



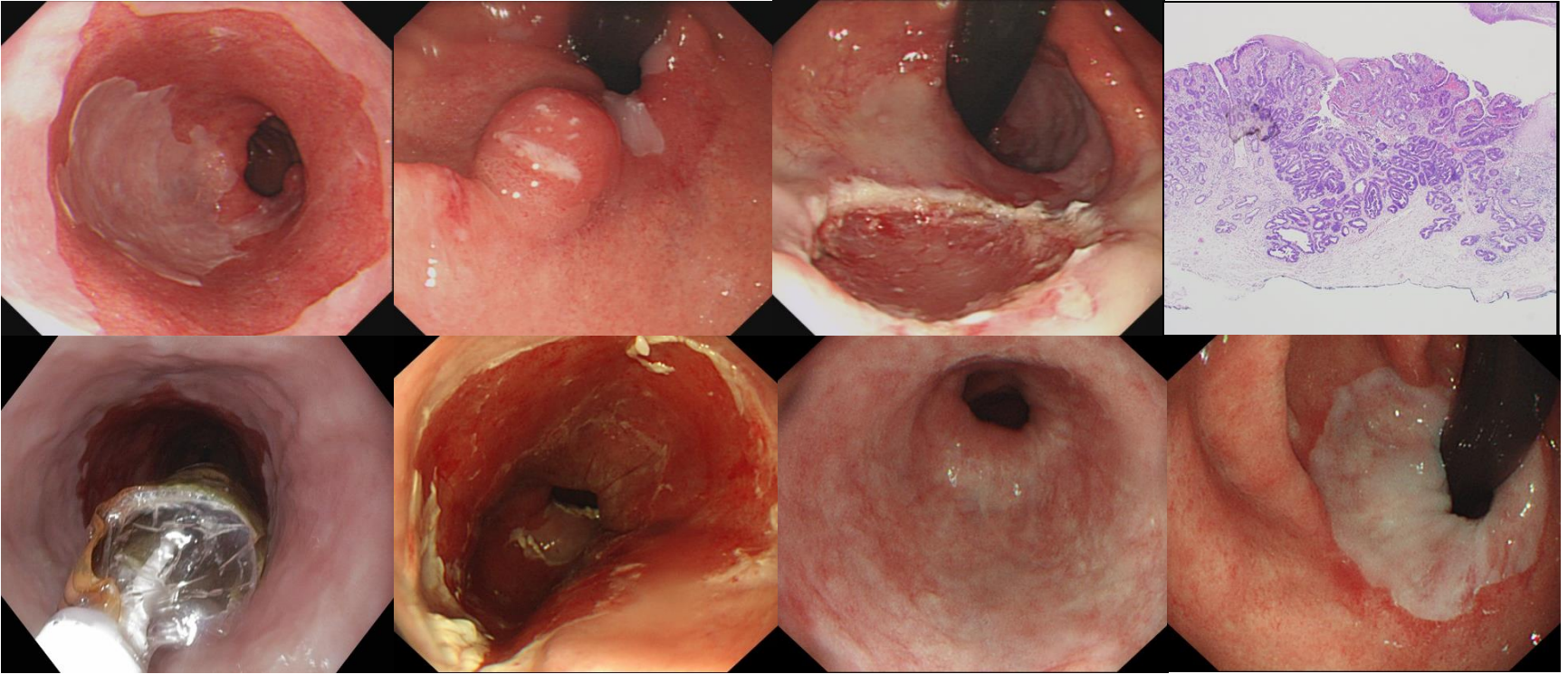
# Changes to the diagnosis and management of Barrett's Oesophagus

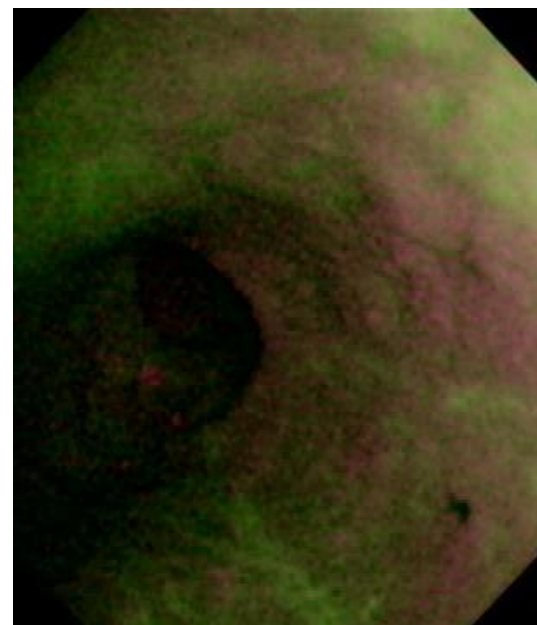
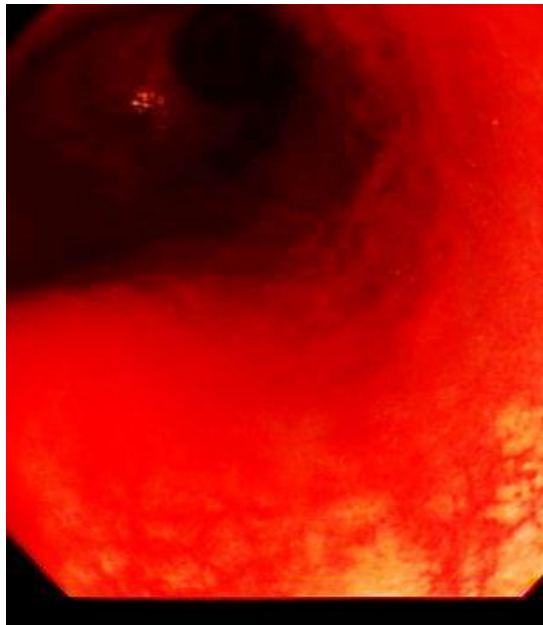
*A review of the new BSG and NICE guidelines and best practice*

**Anjan Dhar**

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*Senior Lecturer in Gastroenterology  
Consultant Gastroenterologist*



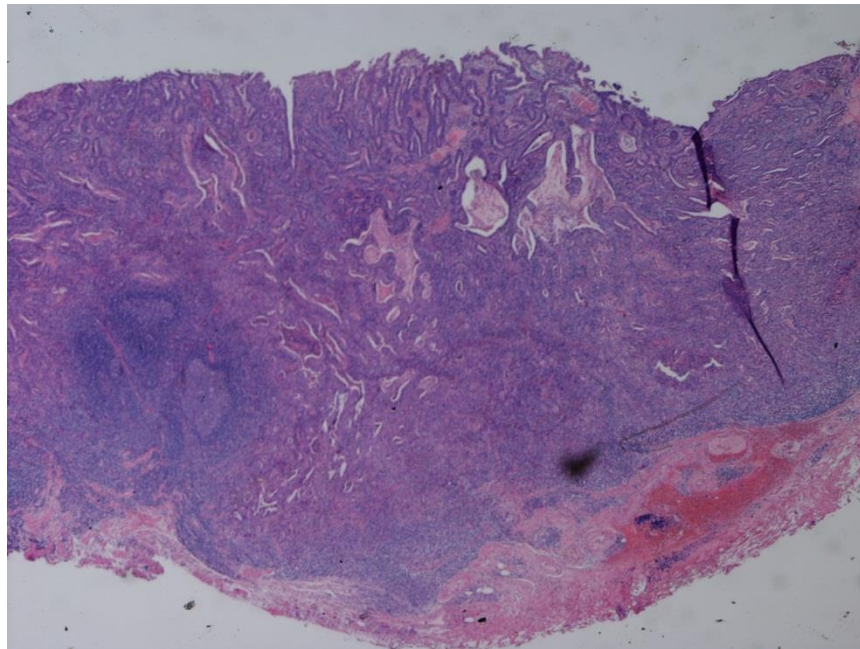
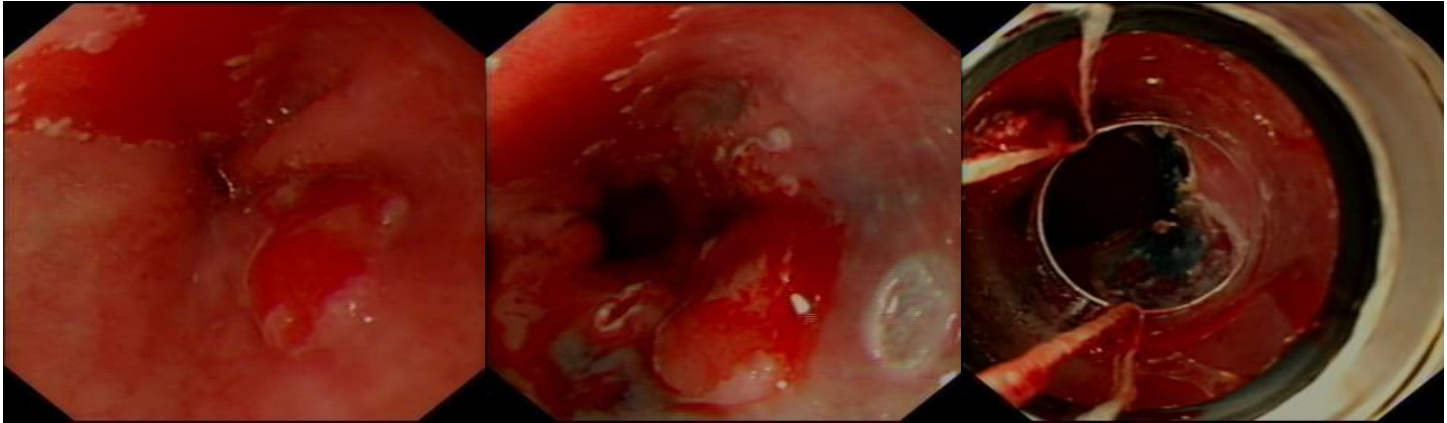


A flavour of  
endoscopic  
appearances  
in Barrett's  
Oesophagus

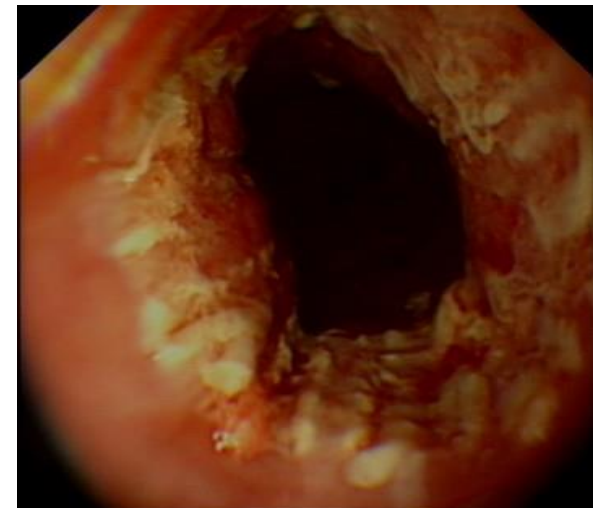
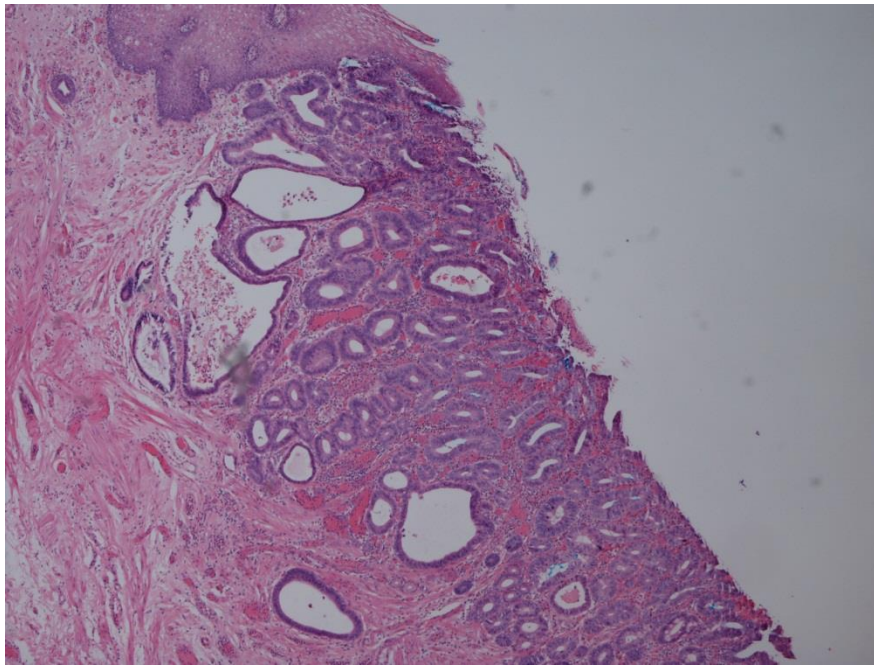
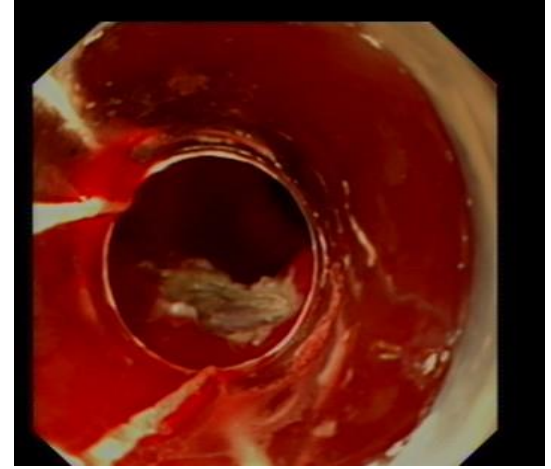
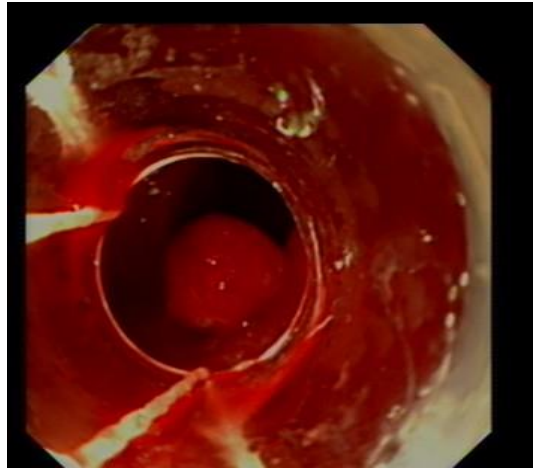
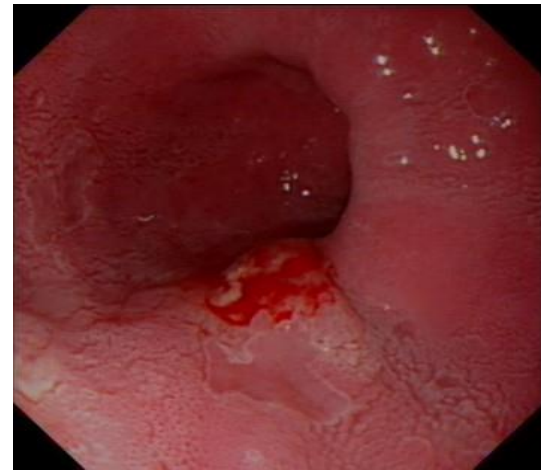


# 2 recent patients with BO and HGD

JH



# TF



# The New BSG Barrett's Guidelines (2013-14)

Guidelines



## British Society of Gastroenterology guidelines on the diagnosis and management of Barrett's oesophagus

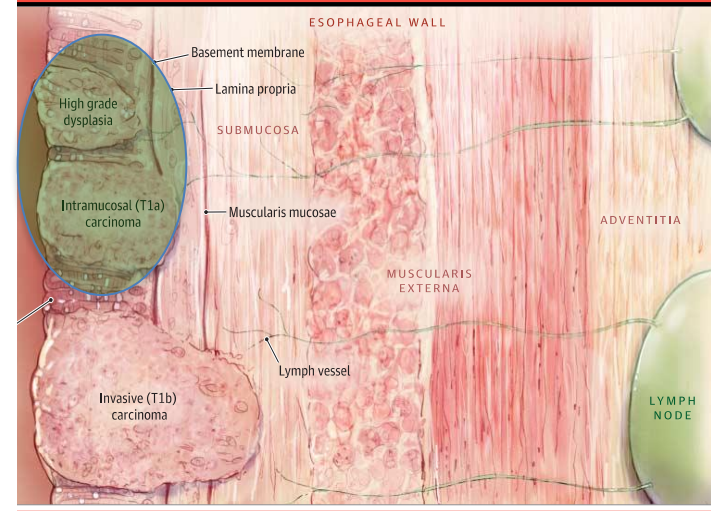
Rebecca C Fitzgerald,<sup>1</sup> Massimiliano di Pietro,<sup>1</sup> Krish Ragunath,<sup>2</sup> Yeng Ang,<sup>3</sup> Jin-Yong Kang,<sup>4</sup> Peter Watson,<sup>5</sup> Nigel Trudgill,<sup>6</sup> Praful Patel,<sup>7</sup> Philip V Kaye,<sup>8</sup> Scott Sanders,<sup>9</sup> Maria O'Donovan,<sup>10</sup> Elizabeth Bird-Lieberman,<sup>11</sup> Pradeep Bhandari,<sup>12</sup> Janusz A Jankowski,<sup>13</sup> Stephen Attwood,<sup>14</sup> Simon L Parsons,<sup>15</sup> Duncan Loft,<sup>16</sup> Jesper Lagergren,<sup>17</sup> Paul Moayyedi,<sup>18</sup> Georgios Lyratzopoulos,<sup>19</sup> John de Caestecker<sup>20</sup>

- Definition of Barrett's Oesophagus
- Who should undergo surveillance
- High risk factors to be taken into consideration for determining surveillance intervals
- Managing dysplasia in Barrett's (NICE guidance followed BSG)
- Standards for training and QA for endoscopic treatment



# BSG guidance 2013 – 14

## Visible dysplasia, HGD and T-1a



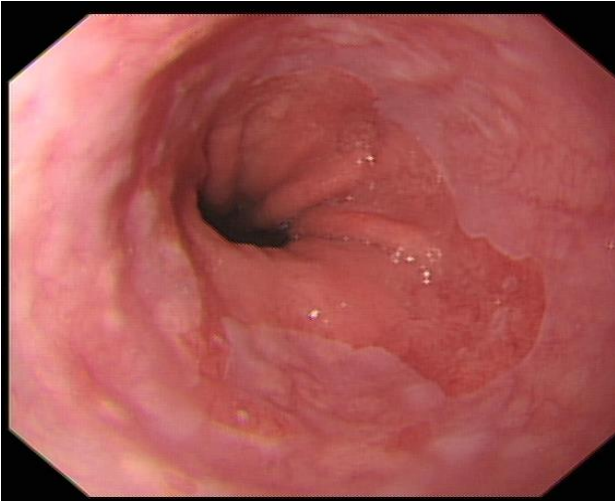
For HGD and Barrett's-related adenocarcinoma confined to the mucosa **endoscopic therapy is preferred** over oesophagectomy or endoscopic surveillance. (*Recommendation Grade B*)

90% agreement (53% A+, 37% A, 10%U)

**ER should be considered the therapy of choice** for dysplasia associated with visible lesions and T1a adenocarcinoma. (*Recommendation Grade B*)

95% agreement (58% A+, 37% A, 5%U)

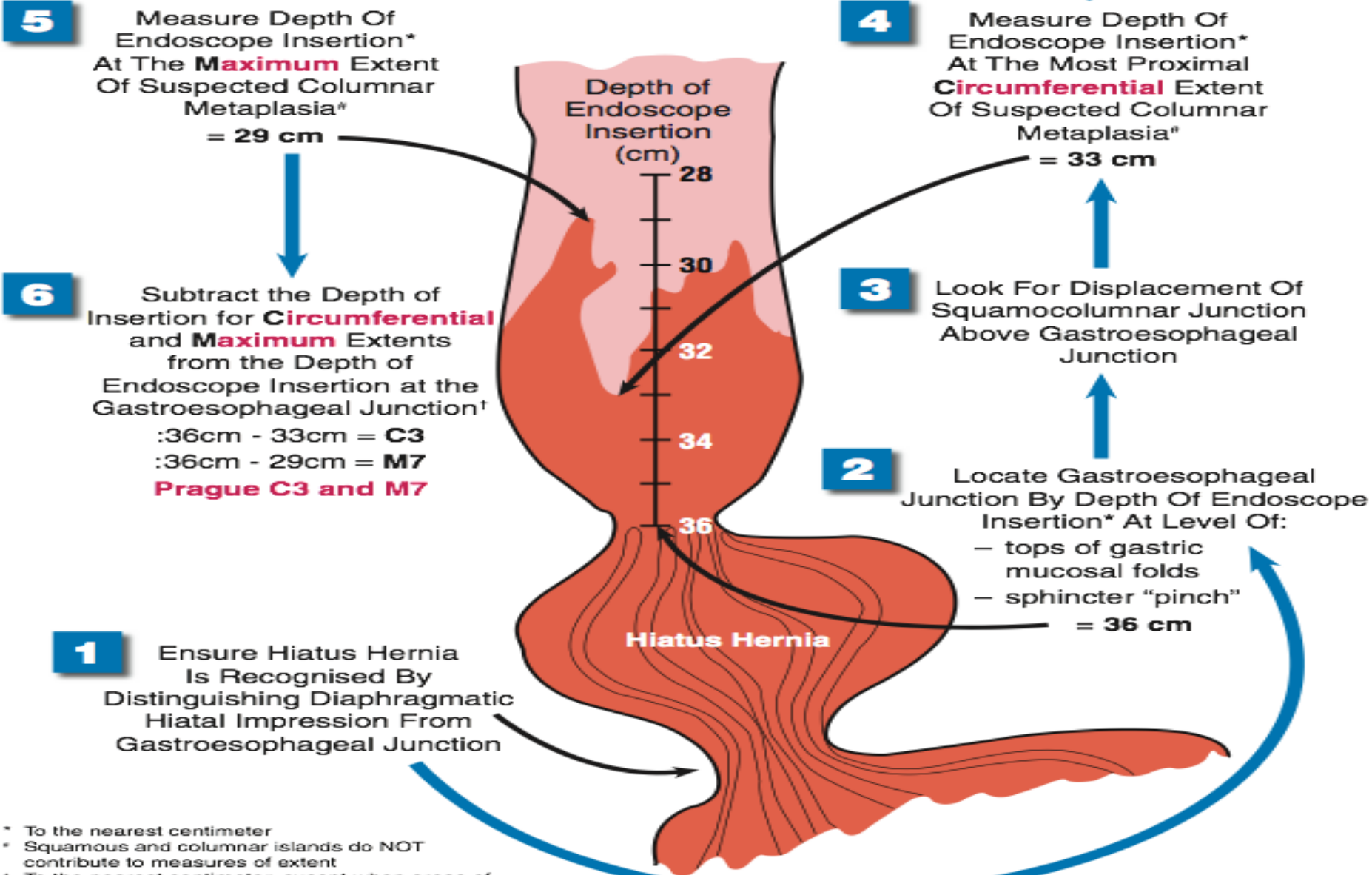
# Diagnosing and reporting BO



*Is this Barrett's Oesophagus?*

- BO defined as change to the distal squamous epithelium by metaplastic columnar epithelium, clearly visible endoscopically ( $\geq 1$ cm) above GOJ, and confirmed histopathologically.
- GOJ is the proximal end of gastric folds





\* To the nearest centimeter  
 \* Squamous and columnar islands do NOT contribute to measures of extent  
 † To the nearest centimeter, except when areas of columnar metaplasia are estimated to be less than 1 cm: report this as <1cm

# Standardisation of BO endoscopic reporting

**Table 1** Minimum endoscopic dataset required when reporting the finding of Barrett's oesophagus

Finding	Reporting system	Nomenclature
Barrett's oesophagus length	Prague classification	CnMn (where n is length in cm)
Barrett's islands	Describe distance from the incisors and length in cm	Descriptive in the text
Hiatus hernia	Distance between diaphragmatic pinch and GOJ	yes/no; cm
Visible lesions	Number and distance from incisors	yes/no; cm
Classification of visible lesions	Paris classification	0-Ip, protruded pedunculated 0-Is, protruded sessile 0-IIa, superficial elevated 0-IIb, flat 0-IIc, superficial depressed 0-III, excavated
Biopsies	Location and number of samples taken	n cm (distance from incisors) Xn

GOJ, gastro-oesophageal junction.

# Standardisation of Histopathology for BO

Barrett's Endoscopic Biopsies						
Specimen Number	1	2	3	4	5	6
Level/cm						
Number of biopsies per level						
Squamous mucosa (Y/N)						
Glandular mucosa (Y/N)						
Native oesophageal structures (Y/N)						
Intestinal metaplasia (Y/N)						
Glandular dysplasia (Y/N)						
- Indefinite (Y/N)						
- Low grade (Y/N)						
- High grade (Y/N)						
- Intramucosal ca (Y/N)						
p53 Significant immuno staining pattern (Y/N/ equivocal / Not performed)						
Highest grade of inflammation :						
Acute (none, mild, moderate, severe)						
Chronic (none, mild, moderate, severe)						
Highest grade of dysplasia:						
<b>SUMMARY</b>						
<i>Barrett's oesophagus with gastric metaplasia only or Barrett's oesophagus with intestinal metaplasia (state degree of dysplasia) or No evidence of Barrett's oesophagus</i>						

**Table 8** Subclassification of T1a and T1b oesophageal adenocarcinoma

Class	Description
T1a	
m1	Carcinoma in situ or with questionable invasion beyond the basement membrane
m2	Invasion into the lamina propria
m3	Invasion into the muscularis mucosa
T1b	
sm1	Invasion into the upper third of the submucosa within 500 µm
sm2	Invasion into the middle third of the submucosa
sm3	Invasion into the lower third of the submucosa

**Table 9** Minimum dataset for reporting endoscopic resection specimens

Intestinal metaplasia	Yes/no
Dysplasia grade	Indefinite/LGD/HGD/adenocarcinoma
Differentiation	Well, moderate or poorly differentiated
T1 subclassification	T1a m1–3/T1b sm1–3
Lymphovascular space invasion	Yes/no
Deep margin	Positive/negative
Distance to deep margins	mm
Lateral margins (en block resection)	Positive/negative

HGD, high-grade dysplasia; LGD, low-grade dysplasia.

# Guidelines-1: Diagnosing BO

## 2005

- CLO, no need for SIM-Histological corroboration
- Screening not recommended

## 2014

- CLO-Report using **Prague criteria (CM)**
- Screening not recommended routinely
- **Consider screening in high risk population**

**Age >50, white race, male sex, obesity, family H/O Barrett's cancer**



# Guidelines-2: Surveillance

## 2005

- 2 yearly surveillance
- Target biopsy + Quadrantic biopsies every 2 cm

## 2014

- High resolution endoscopy should be used
- Short segment (< 3 cm) with no SIM on repeat biopsy-No need for surveillance
- Short segment BO + SIM- Surveillance 3-5 yearly
- Long segment-2-3 yearly
- Target biopsy + Quadrantic biopsies every 2 cm

# Guidelines-3

## 2005

- ID-Re-biopsy after PPI-further surveillance in 6 months
- LGD-re-biopsy after intense acid suppression in 8-12 weeks-6 monthly surveillance

## 2014

- ID-Re-biopsy after PPI-further surveillance in 6 months
- LGD-acid suppression-6 monthly surveillance (note that NICE Guidance now offers them RFA)

# Guidelines-4

## 2005

- HGD-If changes persist after intense acid suppression-Surgery
- If unfit for surgery-ablation/EMR

## 2014

- HGD or early visible lesions-endoscopic therapy preferred
- ER is the therapy of choice for HGD and T1a (lesions)
- CT/PET/EUS has limited role for staging in HGD/T1 cancers prior to ER
- Flat HGD-RFA
- Surgery for T1b and beyond



## Endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia

Issued: July 2014

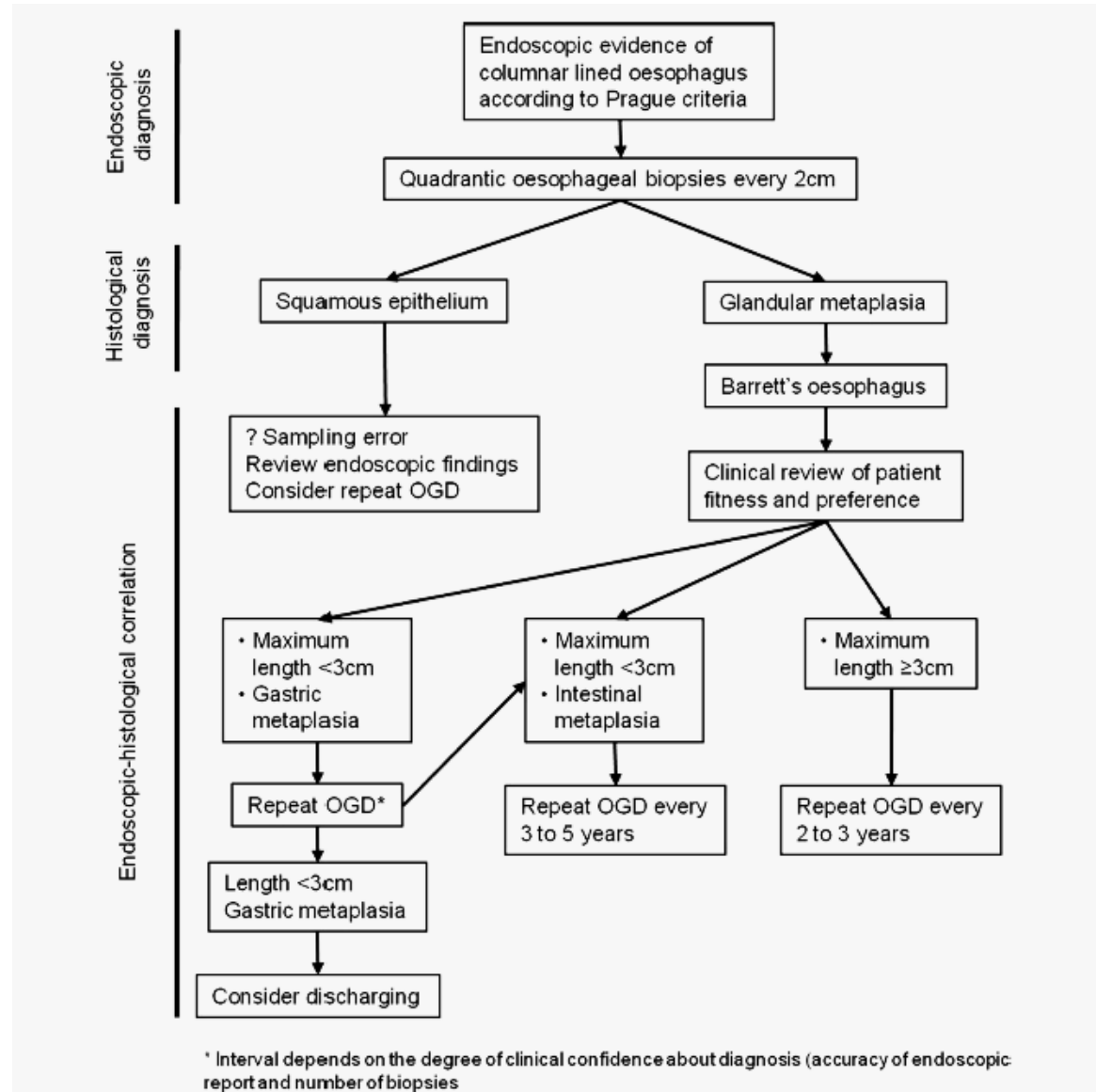
**NICE interventional procedure guidance 496**

[guidance.nice.org.uk/ipg496](http://guidance.nice.org.uk/ipg496)

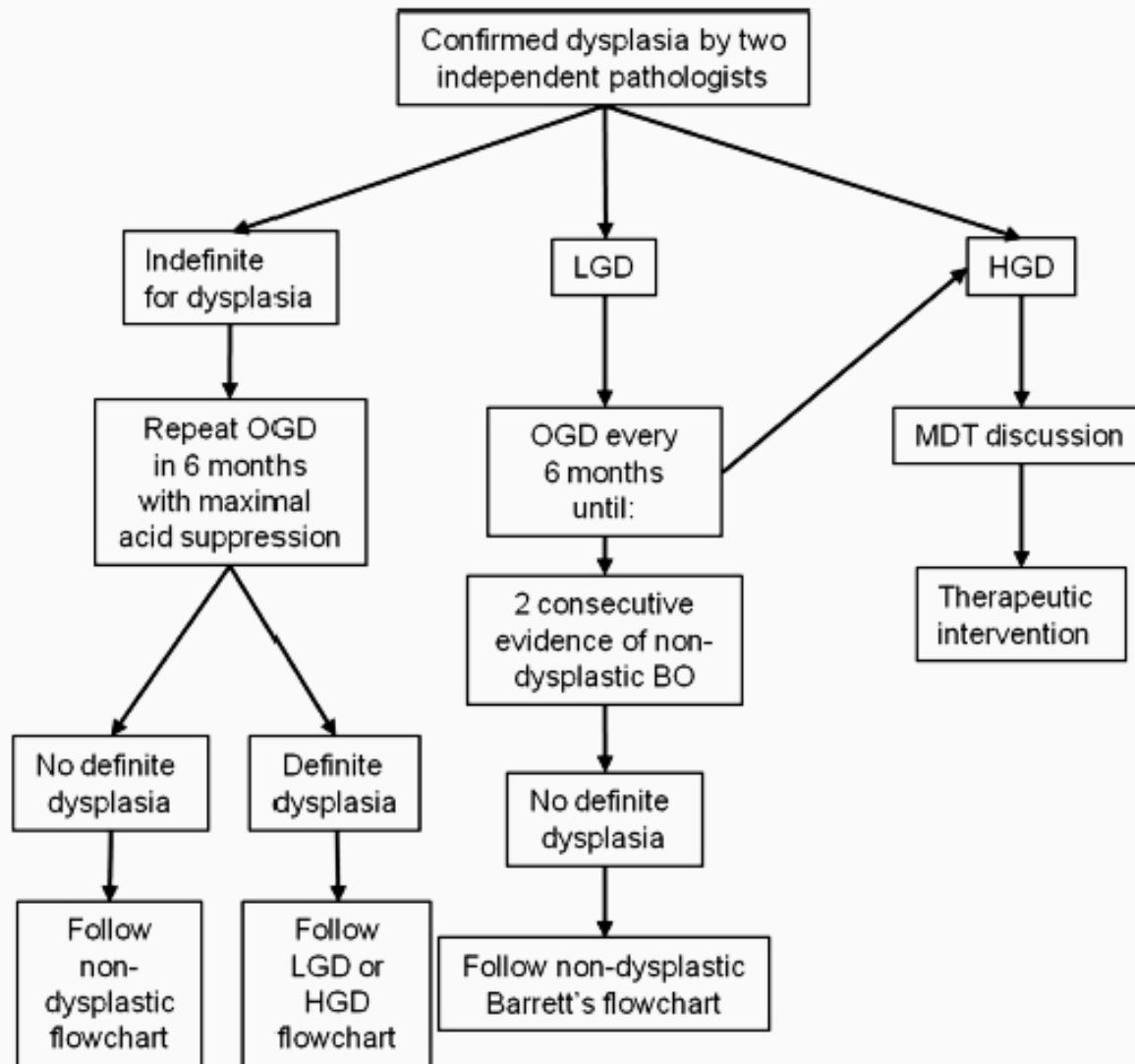
- 1.1 Current evidence on the efficacy of endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia is adequate provided that patients are followed up in the long term. There are no major safety concerns. Therefore, this procedure may be used in patients with Barrett's oesophagus with low-grade dysplasia with normal arrangements for clinical governance, consent and audit or research.



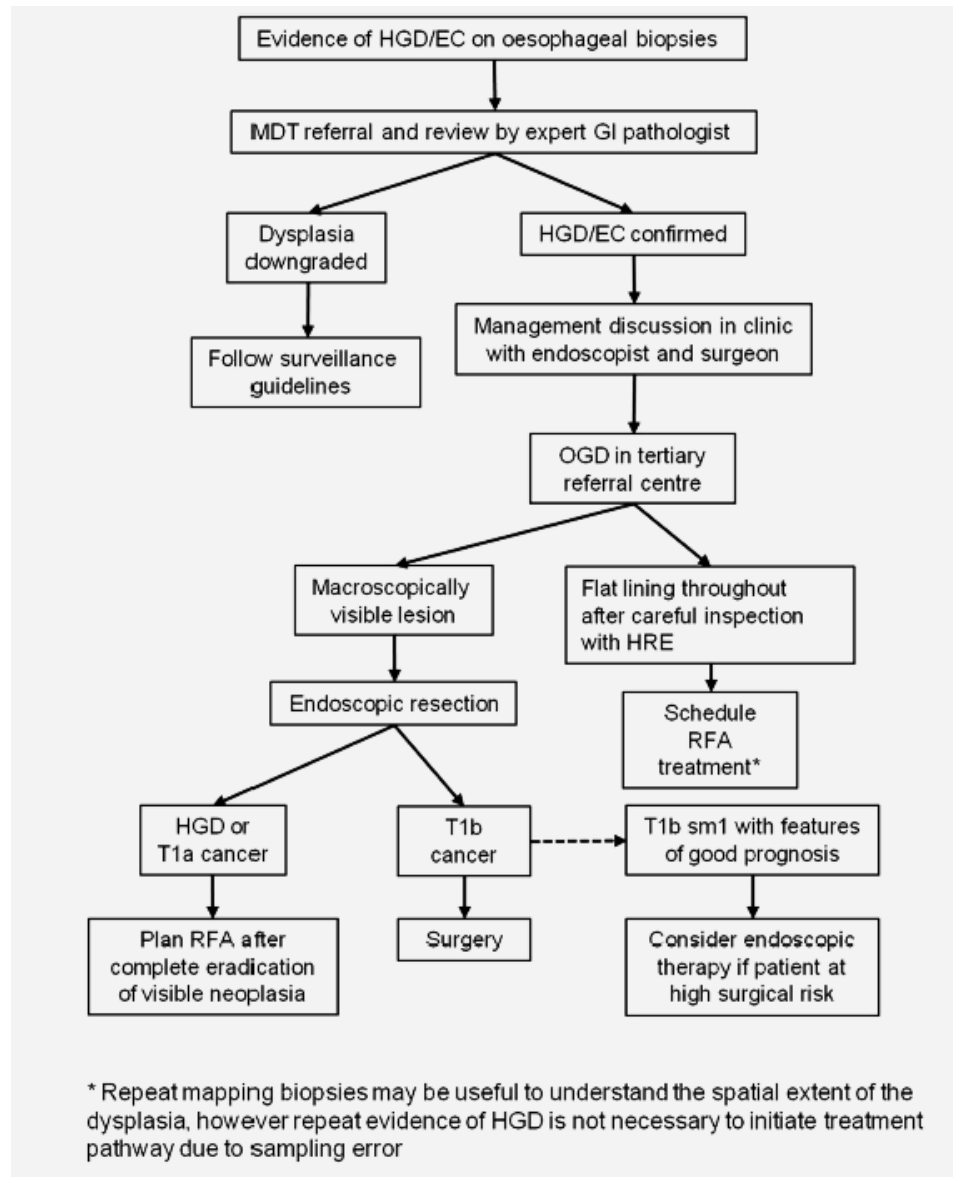
# Surveillance Flow Chart for NDBO



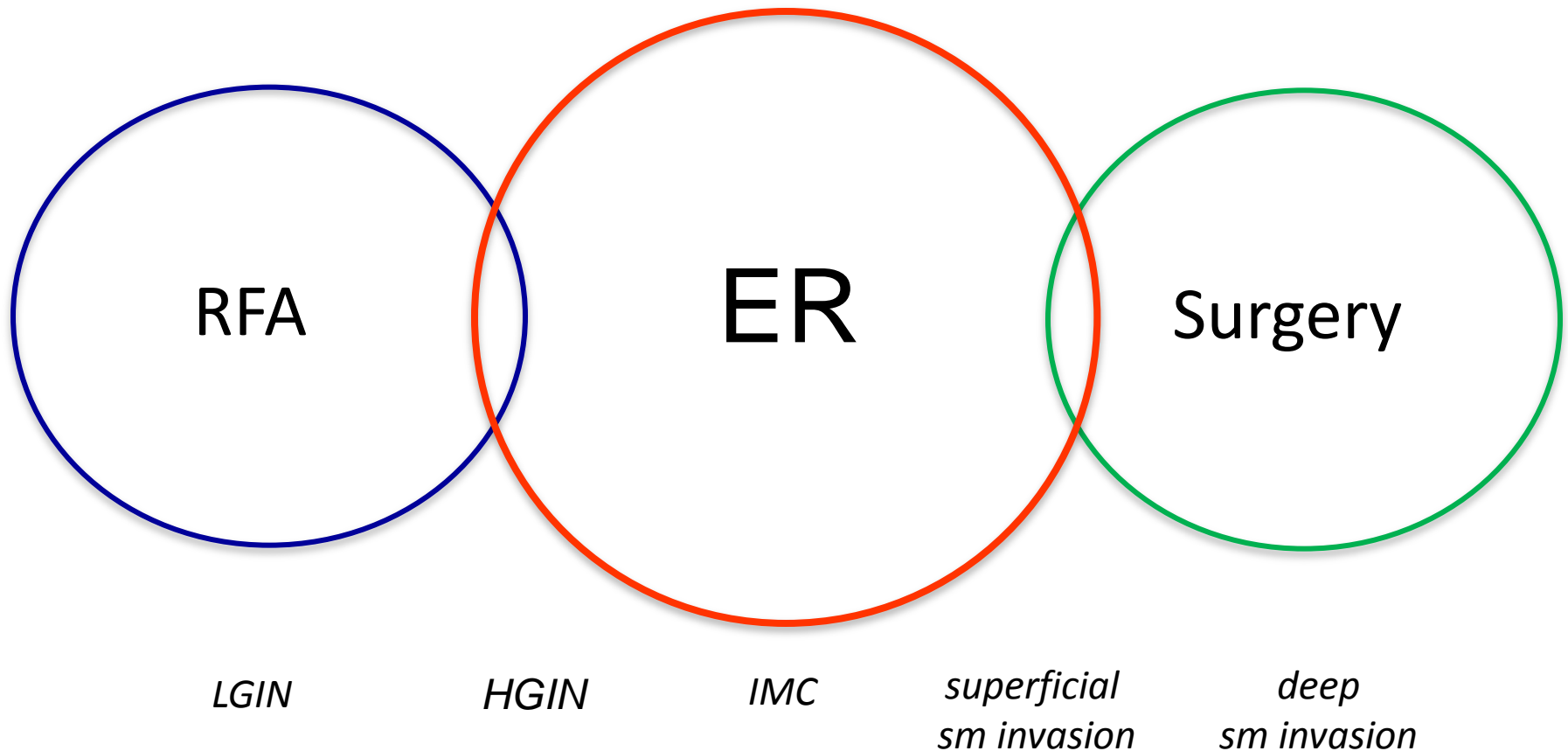
# Surveillance Flow Chart for Dysplastic BO



# Flow Chart for management of HGD/IMC



# Treatment concept and considerations





# Service Provision

Endoscopic therapy of Barrett's neoplasia should be performed at centres where **endoscopic and surgical options** can be offered to patients. (*Recommendation grade C*)

89% agreement (72% A+, 17% A, 11%U)

ER should be performed in **high volume tertiary referral centres**. RFA should be performed in centres equipped with ER facilities and expertise. (*Recommendation Grade C*)

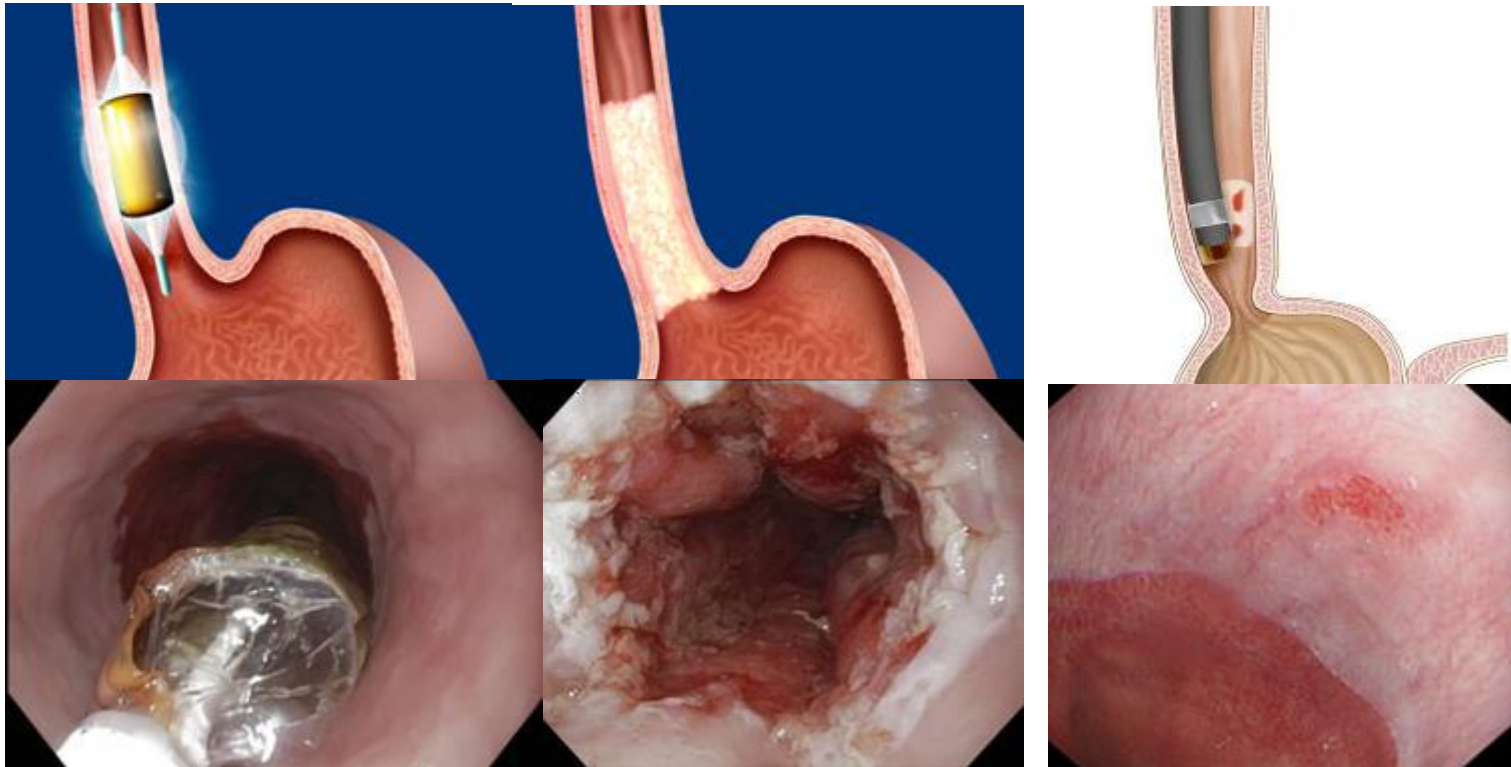
Round 1: 74% agreement (42% A+, 32% A, 16%U, 5% D, 5% D+)

94% agreement (33% A+, 61% A, 6%U)

 **There is not sufficient evidence to guide on minimum procedure volume per centre, however consensus was reached for 15 ERs per year**

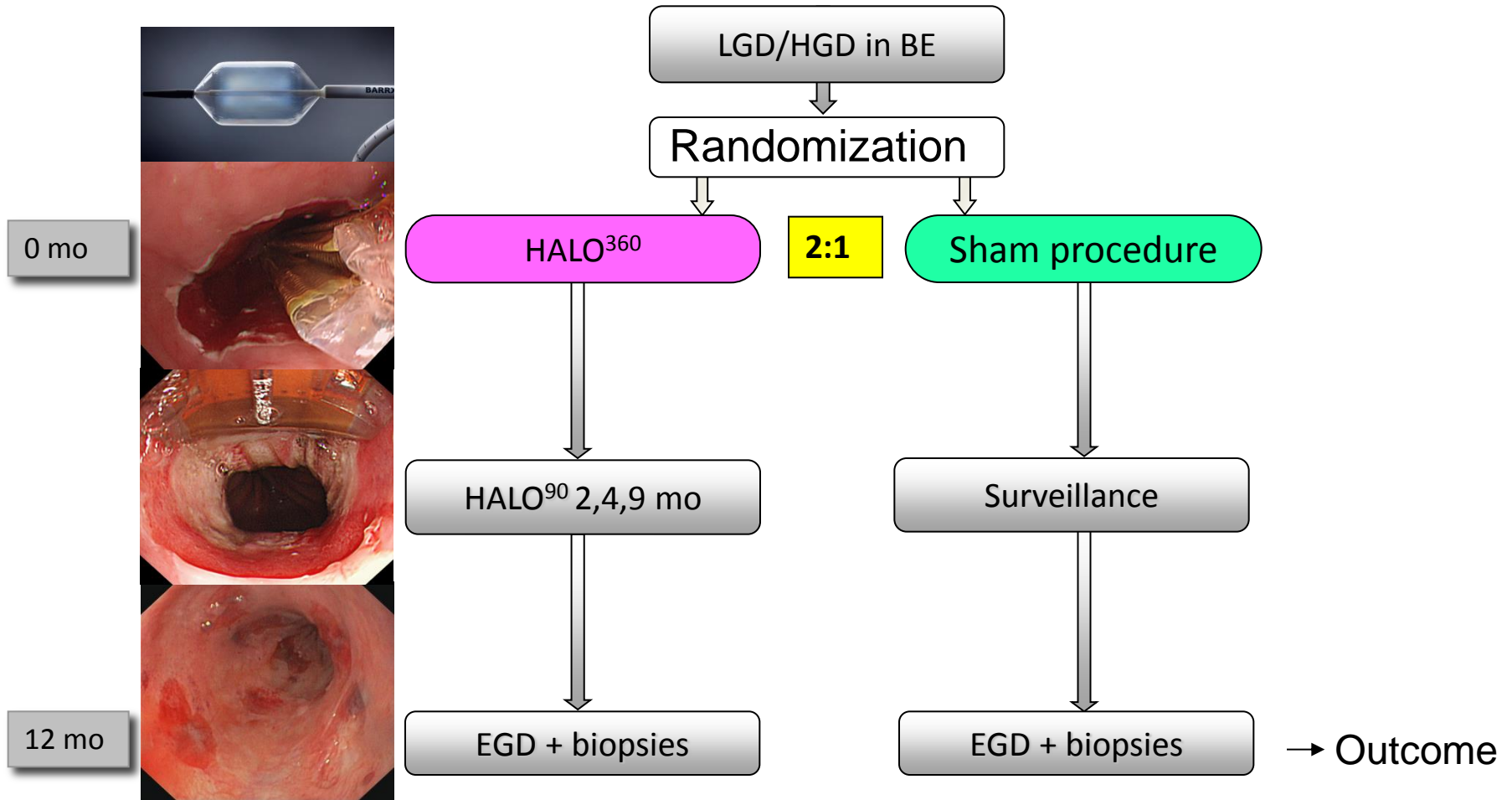
# Radiofrequency ablation

- 2003: new simple, ablation technique for removal of BE
- Balloon-based electrode for circumferential RFA: HALO<sup>360</sup>
- Catheter-based electrode to treat residual islands: HALO<sup>90</sup>



# AIM-dysplasia study

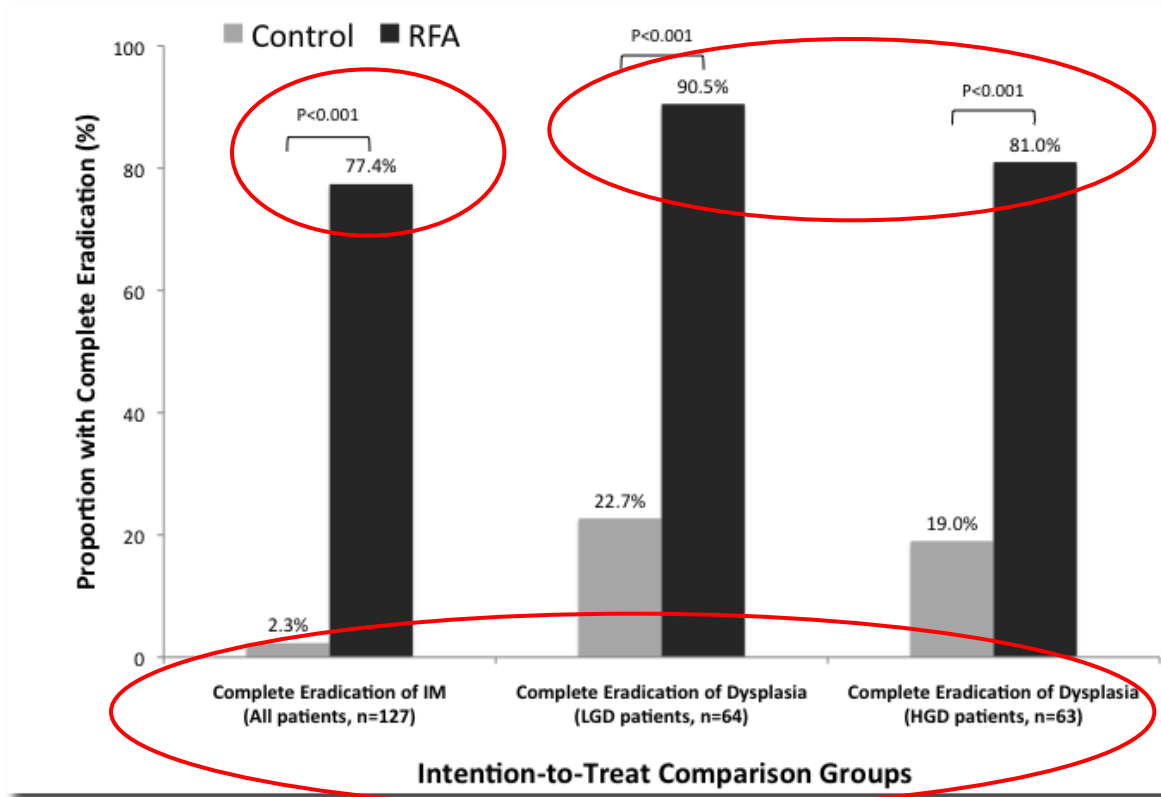
## Treatment protocol



EGD + 4Q/1cm bx: HGD: 3 monthly, LGD: 6 monthly

# AIM-dysplasia study

## Primary outcome



- CR-IM: 77% vs 2% (p<0.001)
- CR-D: 86% vs 21% (p<0.001)
- Note: all lost-to-FU cases were considered 'failures'

# RFA for HGD: EURO II cohort

## Treatment protocol



HGD/EC in BE



ER of visible lesion



Primary HALO<sup>360</sup>



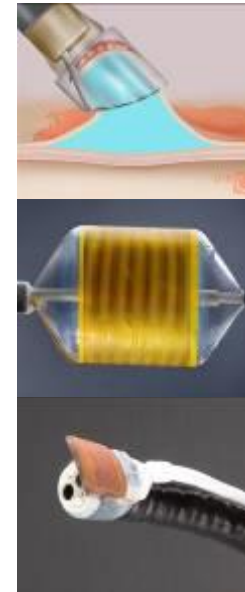
HALO<sup>360/90</sup>  
every 2-3 months  
Max 2 x HALO<sup>360</sup>  
Max 3 x HALO<sup>90</sup>



Residual BE?



EGD with NBI/lugol  
And 4Q/1cm Bx



Escape ER



# EURO II cohort

## Conclusions

### **Results (November 2009):**

118 patients / 55 completed therapy

- **CR-Neoplasia 100%, CR-IM 96%**
- Adverse events (no intervention required)
  - 12 superficial mucosal lacerations
  - 1 melena

### **Conclusions:**

When performed by trained, expert endoscopists in carefully selected patients after ER, adverse events related to RFA are infrequent and mild



# RFA for Dysplasia/Early Cancer Is Durable Out to 5 Years

## AMC 5 Years Data

(Phoa, *Gastroenterology*, 2013)

- First European Prospective Study at 5 years in HGD/EC patients
- >90% of patients remain in CR-IM; CR-NEO at 5 years (3 recurrences all treated endoscopically)
- 3 average RFA sessions, consistent with US registry
- 0% BG in ER specimens (<1% in bx samples, all at the SCJ)
- "The favorable long-term outcomes validate this treatment approach as a safe and effective alternative to esophagectomy "

GASTROENTEROLOGY 2013;145:96-104

### Remission of Barrett's Esophagus With Early Neoplasia 5 Years After Radiofrequency Ablation With Endoscopic Resection: A Netherlands Cohort Study

K. NADINE PHOA,<sup>1</sup> ROOS E. POLJW,<sup>1</sup> FREDERIKE G. I. VAN MILSTEREN,<sup>1</sup> GABRIËL M. T. SONDERMEIJER,<sup>1</sup> FERDO J. W. TEN KATE,<sup>2</sup> MIKE VISSER,<sup>2</sup> SYBRIEN L. MELIER,<sup>2</sup> MARKI VAN BERGE HENEGOUWEN,<sup>3</sup> BAS L. A. M. WEIJSTERS,<sup>4</sup> ERIK J. SCHOON,<sup>5</sup> ROSALIE C. MALLANT-HEINT,<sup>1</sup> and JACQUES J. G. H. M. BERGMAN<sup>1</sup>

<sup>1</sup>Departments of Gastroenterology, <sup>2</sup>Pathology, and <sup>3</sup>Surgery, Academic Medical Center, Amsterdam; <sup>4</sup>Department of Gastroenterology, St Antonius Hospital, Nieuwegein; <sup>5</sup>Department of Gastroenterology, Delftse Ziekenhuis, Delft; and <sup>6</sup>Department of Gastroenterology, Radboud University, Nijmegen, The Netherlands

See Covering the Cover synopsis on page 32; see editorial on page 35.

**BACKGROUND & AIMS:** Radiofrequency ablation (RFA), with or without endoscopic resection effectively eradicates Barrett's esophagus (BE) containing high-grade intraepithelial neoplasia and/or early-stage cancer. We followed patients who received RFA for BE containing high-grade intraepithelial neoplasia and/or early-stage cancer for 5 years to determine the durability of treatment response. **METHODS:** We followed 54 patients with BE (2–12 cm), previously enrolled in 4 consecutive cohort studies in which they underwent focal endoscopic resection in case of visible lesions (n = 40 [72%]), followed by serial RFA every 3 months. Patients underwent high-resolution endoscopy with narrow-band imaging at 6 and 12 months after treatment and then annually for 5 years (median, 61 months; interquartile range, 53–65 months); random biopsy samples were collected from nonsquamous epithelium and gastric cardia. After 5 years, endoscopic ultrasound and endoscopic resection of nonsquamous epithelium were performed. Outcomes included sustained complete remission of neoplasia or intestinal metaplasia (IM), IM in gastric cardia, or buried glands in nonsquamous epithelium. **RESULTS:** After 5 years, Kaplan-Meier analysis showed sustained complete remission of neoplasia and intestinal metaplasia in 90% of patients; neoplasia recurred in 5 patients and was managed endoscopically. Focal IM in the cardia was found in 19 of 54 patients (35%), in 53 of 1143 gastric cardia biopsies (4.6%). The incidence of IM of the cardia did not increase over time, and IM was diagnosed based on only a single biopsy in 89% of patients. Buried glands were detected in 5 of 3543 nonsquamous epithelium biopsies (0.06%, from 3 patients). No endoscopic resection samples had buried glands. **CONCLUSIONS:** Among patients who have undergone RFA with or without endoscopic resection for neoplastic BE, 90% remain in remission at 5-year follow-up, with all recurrences managed endoscopically. This treatment approach is therefore an effective and durable alternative to esophagectomy; [www.trialsregister.nl](http://www.trialsregister.nl) number, NTR2936.

**KEYWORDS:** Recurrence; Esophageal Cancer; Therapy Efficacy; Surgery.

Barrett's esophagus (BE) is a premalignant condition in which the normal squamous lining of the esophagus has been replaced by columnar epithelium containing intestinal metaplasia (IM). Malignant degeneration of BE is gradual, from nondysplastic IM, to low-grade intraepithelial neoplasia (LOIN), to high-grade intraepithelial neoplasia (HGIN), and eventually progressing into invasive cancer.<sup>1,2</sup> Patients with nondysplastic IM or LOIN undergo regular endoscopic surveillance.<sup>3</sup> Patients with HGIN or early-stage cancer limited to the mucosa can be treated endoscopically, whereas more advanced cancers require surgical treatment.<sup>1,4</sup>

For focal lesions, endoscopic resection is the treatment of choice. However, after focal endoscopic resection, the residual Barrett segment remains at risk for malignant progression. Because the risk of developing metachronous lesions is estimated at 30% within 5 years, eradication of any residual BE is recommended.<sup>5,6</sup> Radiofrequency ablation (RFA) is characterized by controlled and uniform delivery of radiofrequency energy. This technique has been shown to be safe and effective in eradicating nondysplastic BE and BE containing LOIN or HGIN.<sup>5,6</sup> The combination of endoscopic resection and RFA has also been shown to be successful for treatment of maximal abnormalities and early-stage cancer. With this treatment approach, not only is neoplasia efficiently removed, but the entire BE segment is successfully eradicated in 77%–100% of patients.<sup>11,14</sup>

Less is known about the longer-term durability of this approach. Several factors can influence the persistence of nonsquamous epithelium after complete eradication of BE and neoplasia. For example, the presence of ongoing reflux exposure can play a role in recurrent disease given the role of reflux in the pathogenesis of BE.<sup>8</sup> Permanent

Abbreviations used in this paper: BE, Barrett's esophagus; CR-IM, complete remission of intestinal metaplasia; CR-neoplasia, complete remission of neoplasia; EUS, endoscopic ultrasound; HGIN, high-grade intraepithelial neoplasia; HRE, high-resolution endoscopy; IM, intestinal metaplasia; IQR, interquartile range; LOIN, low-grade intraepithelial neoplasia; NBI, narrow-band imaging; RFA, radiofrequency ablation; SCJ, squamocolumnar junction.

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0016-5085/13/0000-0000  
<http://dx.doi.org/10.1053/j.gastro.2013.03.048>

# BADCAT Consensus Statement

(Jankowski, Gastro, 2012)

- An int'l multidisciplinary, evidence-based review of different management strategies for BE
- 80% agreement was used to establish consensus for each statement, including
- **“Risk of progression from HGD to cancer is approx 10% per yr.”**
- “Endoscopic treatment should be preferred over surgical treatment for management of most patients with HGD in BE” ...and “over surveillance for HGD/T1m”
- **“RFA is currently the best available ablation technique for the treatment of flat HGD and for eradication of residual BE mucosa after local EMR”**

## Consensus Statements for Management of Barrett's Dysplasia and Early-Stage Esophageal Adenocarcinoma, Based on a Delphi Process

GATHY BENNETT,<sup>1</sup> NARISH VAWL,<sup>2</sup> JACQUES BERGMAN,<sup>3</sup> REBECCA HARRISON,<sup>4</sup> REBECCO COZE,<sup>5</sup> MICHAEL VETH,<sup>6</sup> SCOTT SANDERS,<sup>7</sup> LAURA GAY,<sup>8</sup> OLAVEN PECH,<sup>9</sup> GAUS LONGCOROFT-WHEATON,<sup>10</sup> YVONNE ROMERO,<sup>11</sup> JOHN PADDOA,<sup>12</sup> JAN TACK,<sup>13</sup> DOUGLAS A. CORLEY,<sup>14</sup> FENDIRH MANNERS,<sup>15</sup> SUSI GREEN,<sup>16</sup> DAVID AL DILLIAS,<sup>17</sup> HAYTHEM ALI,<sup>18</sup> BILL ALLUM,<sup>19</sup> MARK ANDERSON,<sup>20</sup> HOWARD CLITEL,<sup>21</sup> GARY FALK,<sup>22</sup> M. BRIAN FORTNEY,<sup>23</sup> GWYNETH FULLERTON,<sup>24</sup> KANGSUA KRISHNADATH,<sup>25</sup> STEPHEN J. MELTZER,<sup>26</sup> DAVID ARMSTRONG,<sup>27</sup> ROBERT GAJEZ,<sup>28</sup> SHARIFALD CENGA,<sup>29</sup> JAMES J. GOVIL,<sup>30</sup> JOHN GOLDBLUM,<sup>31</sup> CHARLES GORDON,<sup>32</sup> HEIKE GRABNER,<sup>33</sup> CHRIS HUGH,<sup>34</sup> MICHO HONGO,<sup>35</sup> DAVID JOHNSTON,<sup>36</sup> RICKY FORRES-YOUNG,<sup>37</sup> ELIANE KAY,<sup>38</sup> PHILIP KAYE,<sup>39</sup> TORI LESLIE,<sup>40</sup> LAURENCE B. LOVAT,<sup>41</sup> LARS LINDSELL,<sup>42</sup> PHILIP MARRS,<sup>43</sup> TAOHUA SHIMODA,<sup>44</sup> STUART SPEICHLER,<sup>45</sup> STEPHEN SCOTAG,<sup>46</sup> PETER MAUFESTHEINER,<sup>47</sup> IAN MURRAY,<sup>48</sup> MANOJ NARAYAN,<sup>49</sup> DAVID POLLES,<sup>50</sup> KRISHN RAGHUNATH,<sup>51</sup> JAROSLAV REGULA,<sup>52</sup> RENZO CESTARI,<sup>53</sup> NEIL SHEPHERD,<sup>54</sup> RAAMINDER SINGH,<sup>55</sup> HUBERT J. STERN,<sup>56</sup> NICHOLAS J. TALLEY,<sup>57</sup> JEAN-PAUL GALACHE,<sup>58</sup> TONY C. K. THAM,<sup>59</sup> PETER WATSON,<sup>60</sup> LISA YERGAN,<sup>61</sup> MASSIMO RUGGE,<sup>62</sup> THOMAS W. RICE,<sup>63</sup> JOHN HART,<sup>64</sup> STUART GITTENS,<sup>65</sup> DAVID FENWICK,<sup>66</sup> JÜRGEN HOOFFSTRA,<sup>67</sup> PETER KAYRILAG,<sup>68</sup> DEAN PRESTON,<sup>69</sup> RICHARD SABLINGER,<sup>70</sup> SHATEEN SHARMA,<sup>71</sup> ROBERT STUART,<sup>72</sup> KENNETH WANG,<sup>73</sup> EMMET WYMAN,<sup>74</sup> CHRIS ABLEY,<sup>75</sup> CLANCY LOFT,<sup>76</sup> IAN PENNMAN,<sup>77</sup> NICHOLAS J. SHARPEL,<sup>78</sup> ANTAHY CHAK,<sup>79</sup> GARETH DAVIES,<sup>80</sup> LORNA DUNN,<sup>81</sup> YINGZE FALCH-YTTER,<sup>82</sup> JOHN DECAESTECKER,<sup>83</sup> PRADEEP SHIVDARI,<sup>84</sup> CHRISTIAN ELL,<sup>85</sup> S. MICHAEL GRIFFIN,<sup>86</sup> STEPHEN ATTWOOD,<sup>87</sup> HUGH DARR,<sup>88</sup> JOHN ALLEN,<sup>89</sup> MARK K. PERGALSON,<sup>90</sup> PAUL MOAYYED,<sup>91</sup> and JARVIS A. Z. JANKOWSKI<sup>92</sup>

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Podcast interview: [www.gastro.org/gastropodcast](http://www.gastro.org/gastropodcast). Also available on iTunes. See Covering the Cover synopsis on page 273; see editorial on page 282.

**BACKGROUND & AIMS:** Esophageal adenocarcinoma (EA) is increasingly common among patients with Barrett's esophagus (BE). We aimed to provide consensus recommendations based on the medical literature that clinicians could use to manage patients with BE and low-grade dysplasia, high-grade dysplasia (HGD), or early-stage EA. **METHODS:** We performed an international, multidisciplinary, systematic, evidence-based review of different management strategies for patients with BE and dysplasia or early-stage EA. We used a Delphi process to develop consensus statements. The results of literature searches were screened using a unique, interactive, Web-based data-entry platform; we used 11,704 papers to

inform the choice of statements selected. An a priori threshold of 80% agreement was used to establish consensus for each statement. **RESULTS:** Eighty-one of the 71 statements achieved consensus despite generally low quality of evidence, including 3 clinical statements: (1) specimens from endoscopic resection are better than biopsies for staging lesions; (2) it is important to carefully map the size of the dysplastic area; (3) patients that receive ablation or surgical therapy require endoscopic follow-up; (4) high-resolution endoscopy is necessary for accurate diagnosis; (5) endoscopic therapy for HGD is preferred to surveillance; (6) endoscopic therapy for HGD is preferred

**Abbreviations used in this paper:** BAD CAT, Barrett's dysplasia and cancer task force; BE, Barrett's esophagus; EA, esophageal adenocarcinoma; EMR, endoscopic mucosal resection; HGD, high-grade dysplasia; LGD, low-grade dysplasia; RFA, radiofrequency ablation.

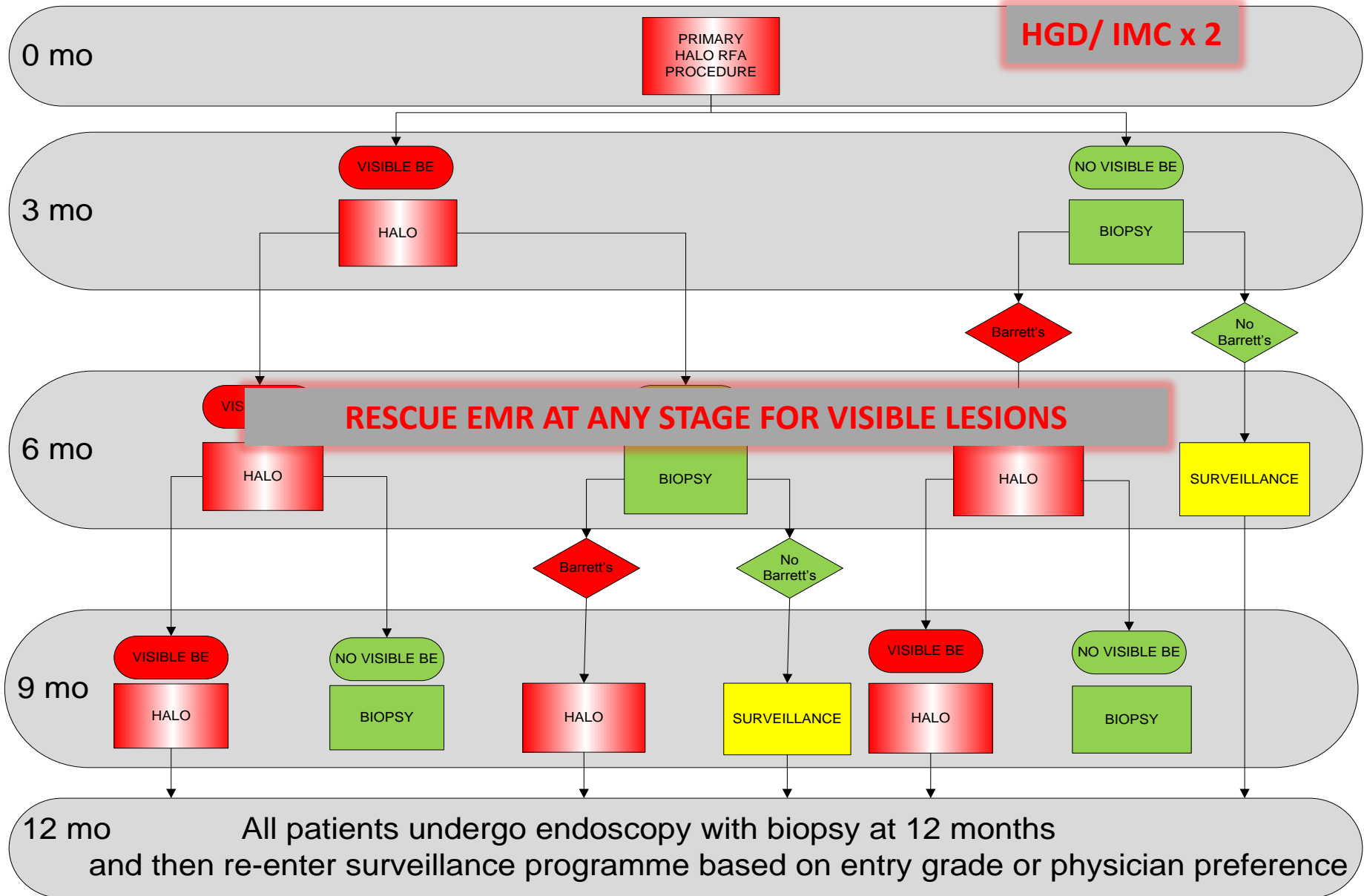
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# United Kingdom RFA Registry Participants 2014



# HALO RADIOFREQUENCY ABLATION (RFA) REGISTRY FLOW CHART

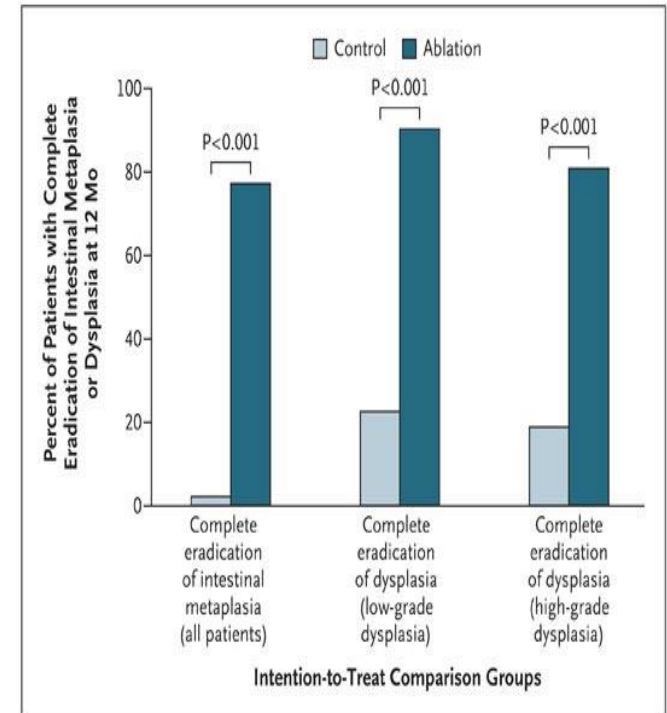
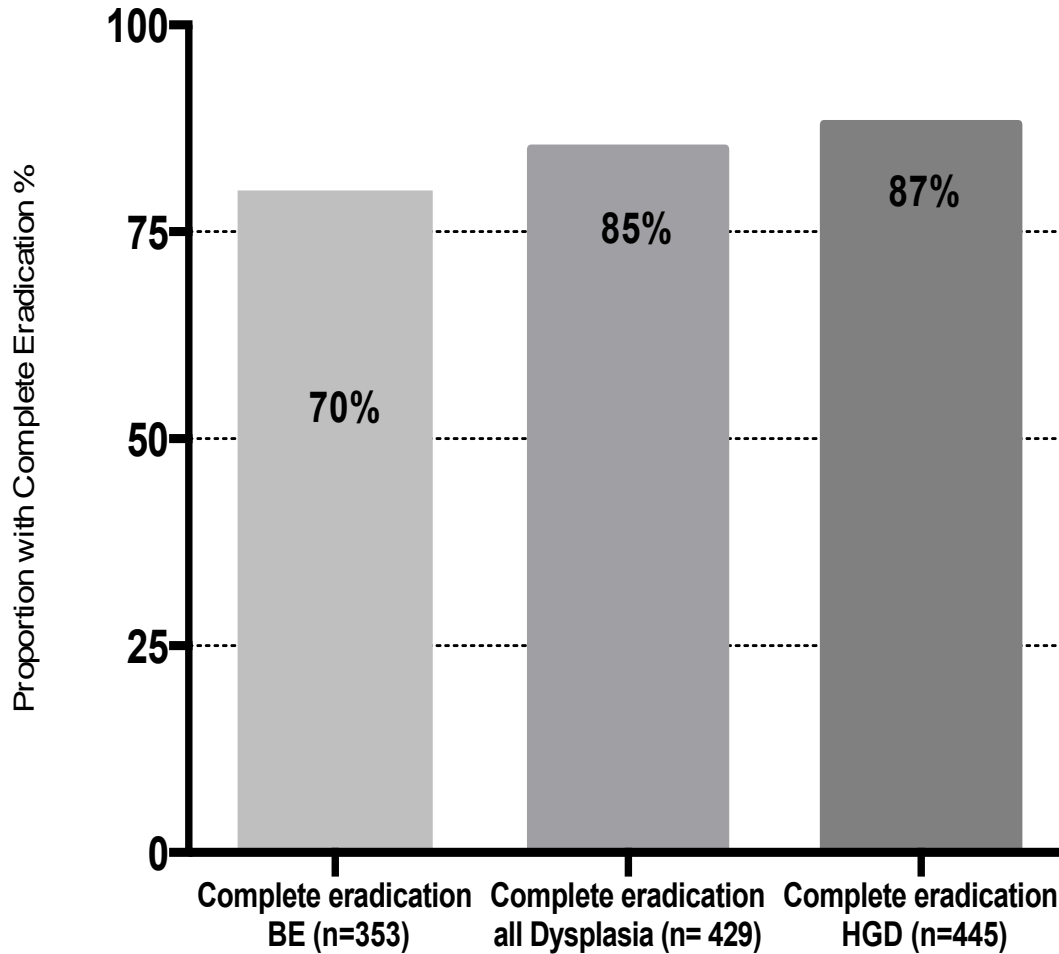


# Results

*(n=508, Completed Protocol 1.1.14)*

Male:Female (%)	81:19
Mean age	69 (40-90)
Baseline Histology (%) <ul style="list-style-type: none"><li>• IMC</li><li>• HGD</li><li>• LGD</li></ul>	25 72 3
Barrett's length (M) prior to RFA (mean)	5.6 cm (1-20)
Mean No. HALO Ablations during protocol (range) <ul style="list-style-type: none"><li>- Mean no. HALO 360</li><li>- Mean no. HALO 90</li></ul>	2.5 (1-6) 1.4 1.8
EMR before RFA (%)	52%
RESCUE EMR DURING RFA	7%
Median follow up after ablation	24 months (IQR 11.0-25.0)

# 12 month outcomes



Shaheen NJ et al. N Engl J Med 2009;360:2277-2288



	2007-2010	2011-2013	P value
<b>No. Patients completed Treatment Protocol</b>	265	245	
<b>Mean age (Range)</b>	68 (40-87)	69 (44-90)	
<b>Male: Female (%)</b>	80:20	84:16	
<b>Baseline Histology (%)</b>			
- LGD	3	3	
- HGD	56	69	
- IMC	41	28	
<b>Previous PDT (%)</b>	9	3	
<b>Baseline BE length at start of RFA (maximum extent, cm)</b>	6 (1-20)	4.7 (1-16)	
<b>EMR prior to RFA (%)</b>	128/265 48%	145/245 59%	P0.0163
<b>Rescue EMR during RFA treatment (%)</b>	35/265 13%	8/245 3%	0<0.0001
<b>Median time to End of protocol (months)</b>	12.6	10.3	
<b>Reversal of IM at end of protocol (%)</b>	149/265 56%	200/245 82%	P<0.0001 CH2
<b>Reversal of Dysplasia at end of treatment protocol (%)</b>	204/265 77%	222/245 91%	P<0.0001 CH2
<b>Progression to Cancer</b>	10/265 (4%)	7/245 (2.9%)	P0.56
<b>Median time to most recent biopsy from first Treatment for those still in follow up, (months)</b>	31 (3-72) n=218	13 (2-32) n=211	
<b>% free of Dysplasia at most recent follow up</b>	97%	90%	
<b>% Free of IM at most recent follow up</b>	91%	93%	

# A surveillance programme in your Trust

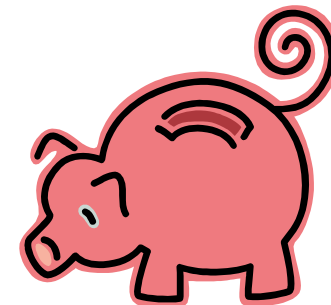
- Is your Trust surveillance strategy designed to detect dysplasia?
  - An agreed surveillance protocol
  - Structured surveillance lists, at least 2 slots/pt.
  - Trained endoscopists to improve lesion recognition
  - Use of simple techniques e.g. good mucosal wash with Infacol®, HRWLE imaging and enhanced imaging (2.5% acetic acid or NBI)
  - Seattle biopsy protocol followed
  - Designated GI Pathologist, x2?

# Surveillance for Barrett's Oesophagus in local Trusts

- Is there an agreed Dysplasia management pathway in your Cancer Network?
  - Are dysplasias discussed at SMDT with appropriate Staging CT
  - 2 pathologists reviewing histology at SMDT
  - Trained Endoscopist to do ER
  - Are your surgeons on board with endoscopic management of HGD
  - Pathway for RFA referral (regional centres)

# So here's what your balance sheet might look like....

<b>CANCER NETWORK</b>	<b>DURHAM &amp; NTH TEES</b>
Population (Taken from cancer network website)	1,200,000
Adult Population	960,000
Estimated Number of patients with Barrett's Oesophagus	15,360
LGD	614
<b>HGD</b>	<b>138</b>
Cancer Risk per Year	77
Actual Mortality Oesophageal Cancer in this Network	385
If 20% of the patients with HGD are treated with RFA	
<b>TOTAL NUMBER OF PATIENTS TO TREAT</b>	<b>28.00</b>
<b>CAPITAL COSTS AND WARRANTY OVER 5 YEARS</b>	
Generator and Trolley	£49,500
Extended warranty for additional 4 years (total 5 years)	£9,000
Total set up costs for 5 years	£58,500
<b>ANNUAL RUNNING COSTS FOR RFA ABLATION</b>	
<b>1st Procedure</b>	£470
1 Halo Sizing Balloon (3441C)	£1,300
1 Halo 360 Ablation Catheter (32041-xx)	£25
1 Halo Cleaning Cap (CP-001B/002B)	
<b>2nd Follow Up at 10 Weeks</b>	£920
Halo 90 Ablation Catheter for focal treatment (90-9100)	
<b>Potential 3rd follow up at 20 Weeks</b>	£920
Halo 90 Ablation Catheter for focal treatment (90-9100)	
<b>Consumable cost per course of treatment per patient</b>	<b>£3,635</b>
<b>Consumables for all patients per year</b>	<b>£101,780</b>
Saving on Oesophagectomy is £2760 per patient (NICE)	£2,760
<b>Savings for all patients per year</b>	<b>£77,280</b>
<b>Savings over 5 years (including set up costs)</b>	<b>£327,900</b>



# A Step by Step approach

- NICE guidance CG 106 & IPG 244/344 to justify
  - need for audit (eg UK National Registry)
- Local ‘new techniques and medical devices panel’
  - Trust and directorate/HoS support; cancer network support
- Training – operator and support team
  - Dedicated lists & organisation
- Business case to CCG commissioners
  - Demand and capacity (Nov-Feb usually)
- OPCS and HRG codes FZ24A/B/C
- Multiple CCGs but usually one will often take lead for specifics
  - Activity paid by PbR; ‘excluded devices’ – ‘pass through’ consumables costs
  - Service developments should be ‘cost neutral’; cost efficiency ; quality benefits; bed days saving; align with Trust objectives
  - QIPP ‘pump priming



*Thank you for your  
attention*

