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## Quality Indicators in Endoscopic Ablation for Barrett's Esophagus

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### Opinion Statement

Barrett's esophagus (BE) is a well-established premalignant condition for esophageal adenocarcinoma (EAC); a cancer that is associated with a poor 5-year survival rate. Several strategies have been explored in the context of reducing the burden of EAC. Endoscopic eradication therapy (EET) is considered the standard of care for the management of patients with BE with dysplasia and early neoplasia; a practice that has been endorsed by all gastroenterology societal guidelines. The effectiveness of EET has been demonstrated in multiple studies and contemporary management includes a combination of endoscopic mucosal resection (EMR) of all visible lesions followed by eradication of the remaining BE using ablative techniques of which radiofrequency ablation (RFA) has the best evidence supporting effectiveness and safety. These techniques are being used increasingly at academic tertiary care centers and community practices. In this era of value-based health care, there is increased focus on the establishment, documentation, and reporting of quality indicators; indicators that are important to physicians, patients, and payers. The purpose of this review is to highlight the current status of quality indicators in EET for the management of patients with BE-related neoplasia and discuss the future steps required to ensure that these quality indicators are uniformly incorporated into practice.

### Keywords

Quality indicators; Barrett's esophagus; Endoscopic eradication therapy; Endoscopic ablation; Radiofrequency ablation

### Introduction

Barrett's esophagus (BE) is a condition characterized by the replacement of the normal stratified squamous epithelium of the distal esophagus with metaplastic intestinal-type columnar epithelium [1, 2]. BE is the only identifiable premalignant condition for EAC; a

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#### Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

cancer that continues to increase in incidence and one that is associated with a dismal 5-year survival rate (<20%) [3]. Several strategies have been explored in the context of reducing the burden of EAC and include identification of individuals with BE (screening) and enrolling patients in surveillance programs with the aim of detecting EAC at an early and potentially curable stage. The probabilistic progression of BE to invasive EAC is believed to occur through the histologic stages of low-grade dysplasia (LGD), high-grade dysplasia (HGD), and intra-mucosal EAC and thus providing opportunities to prevent progression and decrease the incidence of EAC [4–8]. Endoscopic eradication therapy (EET) in patients with LGD, HGD, and intra-mucosal EAC is an effective and safe strategy in prevention of invasive EAC; a practice that has been endorsed by multiple recent gastroenterology (GI) society guidelines and consensus documents [1–2, 9]. Available data suggest that EET is used increasingly among academic, tertiary care centers, and community practices. With the increasing use of EET in patients with BE-related neoplasia, it is critical to define and implement quality indicators in EET. In this review, we discuss the current status of EET and the importance of establishing and implementing quality indicators in clinical practice especially in the field of EET. In addition, we review data from two recent expert consensus documents that defined quality indicators and set benchmarks for the treatment of BE patients in an effort to standardize healthcare delivery.

### **Current status of endoscopic eradication therapy**

EET is now the standard of care for the management of patients with BE with dysplasia (LGD and HGD) and intra-mucosal EAC [1–2, 9]. The effectiveness and safety of EET in the eradication of BE-related neoplasia and maintaining remission has been demonstrated in randomized controlled trials and large observational studies [10•, 11•, 12•, 13, 14]. Contemporary management of patients with BE-related neoplasia includes endoscopic mucosal resection (EMR) of any visible lesions (no matter how subtle) followed by ablation of the remaining flat BE segment (see Figs. 1, 2, 3, and 4 for example of EMR). Of all the ablative techniques, radiofrequency ablation (RFA—see Figs. 5, 6, and 7 for example) is the most widely studied technique supporting the effectiveness and safety of this ablative modality [15, 16].

### **Quality indicators**

Quality of care and quality improvement in medicine and endoscopy in particular, is an evolving field and has garnered a great deal of interest in recent times. Quality measurement and improvement with the help of quality indicators has the potential to ensure the delivery of high-quality care. Defining quality as the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge,” a recent position paper recognized the need for objectively and precisely measuring quality through holistic quality indicators, which would be based on evidence and target the care of specific individuals as well as the entire system [17]. While this ideal is desirable for patients and physicians, quality indicators will also play an important role in the current changing health care environment as we transition from a fee-for-service to a pay for quality and value model. The Department of Health and Human Services aims to reform health care delivery through increased use of incentives to foster

higher value care with the goal of linking 90% of all Medicare fee-for-service payments to outcomes and 50% to alternate payment models by 2018 [18]. Thus, in this era of value-based and quality-based healthcare, the development of quality indicators that benchmark performance is critical. Quality indicators are often reported as ratios between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal [19]. Quality can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark [20]. It should be noted that quality indicators are held to a higher standard compared to published guidelines and non-adherence to a quality indicator reflect suboptimal care [21].

## Quality indicators in endoscopic eradication therapy

This review will focus primarily on two recent articles that addressed quality indicators in EET for BE-related neoplasia patients [22••, 23••]. A recent consensus conference sponsored by the American Gastroenterological Association (AGA) proposed quality indicators for the management of BE, dysplasia, and EAC using a modified Delphi method [22••]. This all-encompassing document included quality indicators that addressed some indicators related to EET. This process involved inclusion of 25 international experts who first drafted potential quality indicators on different domains in BE, and a final approval of each statement was ultimately achieved through a series of electronic and in-person discussions and at least 80% agreement followed by grading of evidence. Of the eight quality indicators, two statements focused on the treatment and management of BE and early EAC. In addition, this expert group also identified statements that were based on low quality evidence but had 80% consensus agreement. Another recent document used a methodologically rigorous process to develop valid quality indicators specifically in EET for the management of BE-related neoplasia [23••]. Quality indicators were developed using the RAND/University of California, Los Angeles Appropriateness Methodology (RAM). RAM is a well-described methodology for the development of quality indicators and addresses the concept of appropriateness; the relative weight of the benefits and harms of an intervention. An appropriate indicator is one in which the expected health benefits exceed the expected negative consequences by a sufficiently wide margin exclusive of costs [24]. A total of 19 international experts participated in Round 1 and Round 2 and identified 14 “appropriate” quality indicators categorized into the pre-procedure, intra-procedure, and post-procedure domains. The strengths of this document include not only the development of appropriate and valid quality indicators in EET using a formal, well-described methodology, but also the development of indicators with well-defined inclusion and exclusion criteria for the numerator and denominator for each indicator, inclusion of outcomes measures tied to key outcomes of interest and defining the threshold benchmarks for each indicator for clinical practice and implementation. This document was recently endorsed by the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG). Tables 1 and 2 describe the quality indicators selected by both consensus groups that are pertinent to this review. They are expounded upon below and have been divided into three categories: (1) pre-procedural quality indicators, (2) intra-procedural quality indicators, and (3) post-procedural quality indicators.

**Appropriate pre-procedure quality indicators:**

1. For patients in whom a diagnosis of dysplasia has been made, the rate at which the reading is made by a GI pathologist or confirmed by a second pathologist before embarking on EET

This statement speaks to the lack of uniformity in the interpretation of grades of dysplasia between pathologists especially regarding the diagnosis of LGD [25–28]. In response to this inter-observer variability, the Vienna classification was developed, which consists of five categories: (1) negative for neoplasia/dysplasia, (2) indefinite for neoplasia/dysplasia, (3) non-invasive low-grade neoplasia (low-grade adenoma/dysplasia), 4) non-invasive high-grade neoplasia (high-grade adenoma/dysplasia, non-invasive carcinoma, and suspicion of invasive carcinoma), and (5) invasive neoplasia (intra-mucosal carcinoma, submucosa carcinoma, or beyond) [29]. Although several advances have been made in the field of biomarkers, the presence and the grade of dysplasia is the best available biomarker to predict progression in patients with BE [30]. Available data suggests that the number of pathologists who agree on the presence of dysplasia correlates with an increased risk of progression to cancer [26–27, 31]. The AGA recently defined an expert GI pathologist as a pathologist with a special interest in BE-related neoplasia who is recognized as an expert in this field by his/her peers [15]. Thus, this statement advocates for the use of a second, preferably GI-specialized pathologist, to confirm diagnoses of dysplasia.

2. Centers where EET is performed should have available high definition white light endoscopy (HDWLE), and expertise in mucosal ablation and endoscopic mucosal resection (EMR) techniques

This statement comments on the importance of having the appropriate resources to perform EET. As patients referred for ablation will frequently have focal lesions and nodular disease, it is important to also have the ability to perform EMR to best provide comprehensive care for each patient [1, 32]. A recent study by Schölvinc et al. demonstrated that community hospitals had a significantly lower detection rate of neoplastic lesions than expert centers, which may support the referral of ablation to expert centers [33]. This study also provided the requirements for an “expert center” regarding management of patients with BE-related neoplasia and include the following requirements: (i) minimum case load of ten new patients per year with dysplasia or EAC in BE to be treated at the expert center, (ii) the specialized care is delivered by one dedicated endoscopist and one or two pathologists, with documented training and expertise, (iii) availability of high resolution endoscopy and equipment for EMR and ablation for dysplasia or EAC in BE, (iv) multidisciplinary consultation with GIs, surgeons, oncologists, and pathologists regarding all patients with early EAC; and (v) expertise in treating adverse events and access to esophageal surgery.

3. The rate at which documentation of a discussion of the risks, benefits, and alternative to EET is obtained from the patient prior to embarking on a course of treatment

As with all procedures, proper informed consent should entail the description of risk of progression to cancer or dysplasia, the possible surveillance and treatment considerations, and risks and benefits of each option [34]. The informed consent should also include what follow-up would consist of, including its frequency and duration.

### Appropriate intra-procedure quality indicators

1. The rate at which landmarks and length of BE is documented, (using Prague criteria) and the rate at which the presence or absence of visible lesions is reported (e.g., Paris classification) in patients with BE before EET

Supported by both consensus agreements [22••, 23••], this statement stresses the importance of systematically documenting the extent of BE as well as visible lesions using a standardized classification system as reporting can have poor inter-observer agreement. Both groups support the use of the Prague criteria, which consists of documenting the circumferential length (C) score, and the maximal length (M) score, which has a high inter-observer agreement between providers [35]. In addition, landmarks such as the diaphragmatic hiatal pinch, the squamocolumnar junction, and the proximal limit of the gastric folds should be documented in an effort to standardize the presence of BE in relation to the gastroesophageal junction, including when a hiatal hernia exists. In terms of visible lesions, Wani et al. support the use of the Paris classification [36], a standardized system for grading visible lesions in BE. Briefly, protruded lesions include: (1) 0–Ip (pedunculated) and (2) 0–Is (sessile), flat lesions include: (1) 0–IIa (superficially elevated), 0–IIb (flat), 0–IIc (superficially depressed), and 0–III (excavated). While the Paris classification does not offer prognostic value, lesions that are 0–Is, 0–IIc, and 0–III are likely to have invasive cancer, while 0–IIa and 0–IIb lesions are unlikely to have invasive cancer.

2. The rate at which the BE segment is inspected using high definition white light endoscopy (HDWLE)

HDWLE, as its name would suggest, offers a greater resolution and aspect ratio than standard definition, which provides greater visualization of the mucosal surface. Despite the lack of head-to-head randomized trials between standard and high definition endoscopy for BE, several studies have suggested that HDWLE is more sensitive in detecting BE-related neoplasia. The use of HDWLE is now considered the standard of care in the evaluation of BE patients referred for surveillance and EET [15, 37–40].

3. The rate at which endoscopic resection (defined as en bloc resection or piecemeal) is performed in patients with visible lesions

Performance of EMR for all visible lesions is supported by both quality indicator documents and published guidelines [1, 2, 9, 22••, 23••]. Several studies have shown that EMR results in a change in the histologic grade of dysplasia (upgrade or downgrade) in BE patients referred for EET [41–45]. In addition, studies have shown that provision of larger specimens obtained by EMR results in an

improvement in the inter-observer agreement among pathologists compared to biopsy specimens [46, 47].

4. The rate at which complete eradication of neoplasia (CE-N) and complete eradication of intestinal metaplasia (CE-IM) is achieved by 18 months in patients with Barrett's-related dysplasia or intra-mucosal cancer referred for EET

There is consensus among both documents that the goal of EET should be CE-IM and CE-N alone as the optimal endpoint for EET given the risk of metachronous neoplasia [22••, 23••]. The efficacy, effectiveness, and safety of EET has been demonstrated in several large randomized controlled trials, prospective, and retrospective studies [10••, 11••, 12•, 13, 14]. The proposed threshold for CE-IM by 18 months from initiation of EET for a patient with dysplastic BE was 70% and that for CE-N was 80% [23••]. These indicators were drafted after accounting for patient non-compliance and those referred for surgery. The decision to specify an 18-month time period to achieve CE-IM was primarily made to make these quality indicators more specific and also after accounting for the median number of sessions required to achieve CE-IM [23••].

#### Appropriate post-procedure quality indicators

1. Among patients who achieve CE-IM, the rate at which a recommendation for endoscopic surveillance at a defined interval is documented

While studies have demonstrated the efficacy of EET, recurrence of intestinal metaplasia and dysplasia represents a true concern with rates ranging from 5 to 39% and 0–15%, respectively. While no evidence suggests a specific timeline for surveillance after CE-IM, surveillance after CE-IM is essential [13, 48–58].

2. During endoscopic surveillance after EET, the rate at which biopsies of any visible mucosal abnormalities are performed

This statement speaks to the importance of obtaining tissue for histology to confirm persistent or recurrent metaplasia. There is currently no standardized technique for surveillance biopsies after EET. Obtaining biopsies from the gastric cardia and the neo-squamocolumnar junction along with Seattle protocol for sampling every 1–2 cm in a 4-quadrant fashion for the entire length of the pretreatment BE segment is based on expert opinion and not uniformly practiced. At the very least, surveillance biopsies should target any visible mucosal abnormalities during surveillance endoscopy post successful EET and CE-IM.

3. The rate at which an anti-reflux regimen is recommended after EET

This statement reflects several recent studies demonstrating that uncontrolled reflux was associated with persistence of intestinal metaplasia after RFA [59–61]. Krishnan et al. [59] found that patients with an incomplete response to RFA had more acidic and reflux events than those who had a complete response to RFA while Akiyama et al. [61] noted that effective intra-esophageal pH control in patients with BE was associated with improved outcomes from RFA. The data

thus supports the necessity of maintaining adequate control of reflux, which is most easily accomplished with anti-reflux therapy.

4. The rate at which adverse events are being tracked and documented in individuals post EET

As with all procedures, this outcome measure is crucial in creating safety benchmarks for EET. A recent systematic review and meta-analysis found an adverse event rate of 8.8%, with the most common adverse event being stricture (6%), while perforation accounted for 0.6% of adverse events [16]. Given that endoscopic ablation is not a risk-free procedure, documentation of adverse events is critical in establishing quality indicators and allowing endoscopists to accurately relay these risks to their patients.

## Conclusion

Quality indicators will continue to play an important role in the current healthcare system. This review highlights the quality indicators for EET driven by the need to promote best practice among individual practitioners and institutional EET programs and foster evidence-based care. Establishing and implementing quality indicators is in line with the current health care landscape as it transitions from a fee-for-service model to a pay for quality and value model. The benchmarks established will also be useful for training in EET and for understanding competency of individuals and EET programs. The future of quality indicators in endoscopy in general will focus on research specifically relating to the implementation of quality indicators. Studies will have to evaluate whether implementation of these quality indicators impacts patient outcomes. The feasibility of implementing quality indicators (process of measurement and evaluation) in routine clinical practice using data repositories such as the GI Quality Improvement Consortium, Ltd. (GIQuIC) will need to be addressed [62]. Furthermore, this will likely require changes in our electronic medical record systems which could potentially allow for effective measurement of adherence to quality indicators [63]. Adherence to these quality indicators has the potential to improve quality of care, reduce variability in healthcare, and ultimately improve patient outcomes.

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## Abbreviations:

<b>BE</b>	Barrett's esophagus
<b>EAC</b>	Esophageal adenocarcinoma
<b>EET</b>	Endoscopic eradication therapy
<b>GI</b>	Gastroenterology
<b>AGA</b>	American Gastroenterological Association

<b>ASGE</b>	American Society for Gastrointestinal Endoscopy
<b>ACG</b>	American College of Gastroenterology
<b>RAM</b>	RAND/University of California, Los Angeles Appropriateness Methodology
<b>HDWLE</b>	High definition white light endoscopy
<b>CE-IM</b>	Complete eradication of intestinal metaplasia
<b>CE-N</b>	Complete eradication of neoplasia

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Papers of particular interest, published recently, have been highlighted as:

• Of importance

•• Of major importance

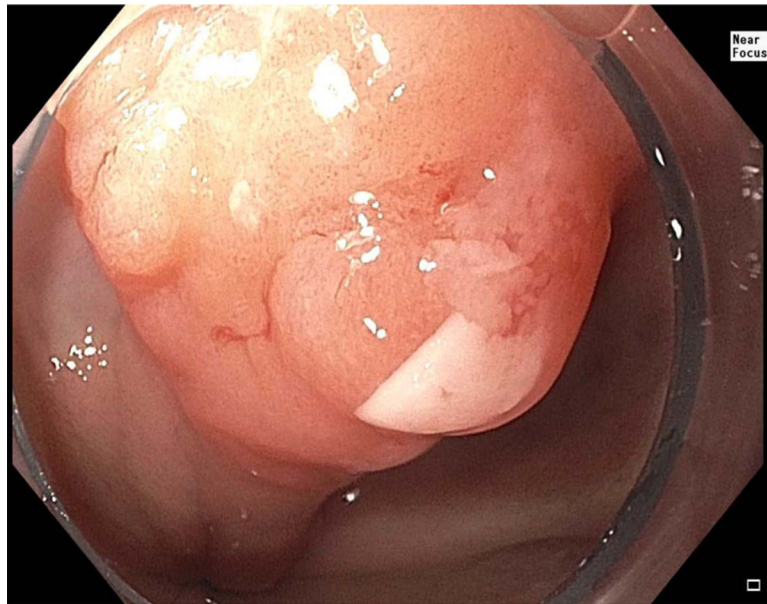
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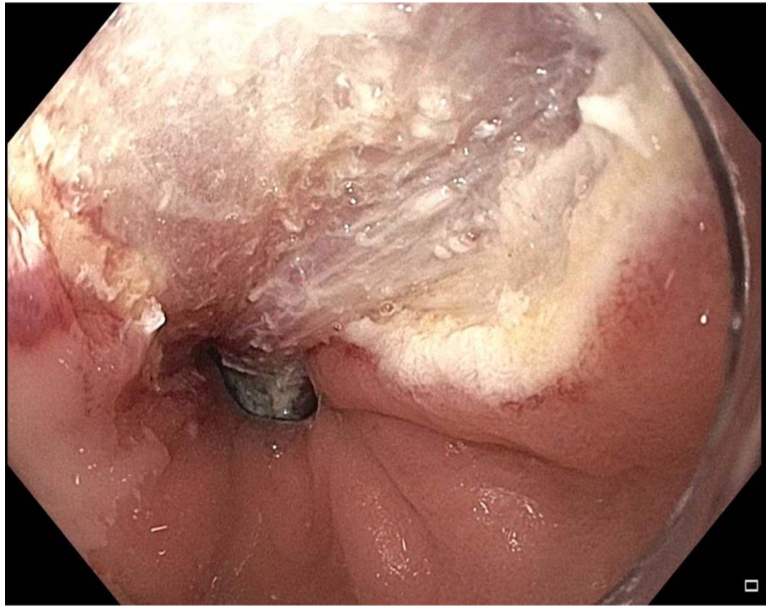
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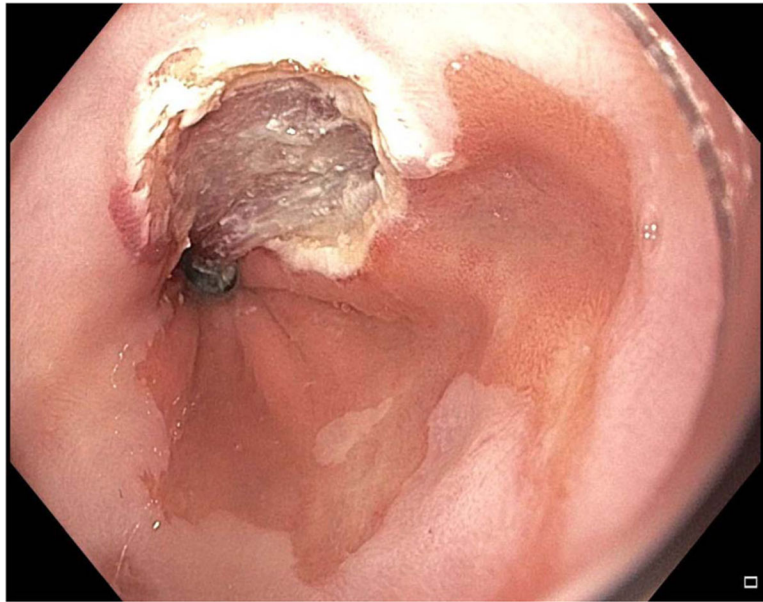
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**Fig. 1.**  
Example of nodular lesion with Barrett's esophagus.



**Fig. 2.**  
Lesion from Fig. 1 during endoscopic mucosal resection.



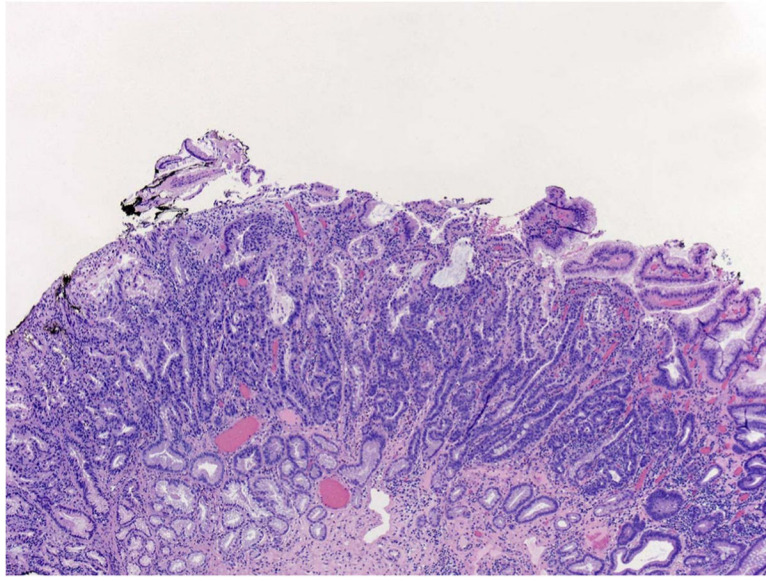
**Fig. 3.**  
Image post-endoscopic mucosal resection of lesion from Fig. 1.

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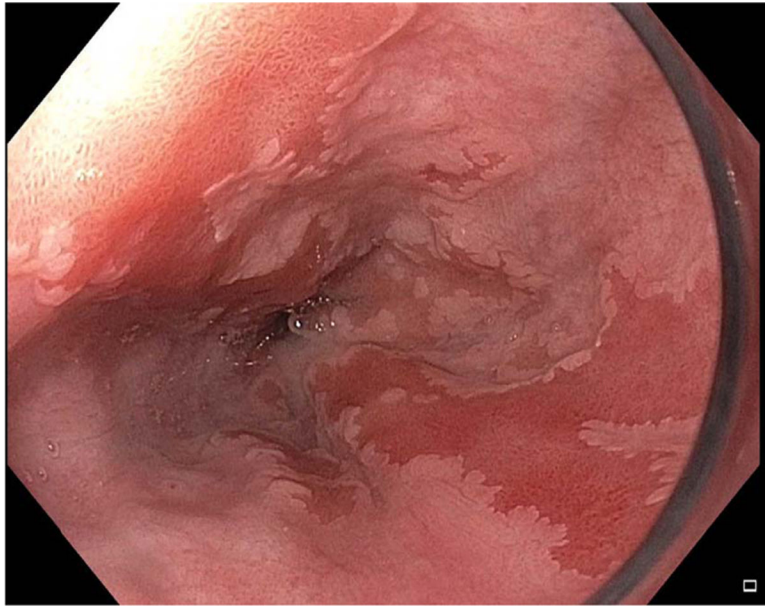
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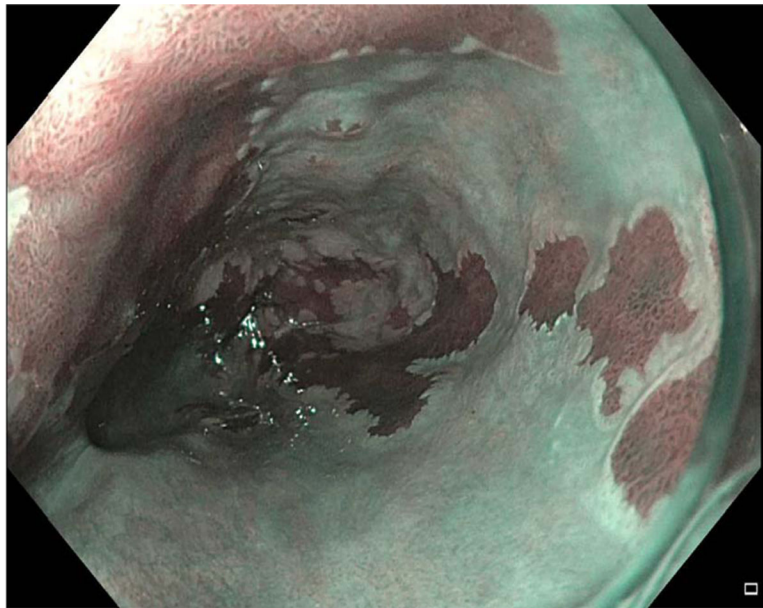


**Fig. 4.** Histology of specimen from endoscopic mucosal resection from lesion in Fig. 1 demonstrating extensive high-grade dysplasia in Barrett's esophagus.

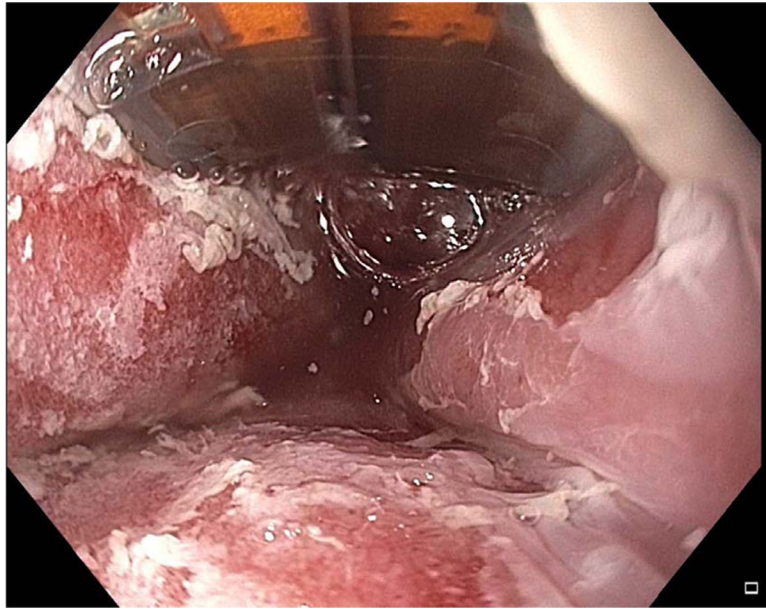


**Fig. 5.**  
Example of flat Barrett's esophagus using white light endoscopy.





**Fig. 6.**  
Image of flat Barrett's esophagus using narrow-band imaging.



**Fig. 7.**  
Image of Barrett's esophagus during radiofrequency ablation.

Quality indicators for endoscopic eradication therapy using the RAND/UCLA appropriateness methodology from Wani et al. [23]

Table 1.

Quality indicator	Threshold	Process or outcome measure
Pre-procedure	90% [75, 100]	Process
		For patients in whom a diagnosis of dysplasia has been made, the rate at which the reading is made by a GI pathologist or confirmed by a second pathologist before embarking on EET.
	N/A	Process
	99% [85, 100]	Process
		If EET is performed, then centers should have high definition white light endoscopy (HDWLE), mucosal ablation, and EMR techniques available. The rate at which documentation of a discussion of the risks, benefits, and alternatives to EET is obtained from the patient prior to embarking on a course of treatment.
Intra-procedure	90% [75, 100]	Process
		The rate at which landmarks and length of BE is documented (e.g., Prague grading system) in patients with Barrett's esophagus before EET.
	90% [60, 100]	Process
	95% [0, 100]	Process
	90% [0, 100]	Process
	70% [50, 80]	Outcome
	90% [50, 100]	Process
		The rate at which presence or absence of visible lesions is reported (e.g., Paris classification) in patients with Barrett's esophagus referred for EET. The rate at which the Barrett's esophagus segment is inspected using high definition white light endoscopy (HDWLE).
		Among patients undergoing EET who have not yet achieved CE-IM, the rate at which a defined interval for subsequent EET is documented. The rate at which CE-IM is achieved by 18 months in patients with Barrett's-related dysplasia and intra-mucosal cancer referred for EET.
Post-procedure		Process
		Among patients who achieve CE-IM, the rate at which a recommendation for endoscopic surveillance at a defined interval is documented.
	95% [50, 100]	Process
	90% [50, 100]	Process
	90% [50, 100]	Process
		During endoscopic surveillance after EET, the rate at which biopsies of any visible mucosal abnormalities are performed. The rate at which an anti-reflux regimen is recommended after EET.
		The rate at which adverse events are being tracked and documented in individuals post EET.

EET endoscopic eradication therapy, EMR endoscopic mucosal resection, BE Barrett's esophagus, CE-IM complete eradication of intestinal metaplasia

Quality indicators for treatment and management of Barrett's esophagus and early cancer using a modified Delphi method from Sharma et al. [22••]

Table 2.

Quality indicator	Agreement	Grade of recommendation
Screening, diagnosis, and staging	87% [35% strongly agree, 52% agree]	Weak
Surveillance	82.6% [43.5% strongly agree, 39.1% agree] 86.3% [68.1% strongly agree, 18.2% agree] 91.3% [17.3% strongly agree, 74% agree]	Weak Strong Weak
Treatment and management	95.7% [52.2% strongly agree, 43.5% agree] 95.7% [65.2% strongly agree, 30.5% agree] 95.6% [65.2% strongly agree, 30.5% agree] 100% [65.2% strongly agree, 34.8% agree]	Strong Strong Strong Strong

*BE* Barrett's esophagus