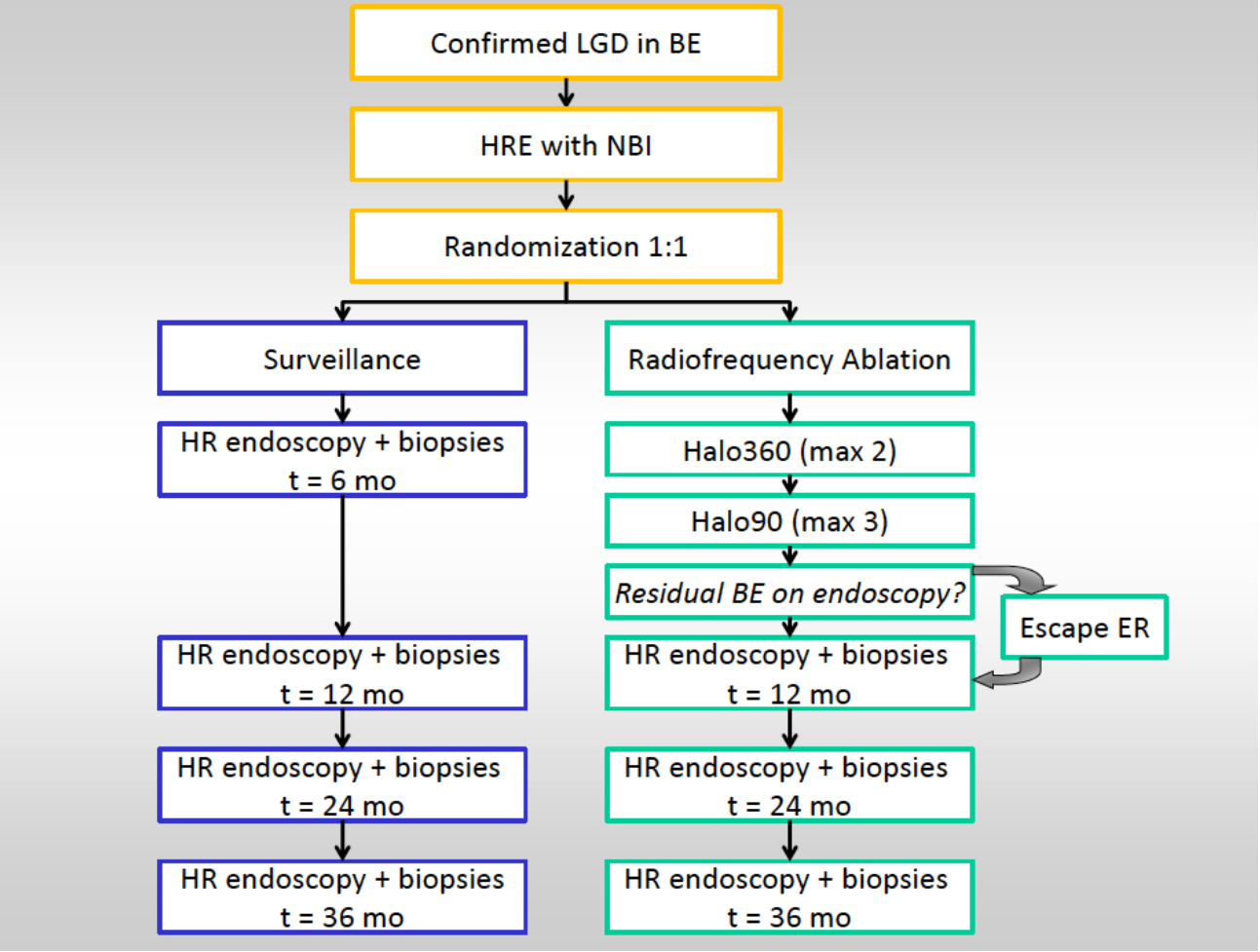
JAMA. 2014;311(12):1209-1217. doi:10.1001/jama.2014.2511

Patient Selection



Trial Protocol



SURF Trial: Baseline Data

Baseline characteristics and FU

	RFA n=68	Surveillance n=68
Male sex	55 (81%)	61 (90%)
Age in years (mean)	63	63
BE length (median)	C2M4	C2M4
Follow-up (median)	30 mo	24 mo
Follow-up visits (mean)	3	3
Biopsy specimens (median)	37	31

SURF Trial Results

Table 2. Primary and Secondary Efficacy Outcomes

Efficacy Outcomes	No. of Patients (%)		Risk Difference, % (95% CI)	*P* Value
	Ablation Group (n = 68)	Control Group (n = 68)		
Progression to high-grade dysplasia or cancer	1 (1.5)	18 (26.5)	25.0 (14.1-35.9)	<.001[a]
Progression to cancer	1 (1.5)	6 (8.8)	7.4 (0.0-14.7)	.03[a]
Complete eradication of dysplasia at the end of endoscopic treatment	63/68 (92.6)[b]			NA
Complete eradication of IM at the end of endoscopic treatment	60/68 (88.2)[b]			NA
Complete eradication of dysplasia during follow-up, No. of events/total patients (%)[c]	62/63 (98.4)[b]	19/68 (27.9)	70.5 (59.4-81.6)	<.001
Complete eradication of IM during follow-up, No. of events/total patients (%)[c]	54/60 (90.0)[b]	0/68 (0.0)	90.0 (82.4-97.6)	<.001

3 year f/u – trial stopped early by DSMB **Phoa et al, JAMA, 3/2014**

BE: Risk of LGD Progression

Abstract 817 –Duits et al

- Looked at factors that could predict if LGD would progress
  - Age
  - Years of BE Diagnosis
  - BE length/circumferential or not
  - # of pathologists (out of 3) agreeing on LGD diagnosis
  - Unifocal vs. multifocality of LGD

BE: Risk of LGD Progression

- Abstract 817 Duits et al

Variable	Odds Ratio	95% CI
Circumferential BE extent (per cm)	1.05	0.85 to 1.28
Age (per year)	1.00	0.95 to 1.05
Years since BE diagnosis (per year)	**0.91**	0.82 to 1.00
Focality of LGD		
Unifocal LGD	-	-
Multifocal LGD	1.92	0.52 to 7.14
Number of pathologists confirming LGD		
1	-	-
2	**4.25**	0.95 to 19.00
3	**11.89**	2.98 to 47.39

BE: Risk of LGD Progression

- Treat RFA and LGD:
  - Multifocal confirmed LGD
  - LGD confirmed by > 1 pathologist
- Consider surveillance for:
  - LGD confirmed by only 1 pathologist
  - Long-standing BE in surveillance
  - Short-segment

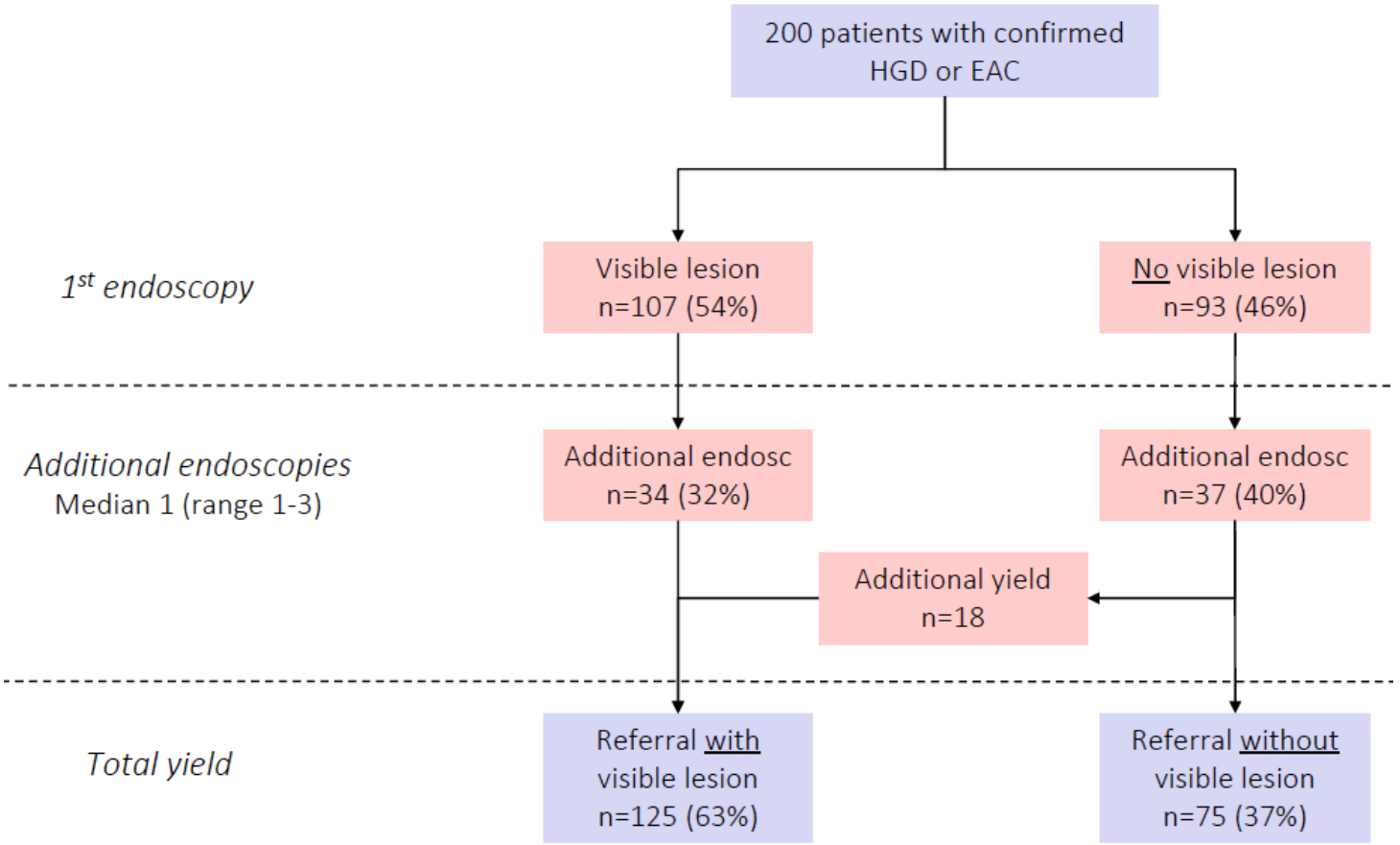
Finding Dysplasia During Surveillance

Abstract 341: Scholvinck et al

- Goal: Compare detection of dysplasia/neoplasia in expert vs. community centers
- Retrospective
- 200 patients from 37 centers in the Netherlands (1 expert center)
- Median 56 [34-90] days from referral EGD to expert center EGD

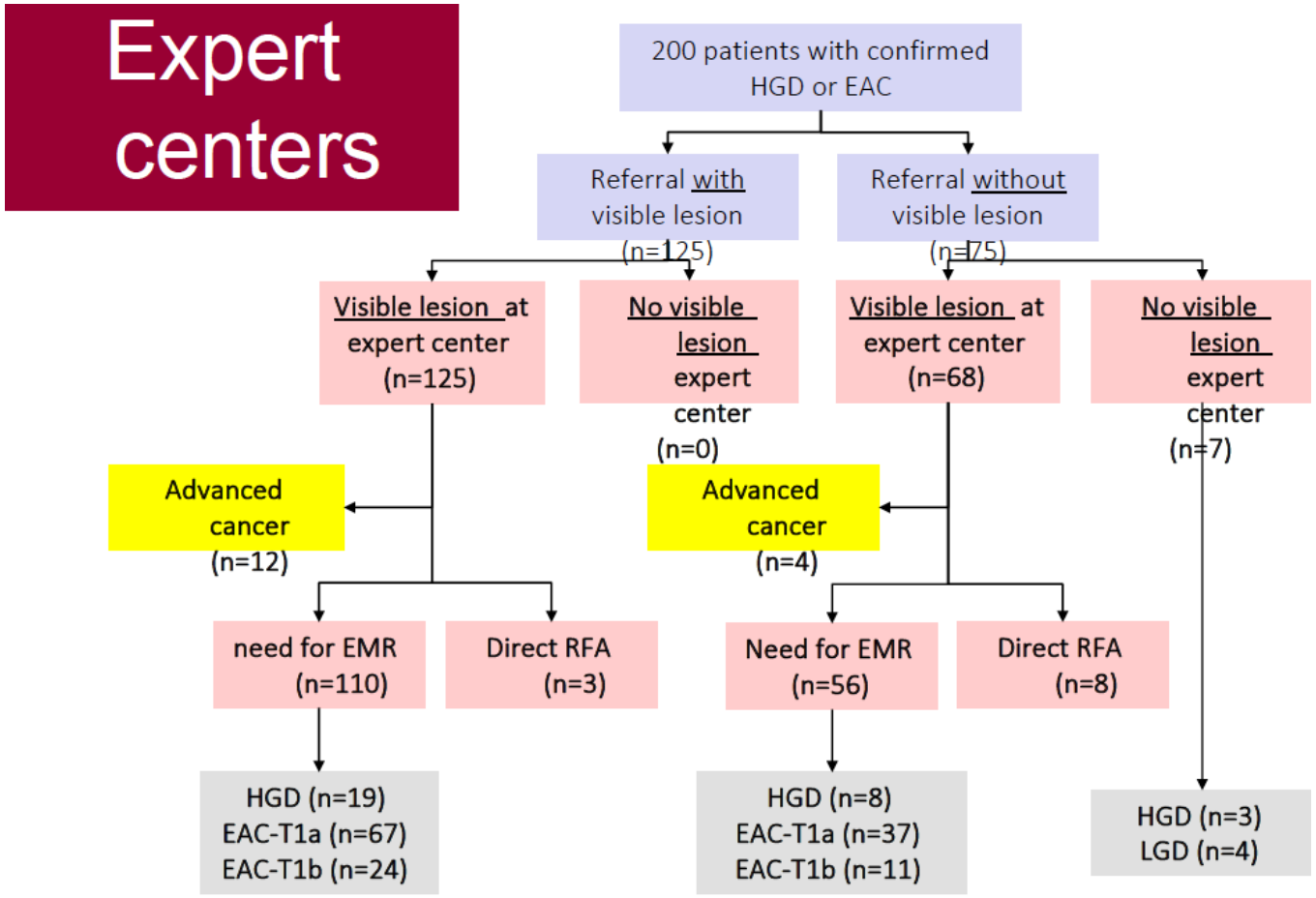
Finding Dysplasia During Surveillance

Abstract 341: Scholvinck et al

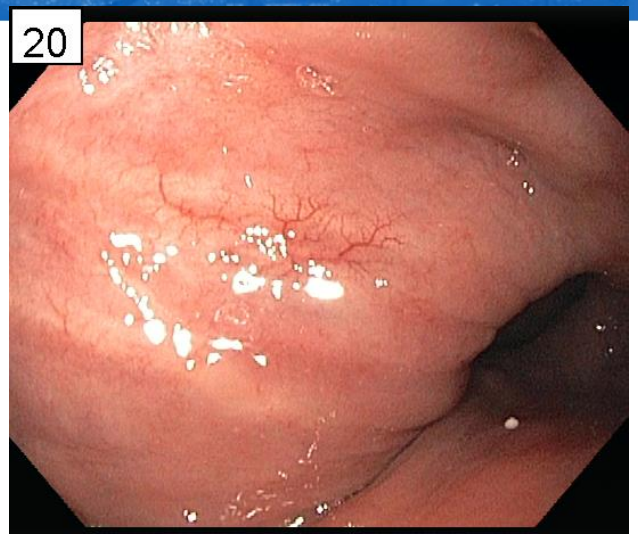


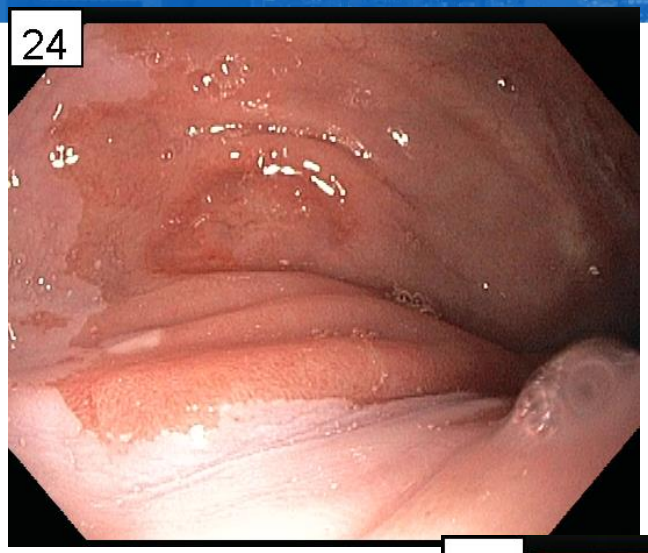
Finding Dysplasia During Surveillance

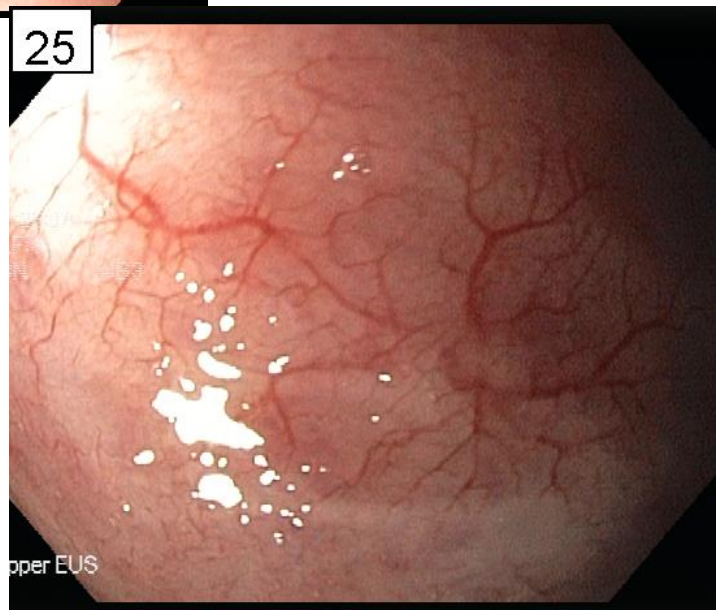
Abstract 341: Scholvinck et al



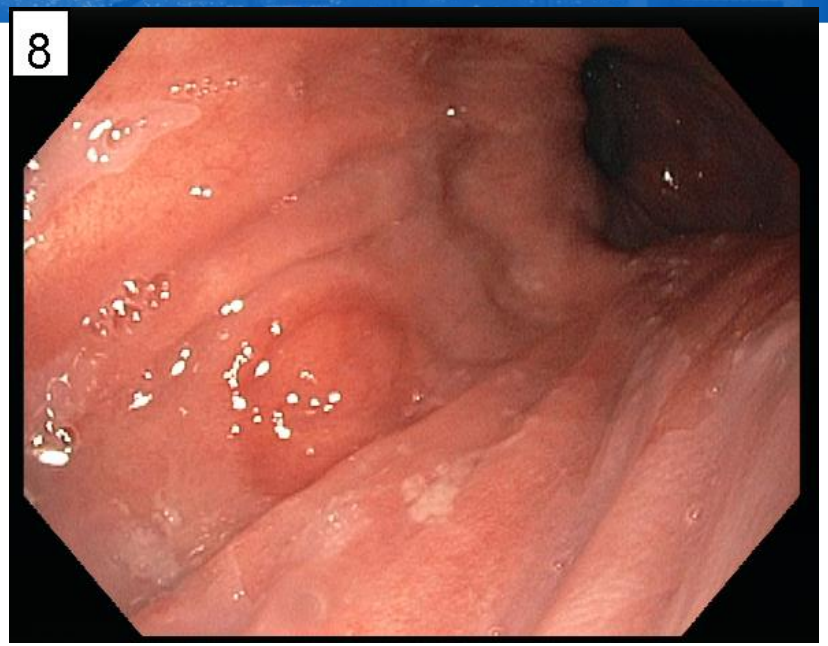
This Happens! : July 2013 EGD

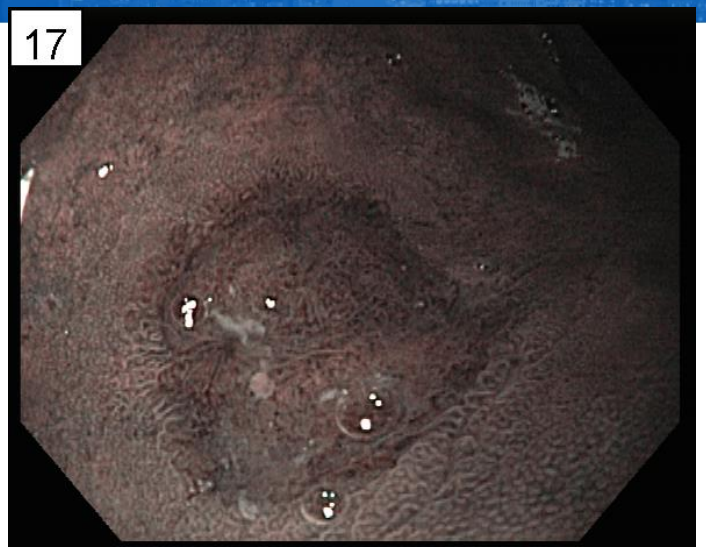


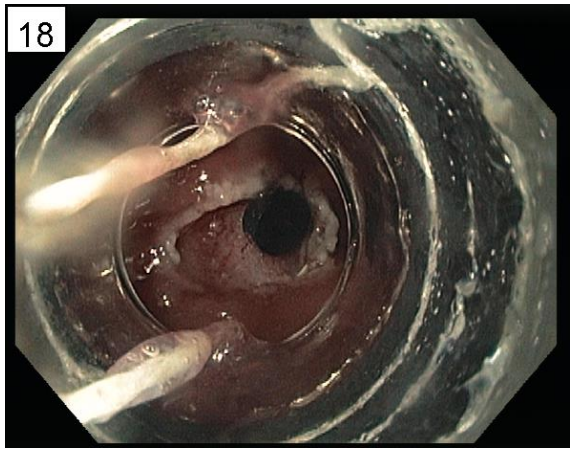


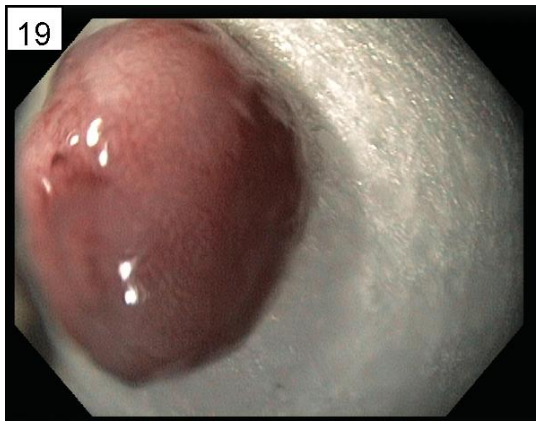


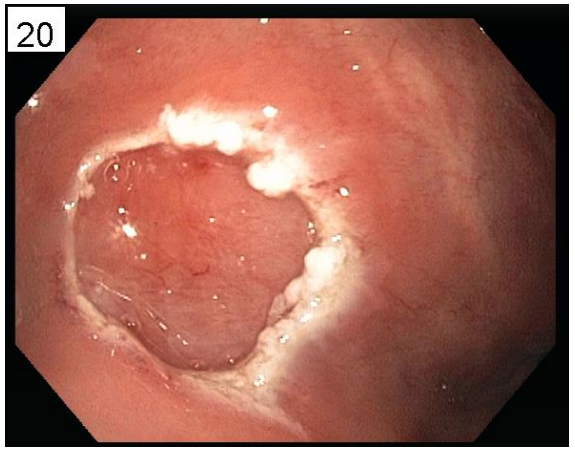
Late Aug 2013



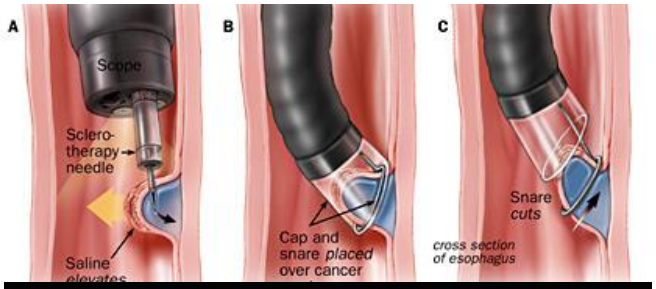


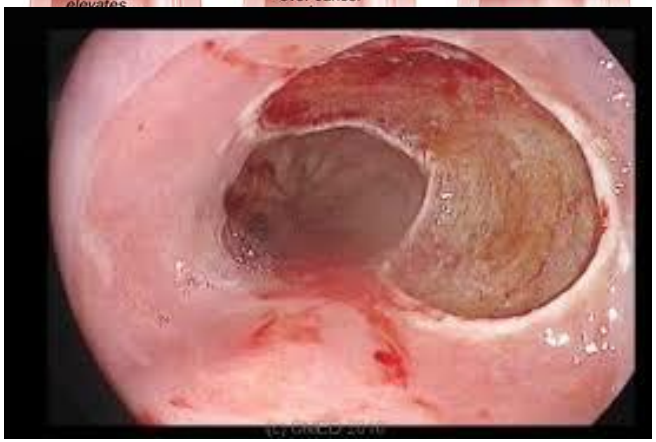


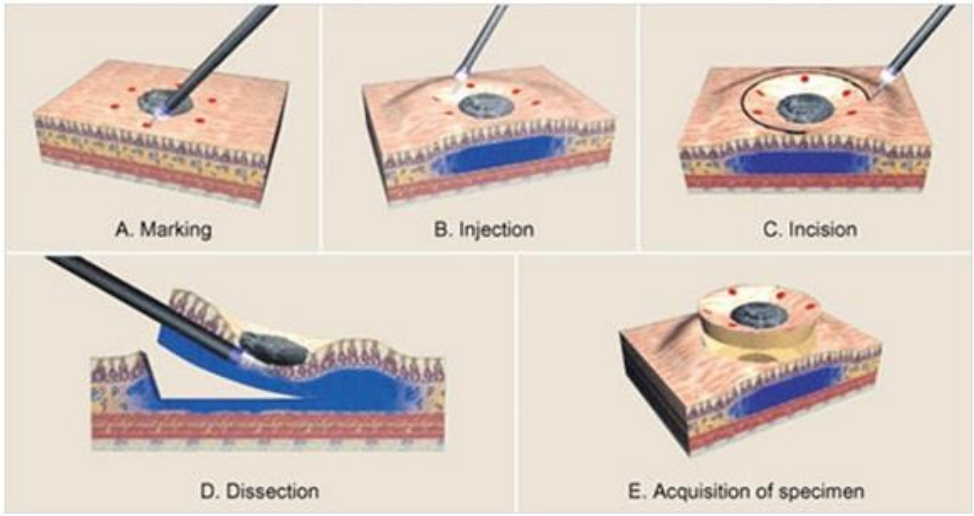


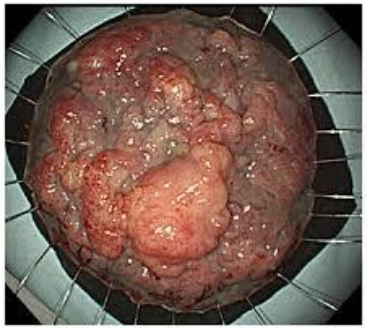


Esophageal EMR vs. ESD: Is ESD Really Better?









EET: ESD vs. EMR – which is better?

Abstract 216: Terheggen et al..

- 40 patients (31 cancer/9 HGD; elevated/depressed; ≤ 3 cm)
- Randomized to either:
  - Waterjet hybridknife ESD (N=20)
  - Cap-assisted EMR (N=20)
- Reviewed by 2 pathologists
- F/u at 3,6,9,12, and 18 months
- RFA offered for residual Barrett's at 6 mos if no cancer/nodular lesions

EET: ESD vs. EMR – which is better?

Abstract 216: Terheggen et al..

RESULTS:

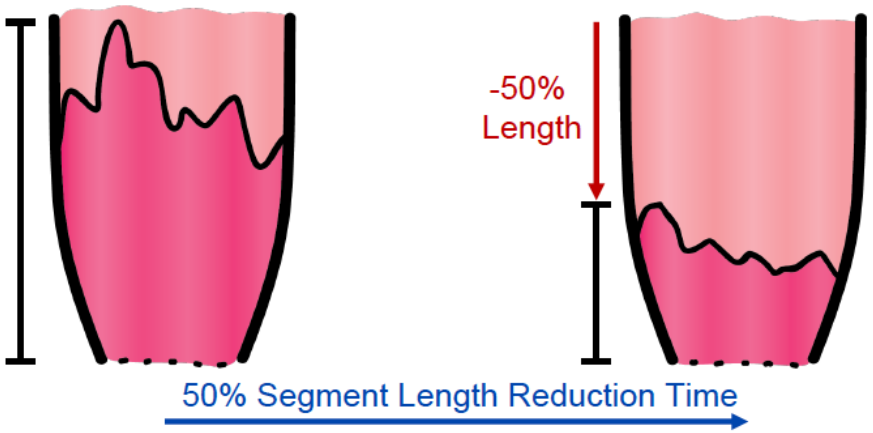
- ESD with fewer mean pieces than EMR (1+/-0; 3+/-1)
- ESD took longer (mean 54 min vs. 22 min); p =0.002
- 3 Adverse events with ESD vs. 0 for EMR
  - 1 aspiration; ***2 perforations***
- En bloc resection greater with ESD (20/20 c/t 3/20); p<0.001
- Similar rates of subsequent need for surgery (ESD-4; EMR-3) and no 30 d mortality in either group
- **No difference in complete eradication of neoplasia between ESD (16/16) and EMR (16/17) at first f/u EGD**

EET: Predicting Failures

Abstract 221: Chan et al

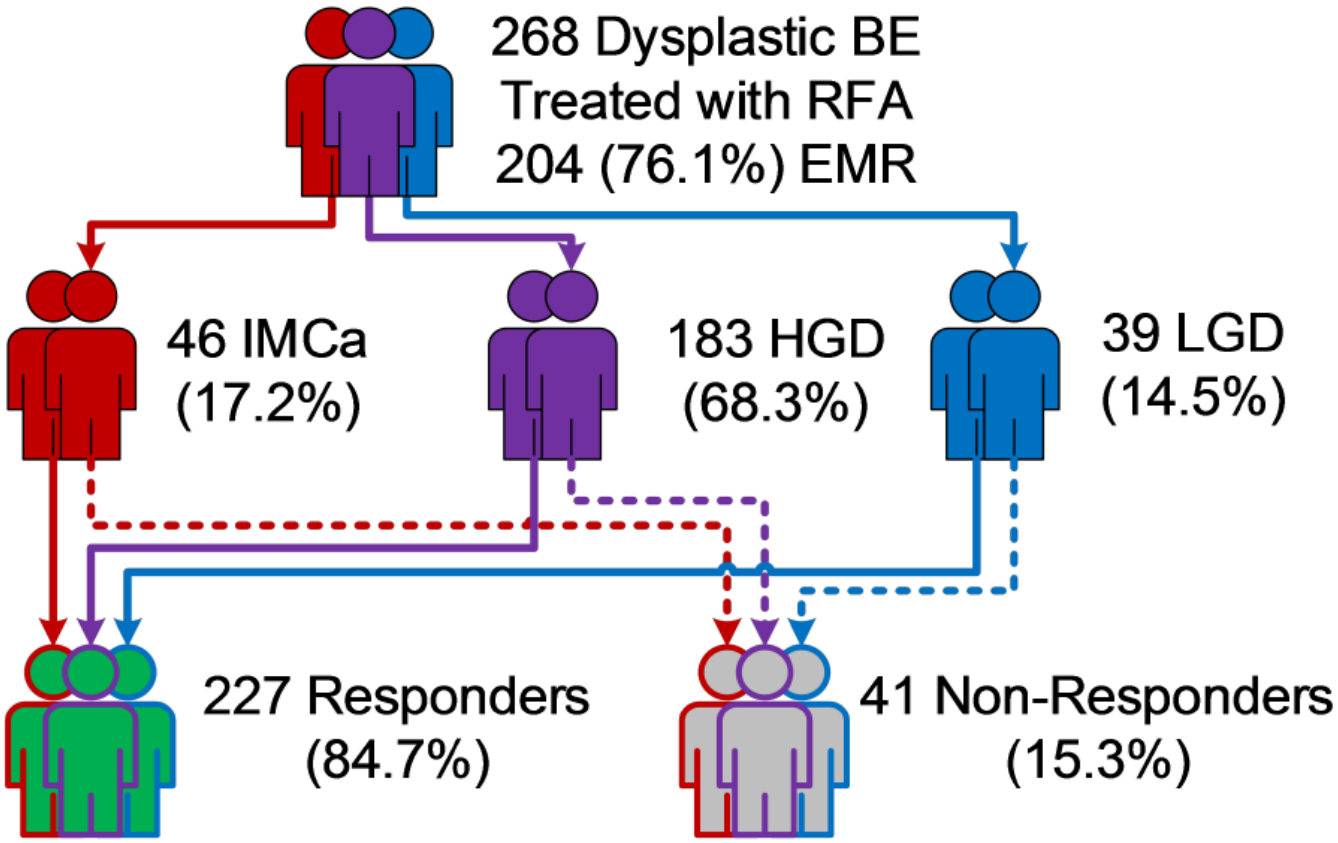
- Goals:
  - Determine if rapid ablation response predicts overall successful eradication of BE
  - Determine # of ablations after which response is diminished

- **50% Segment Length Reduction Time** (50% SLR):
  - Time to 50% relative reduction of pre-treatment BE maximal length



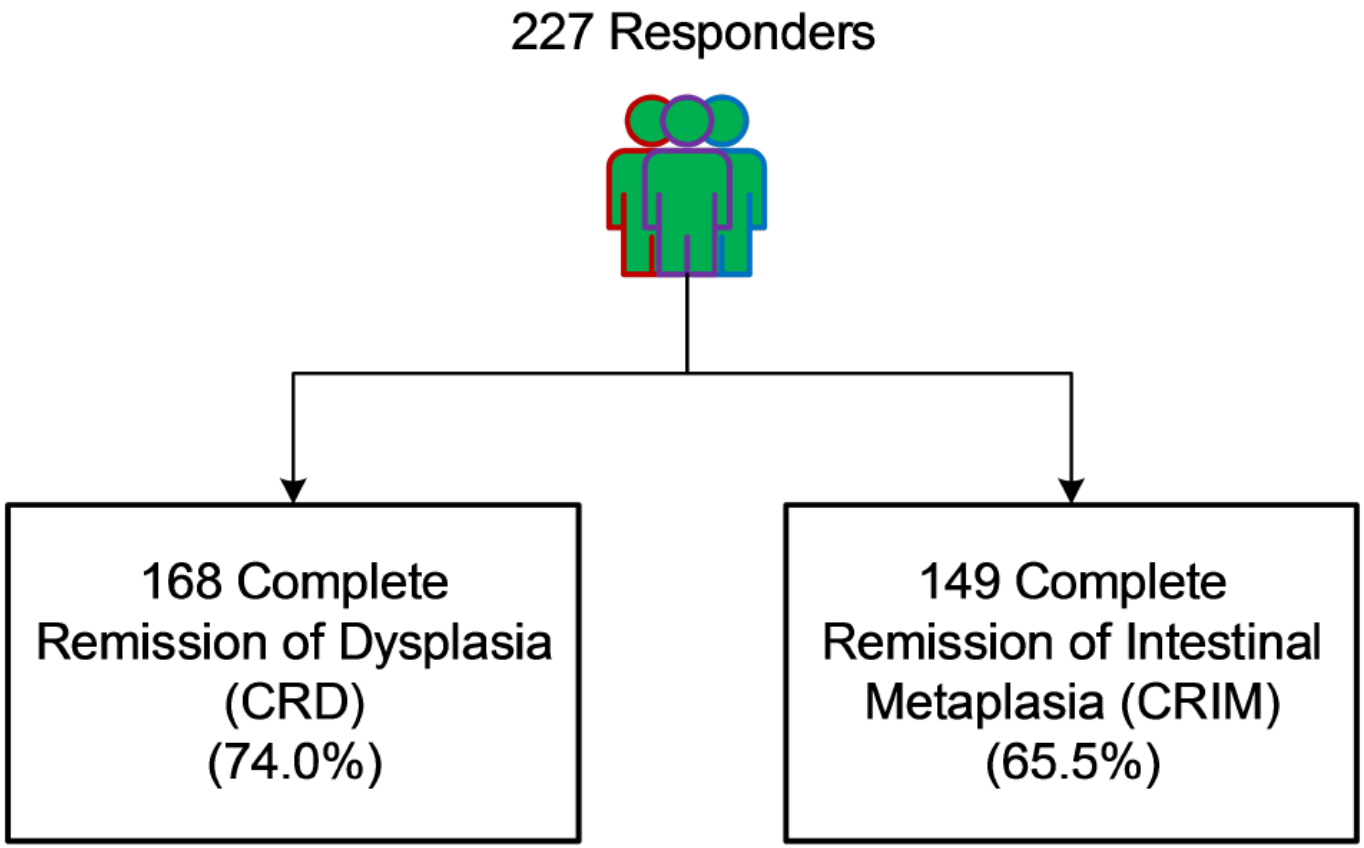
EET: Predicting Failures

Abstract 221: Chan et al



EET: Predicting Failures

Abstract 221: Chan et al



EET: Predicting Failures

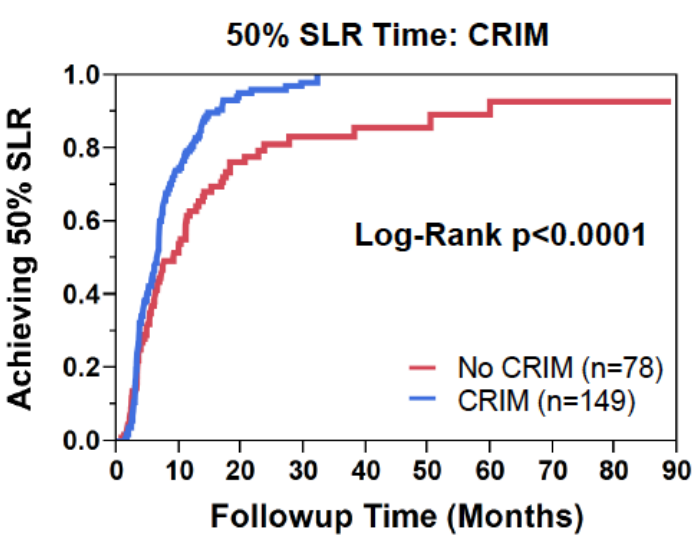
Abstract 221: Chan et al

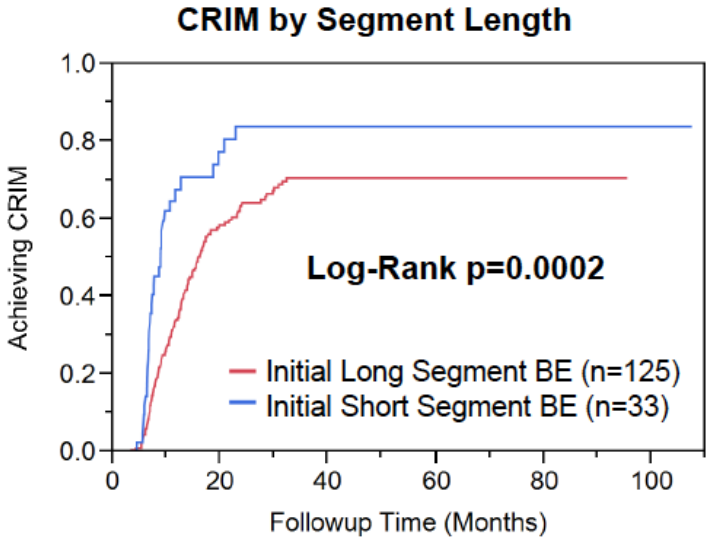
- Initial Length and 50% SLR Time were independent predictors of achievement of CRIM

Variable	CRIM Time (Months)	
50 SLR Time (months)	• Unit HR (per month) 0.95 (0.93-0.98) • Range HR 0.07 (0.01-0.33)	**p = 0.0003**
Length BE at RFA (cm)	• Unit HR (per cm) 0.93 (0.88-0.99) • Range HR 0.38 (0.17-0.82)	**p = 0.01**

EET: Predicting Failures

Abstract 221: Chan et al

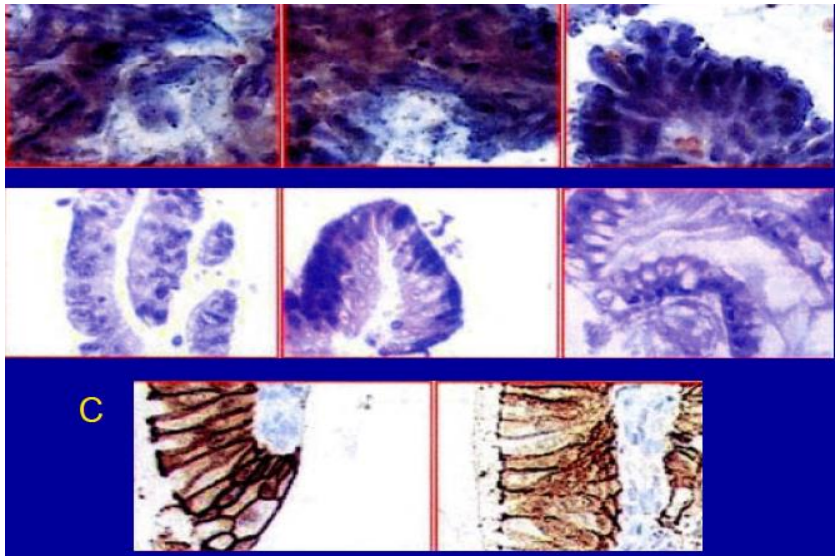




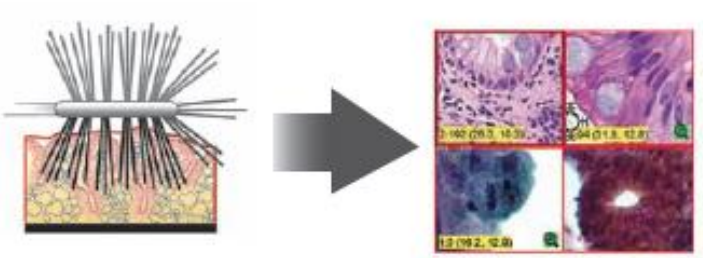
- Both 50% SLR Time and initial BE length are independent predictors of RFA response for achievement of CRD and CRIM
- 50% SLR by 2 follow-up sessions predicts eventual achievement of CRIM (HR 1.94)
- 50% SLR Time can serve as a marker for clinical response to RFA therapy

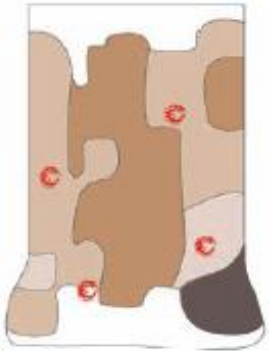
Surveillance Post –EET: Is a Brush Better than Biopsies?

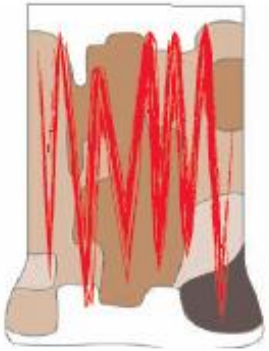
- Wide Area Transepithelial Sampling (WATS^{3D})
- Abrasive brush that samples entire squamous or glandular thickness
- Specimen includes tissue fragments, cell clusters, and individual cells

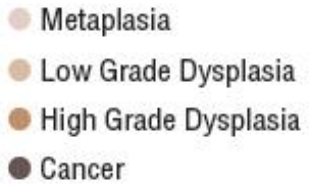


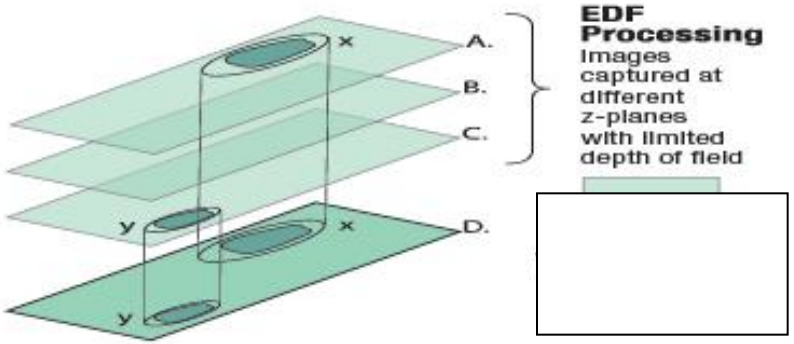
Increased Yield with Specialized Brush











- 39.8% increase in Barrett's esophagus detection in GERD patients
- 42.1% increase in dysplasia detection c/t biopsy in patients w/ dysplasia undergoing surveillance

Anandasapathy, Dig Dis Sci, 2011
Johanson, Dig Dis Sci, 2011

Surveillance Post –EET: Is a Brush Better than Biopsies?

Abstract #345, Iorio et al

- AIM: Evaluate adjunctive value of Brush biopsy to forceps biopsy for detection of residual/recurrent BE after Barrett's ablation.
- 2 centers
- WATS bx and standard biopsies taken at same session
- WATS brushing/bx taken first, then 4 quadrant q 1 cm random biopsies

Surveillance Post –EET: Is a Brush Better than Biopsies?

Abstract #345, Iorio et al

Mean BE Length = 3.88 cm

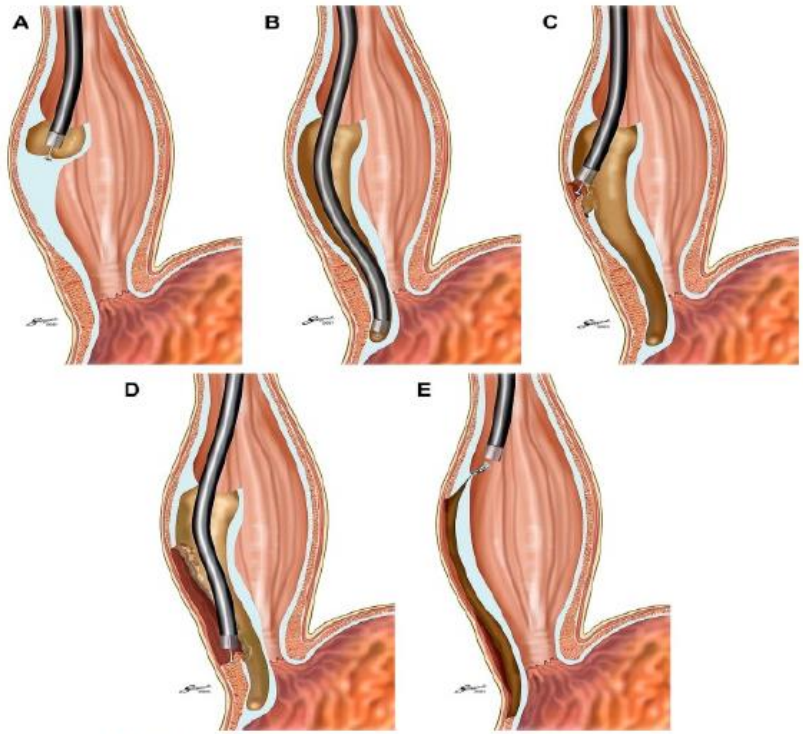
IM/Dysplasia/ Neoplasia	Forceps Biopsy Positive	Forceps Biopsy Negative	Total
WATS^{3D} Positive	15	**24**	**39**
WATS^{3D} Negative	24	145	169
Total	**39**	169	208

- 18.8% (39/208) w/ IM, dysplasia, or neoplasia on forceps biopsy alone
- WATS brush detected 24 additional cases (incremental yield of 11.5%) – increasing detection of endpoint from 18.8% to 30.3%
- This is a 61% augmentation of the yield for IM, dyplasia, or neoplasia
- NNT = 8.7 to find one additional recurrence

Updates in Esophageal Disease

- Barrett's Esophagus
- POEM/Achalasia
- GERD

POEM: Per Oral Endoscopic Myotomy



Inoue et al 2011

(*A*) Submucosal injection and mucosal incision toward submucosal space.
(*B*) Creation of submucosal tunnel.
(*C*) Myotomy started at inside submucosal tunnel.
(*D*) Completion of myotomy beyond esophago-gastric junction.
(*E*) Closure of mucosal entry

First performed in a human by Inoue in 2008

Eckardt Score: Measures Achalasia Symptoms

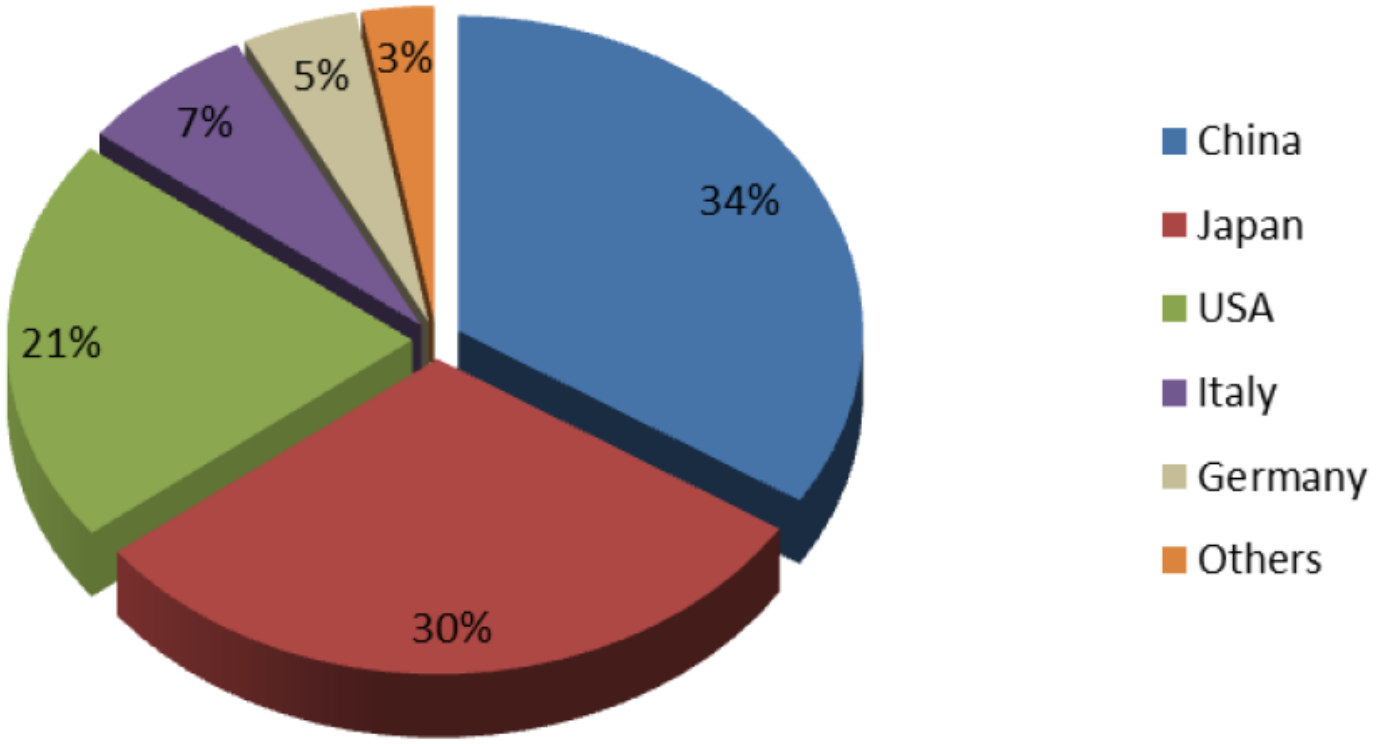
Score	Symptoms			
	Weight loss (Kg)	Dysphagia	Retrosternal pain	Regurgitation
0	None	None	None	None
1	<5	Occasional	Occasional	Occasional
2	5-10	Daily	Daily	Daily
3	>10	Each meal	Each meal	Each meal

POEM: Per Oral Endoscopic Myotomy

Abstract 176: Akintoye et al

- Aim: Systematic Review of Literature on POEM re: Safety/Efficacy
- Efficacy assessed by:
  - % pts with Eckardt score < 3 post POEM = primary outcome
  - Mean Eckardt score
  - Manometry parameters
  - Timed barium esophagram
  - Weight gain

RESULTS



Percentage distribution of 1733 patients undergoing POEM procedure between 2008 and 2014 in 27 studies in 10 countries

South Korea, India, Netherlands, Switzerland and Canada contributed ≤1% each

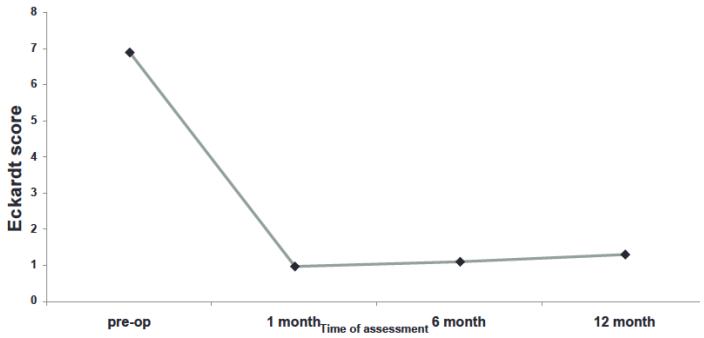
RESULTS: Procedure Data

Abstract 176: Akintoye et al

- N=1733 (53% F)
- Avg. Age = 46 (3-93)
- Indications: Achalasia (97%), Others include nutcracker and jackhammer esophagus, DES
- Avg procedure: 88 min (30-245)
- Post-op hospitalization: 3.9 days (1-19)
- Failure in 13 (unable to create submucosal tunnel due to fibrosis)

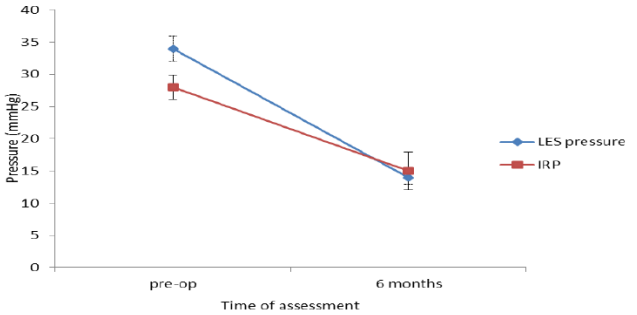
RESULTS: Efficacy of POEM

Abstract 176: Akintoye et al



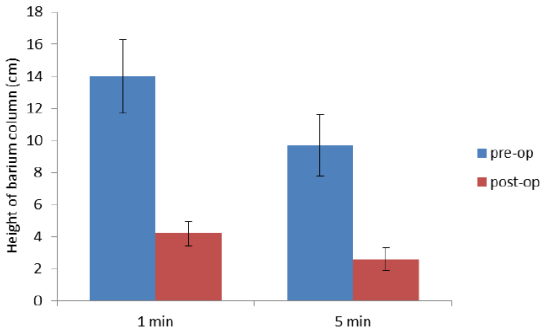
Studies, *n*	24	8	12	7
Patients, *n*	648	917	605	895

Manometry



Studies, n	21	17
Patients, n	1526	1335
Studies, n	8	6
Patients, n	283	175

Barium esophagogram



Studies, n	3	4
Patients, n	186	232

Average weight gain in 439 pts was 5.4 +/- 0.85 kg after mean 8.4 mo f/u

RESULTS: Adverse Events of POEM

Abstract 176: Akintoye et al

Adverse outcomes	Studies, *n*	Patients, *n*	Rate (95% CI), %	I^2, %
Perioperative				
Pneumomediastinum	8	194	15 (1-37)	90
Pneumoperitoneum	13	832	13 (5.3-22)	91
Subcutaneous emphysema	13	738	11 (4.2-19)	87
Pleural effusion	4	793	9.5 (0-52)	99
Mucosal injury	15	1404	9.4 (4.4-16)	90
Pneumothorax	8	1090	5.4 (0.3-15)	95
Major bleeding	15	1141	0.6 (0-2.4)	62
Esophageal perforation	17	1269	0.3 (0-1.6)	58
Gastroesophageal reflux				
Symptomatic	18	1521	15 (11-19)	69
Esophagitis on EGD	12	829	19 (9.7-29)	91
Abnormal exposure on 24-hr pH study	4	261	39 (27-53)	76

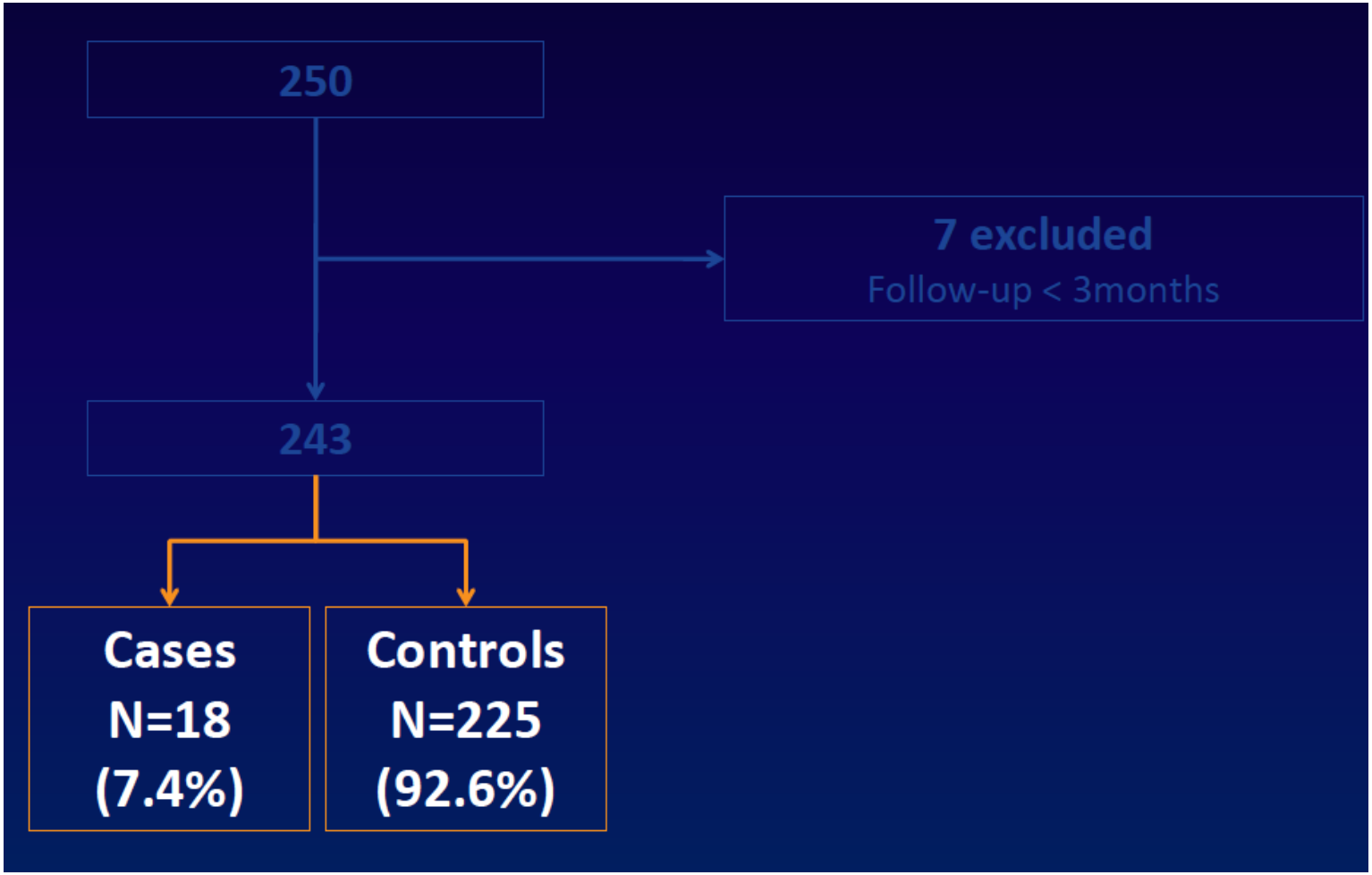
POEM: What Predicts Failure?

Abstract 176: Kumbhari et al

- Retrospective review of prospective multicenter database (7 centers: 1 US, 5 European, 1 Asian)
- Minimum f/u needed: 3 months
- Cases: Eckardt score >3 post POEM
- Controls: Eckardt score $\leq$ 3 post POEM
- Goals:
  - Identify pre- and intra-procedure variables associated with POEM failure (Primary)
  - Evaluate the physiology of the LES post-POEM (Secondary)

Study Population

Abstract 176: Kumbhari et al



Risk Factors for POEM Failure

Abstract 176: Kumbhari et al

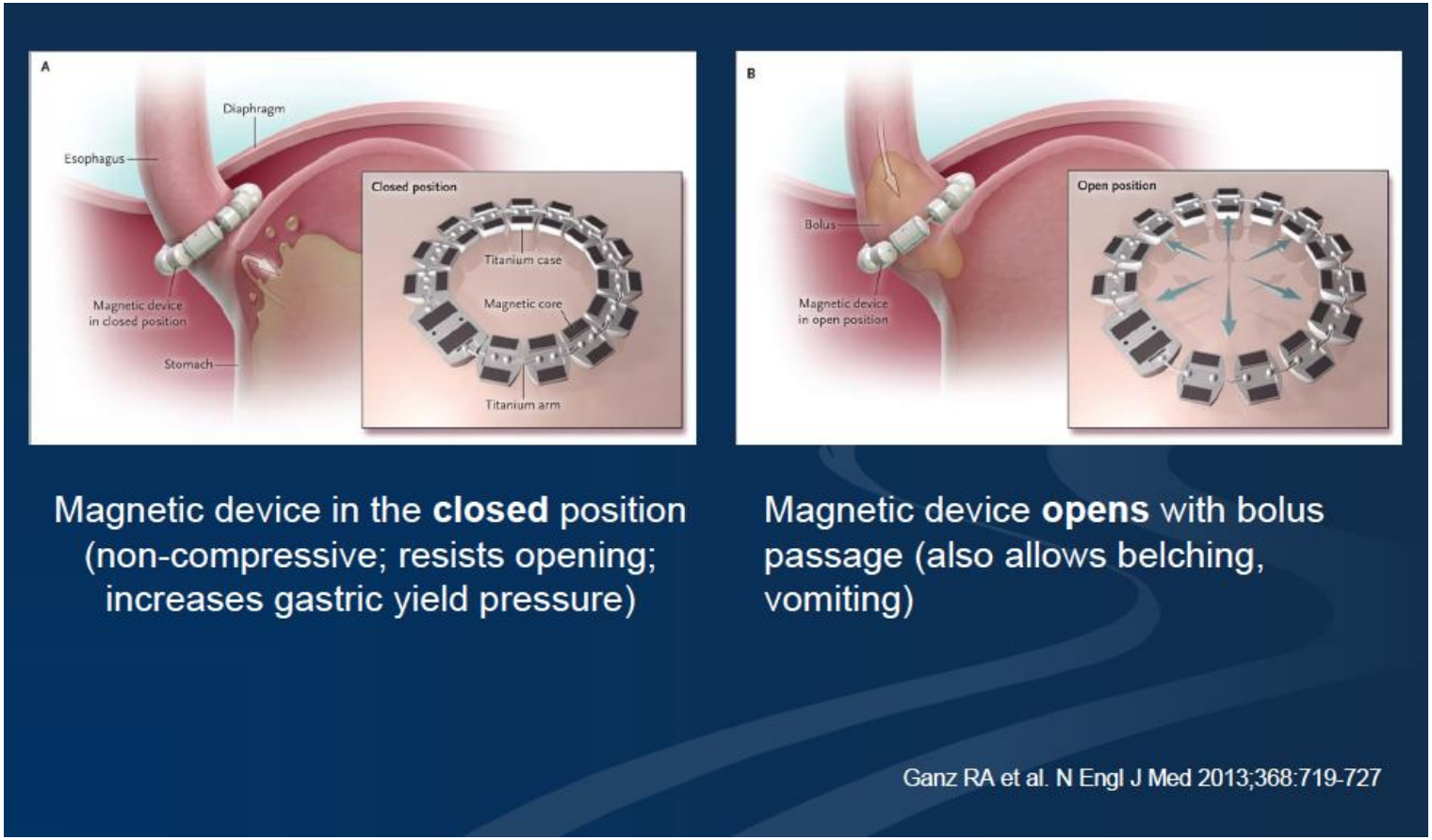
	Adjusted OR	95% CI	P value
Prior Heller myotomy	5.0	0.7-35.4	0.09
Pre POEM Eckardt score	1.5	1.04-2.1	0.03
Achalasia Type I vs II	4.0	1.1-14.7	0.04
Length of Esoph myotomy	1.5	1.2-1.9	0.01

Updates in Esophageal Disease

- Barrett's Esophagus
- Eosinophilic Esophagitis
- POEM/Achalasia
- GERD

Magnetic Device for GERD: 5 year data

Abstract 688, Ganz et al



FDA Approved in 2012

Magnetic Device for GERD: 5 year data

Abstract 688, Ganz et al

- Prospective, multicenter study
- Endpoints:
  - pH control (1 year)
  - PPI use (1-5 years)
  - GERD symptom scores (1-5 years)
- Definitions of Success:
  - 60% of patients much achieve at least 50% improvement in:
    - pH scores (normal is pH < 4 < 4.5% of the time)
    - PPI use
    - GERD symptom scores

Magnetic Device for GERD: 5 year data

Abstract 688, Ganz et al

- 100 pts; 14 centers (13 US; 1 Netherlands)
- 9 academic (N=51); 5 community (N = 49)
- Follow-up:
  - Year 1: 98 patients (96 w/ pH data)
  - Year 5: 85 patients

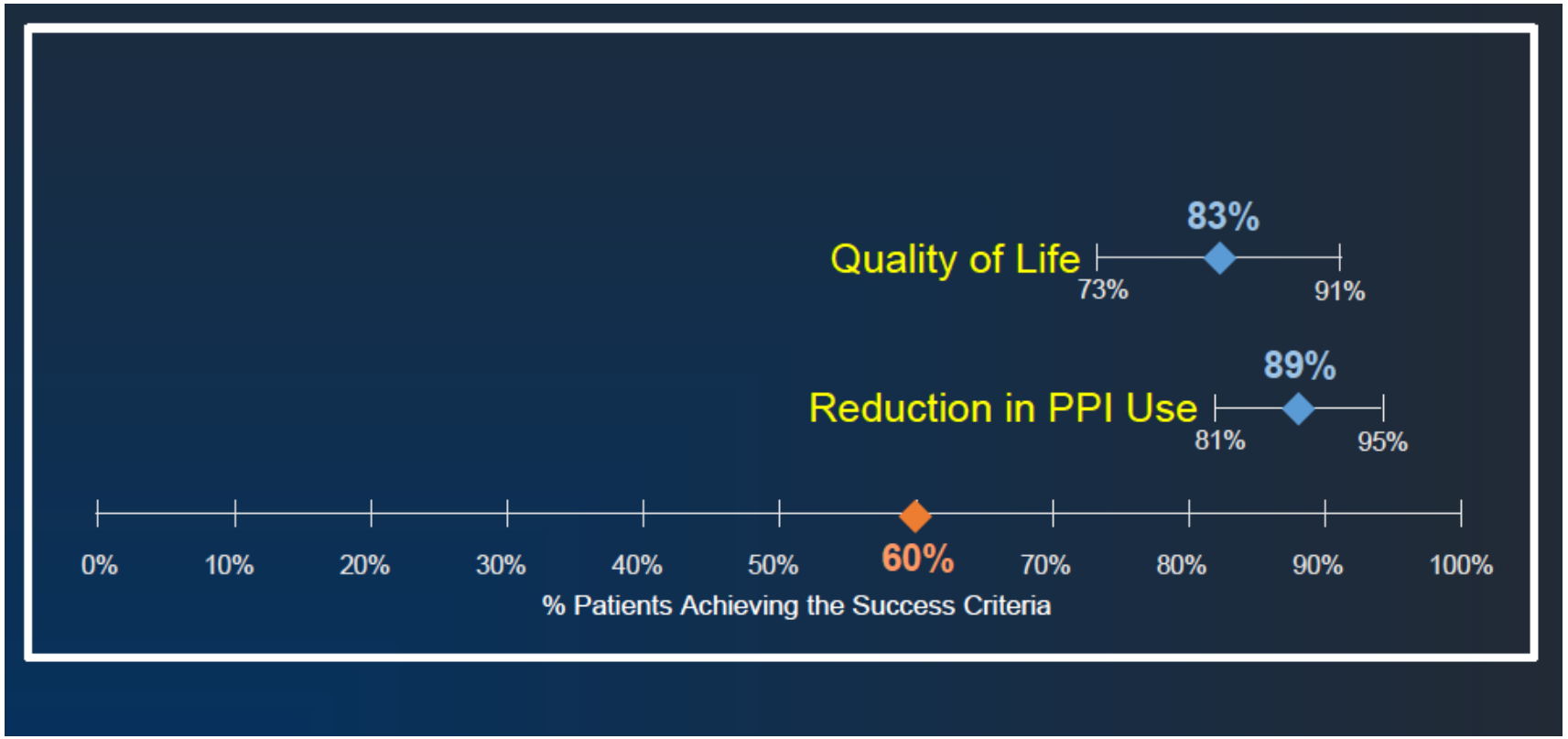
Follow-up Schedule

Abstract 688, Ganz et al

Evaluation	Year 1	Year 2	Year 3	Year 4	Year 5
GERD-HRQL*	✓	✓	✓	✓	✓
Foregut Symptom Questionnaire**	✓	✓	✓	✓	✓
Medication Use	✓	✓	✓	✓	✓
Ambulatory pH (BRAVO)	✓				
Esophageal Manometry	✓				
Endoscopy	✓	✓			✓
Barium Esophagram	✓				
Chest X-ray	✓	✓			✓
Adverse Events	✓	✓	✓	✓	✓

5 year Data: QOL and PPI Use

Abstract 688, Ganz et al



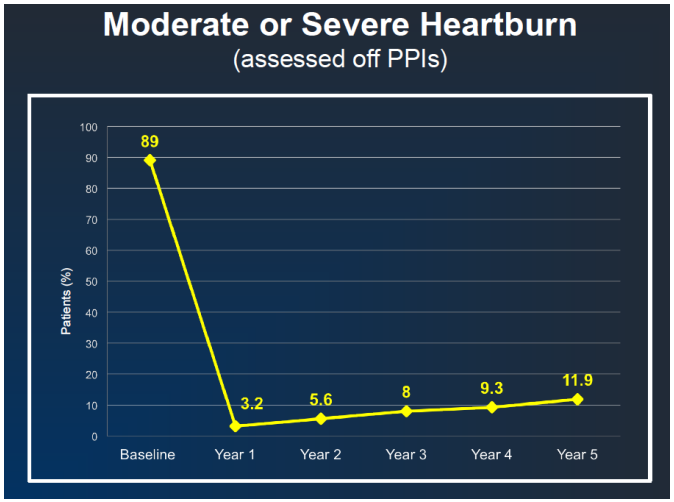
1 year Data: pH testing

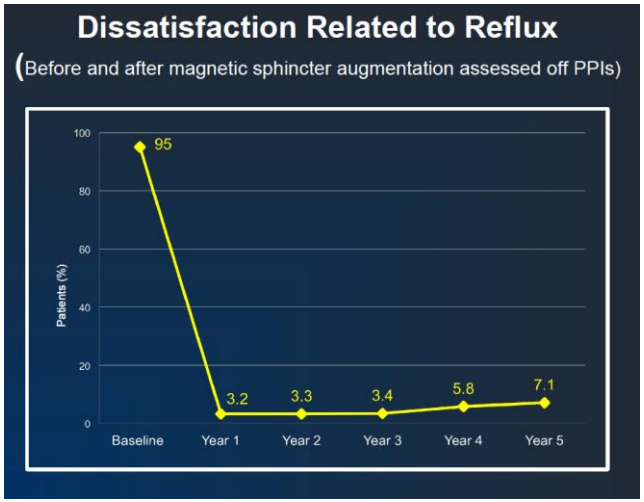
Abstract 688, Ganz et al

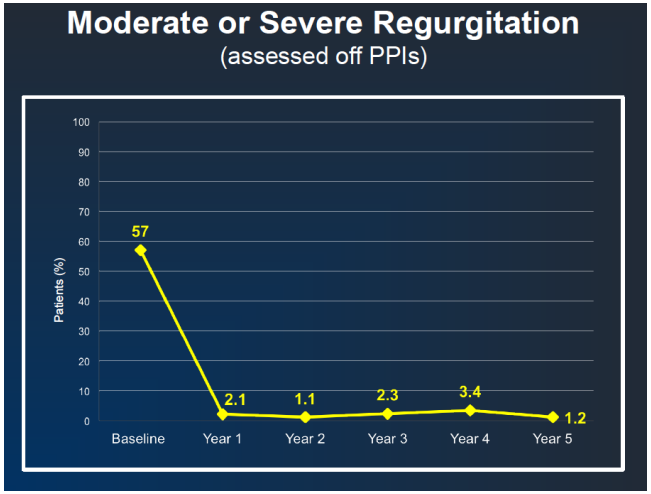
Variable	Baseline # Patients	Baseline Median Value	1 Year # Patients	1 Year Median Value	P Value
pH < 4					
• Total % of Time	100	10.9	96	3.3	< 0.001
• % of Time Upright	100	12.7	96	4.3	< 0.001
• % of Time Supine	90	6.0	96	0.4	< 0.001
Total # Reflux Episodes	100	161.0	96	67.0	< 0.001
# Reflux Episodes Lasting > 5 Minutes	99	12.0	96	4.0	< 0.001
Longest Reflux Episode (minutes)	99	29.0	96	13.0	< 0.001
DeMeester Score	97	36.6	96	13.5	< 0.001

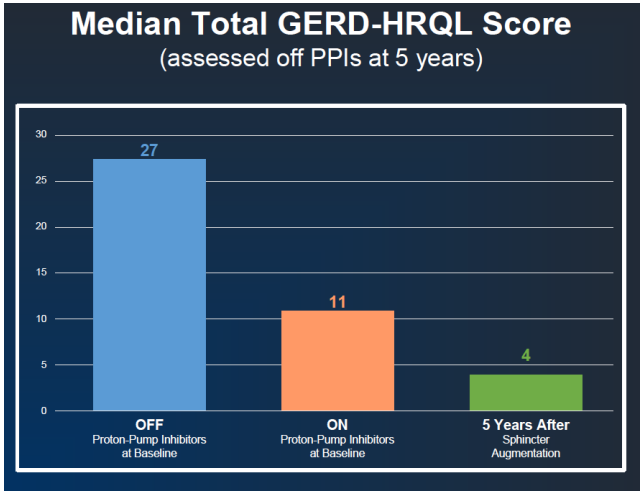
Ganz RA et al. N Engl J Med 2013;368:719-727

Magnetic Device for GERD: 5 year data



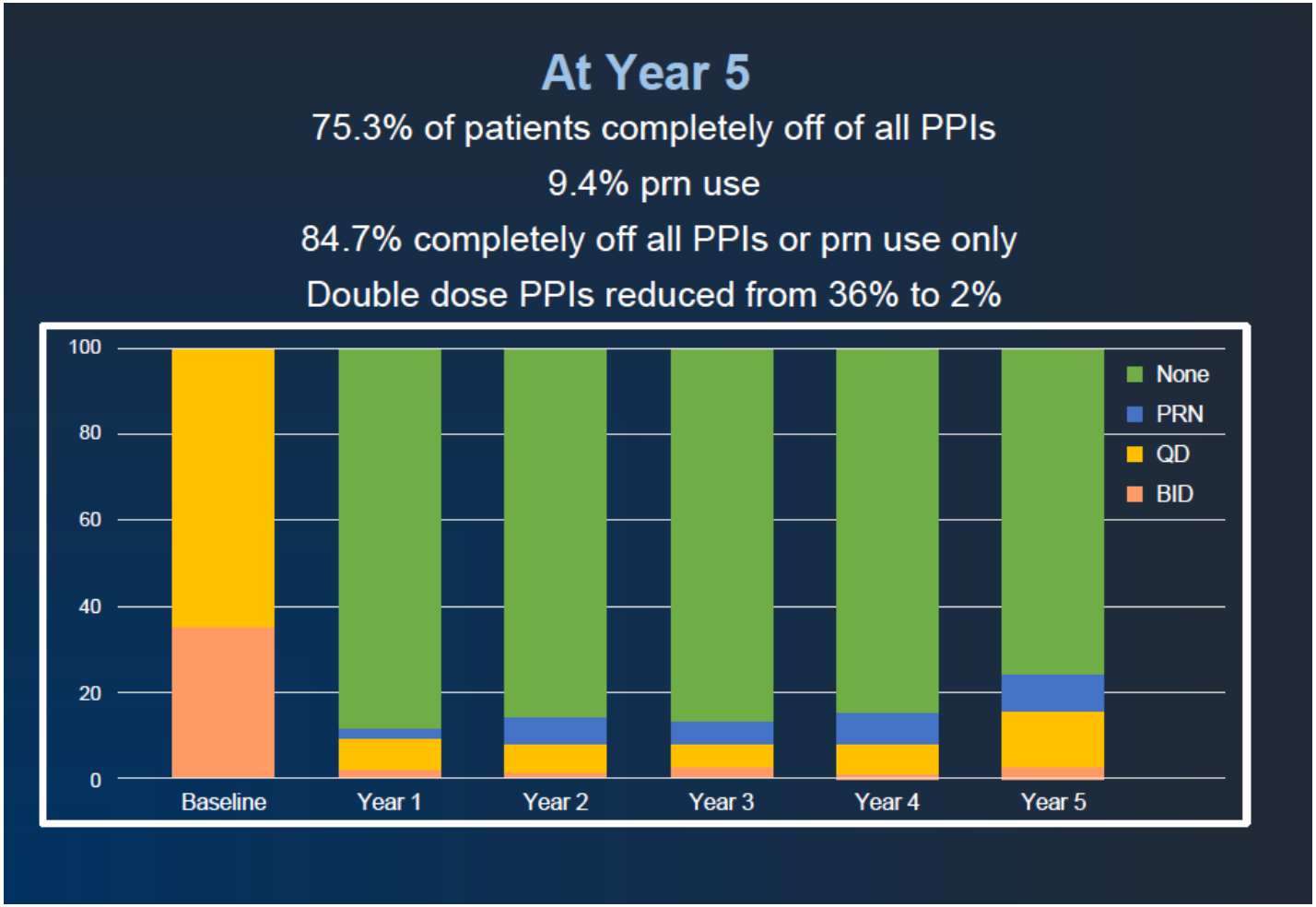






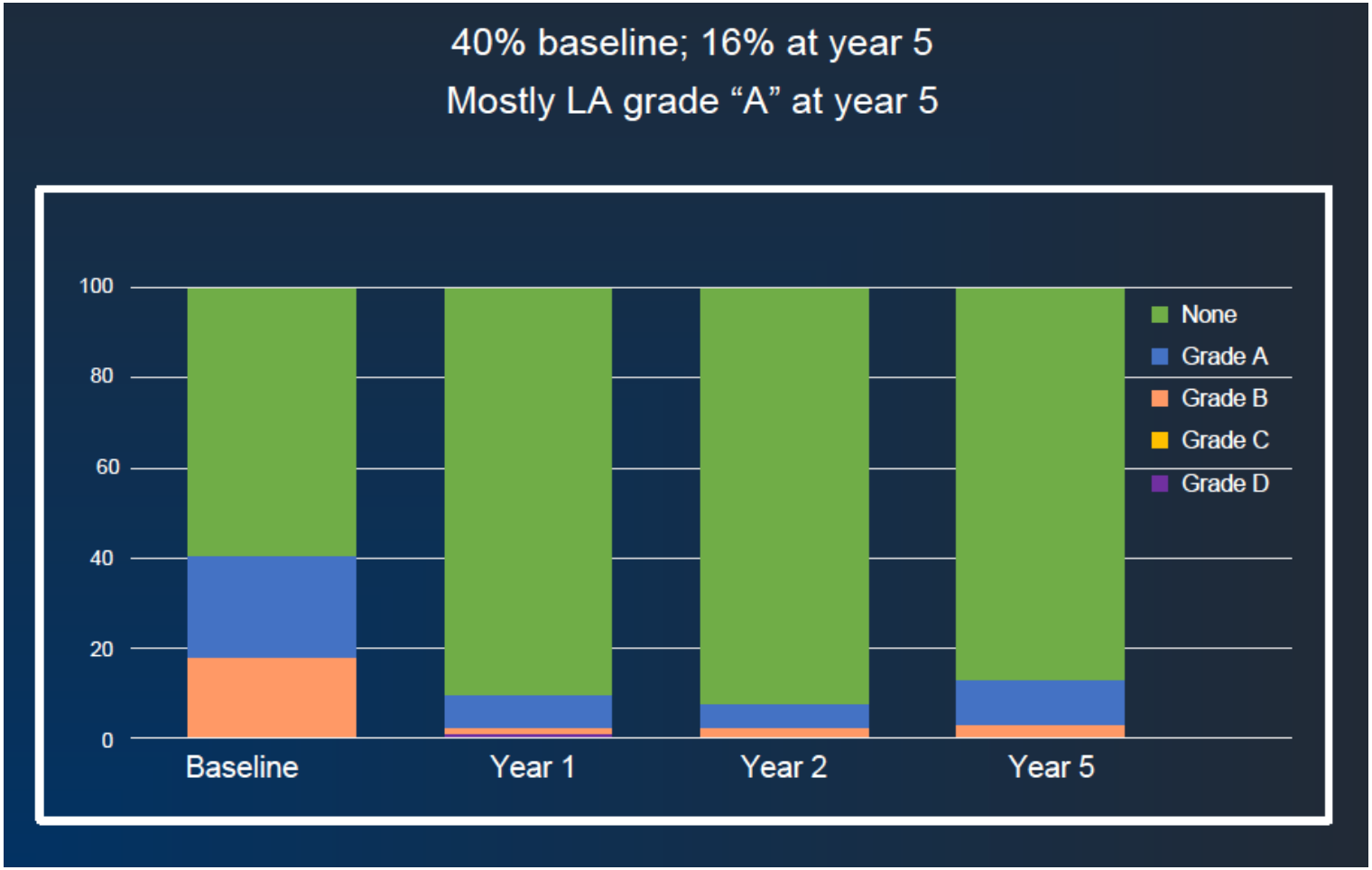
Abstract 688, Ganz et al

5 year data: PPI Use



Abstract 688, Ganz et al

5 year data: Esophagitis



Abstract 688, Ganz et al

5 year data: Other Parameters

- 100% able to belch; 16% w/ intermittent emesis without difficulty
- Safety: No AEs other than dysphagia
- Dysphagia: 7% at year 5 (68% post-op; 11%at 1 year)
- 7 w device removal (4 dysphagia; 1 vomiting; 2 lack of effect)

Abstract 688, Ganz et al