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Endoscopic Eradication Therapy in Barrett's Esophagus

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Abstract

Endoscopic eradication therapy (EET), the standard of care for treatment of Barrett's esophagus with dysplasia and early neoplasia, consists of a combination of endoscopic resection and ablative modalities. Resection techniques primarily include endoscopic mucosal resection or endoscopic submucosal dissection. Resection of nodular disease is generally followed by one of multiple ablative therapies among which radiofrequency ablation has the best evidence supporting safety and efficacy. These advanced endoscopic procedures require both experience and expertise in the cognitive and procedural aspects of EET. However, very few formal programs exist that teach endoscopists the necessary skills to perform EET in a safe, standardized, and efficacious manner. Case volume at both the endoscopist and center level has been shown to impact clinical outcomes based on limited data. As a result, some recent guidelines endorse case volume as a measure of competency. Quality indicators, which can be used as benchmarks for training and as part of pay for quality initiatives, have recently been derived for EET. However, quality metrics in EET have not been widely accepted, nor are they broadly used currently. While the efficacy of EET for BE is established, there is a need for application of quality metrics to both assure adequate training in these procedures, as well as to assess treatment outcomes. A standardized EET training curriculum during endoscopic training, with competency assessment of both new clinicians and endoscopists in practice has potential to improve care in EET.

Keywords

Barrett's esophagus; endoscopic eradication therapy; endoscopic training; competency assessment; quality metrics

Introduction

Barrett's esophagus (BE) is a premalignant condition of the esophagus that can progress to esophageal adenocarcinoma (EAC). While only a small proportion of those with BE develop EAC, the increasing incidence of EAC and high associated mortality provide the rationale

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for screening of high risk patients and routine surveillance to assess for progression to neoplasia. BE with low-grade dysplasia (LGD) or higher is treated with endoscopic eradication therapy (EET). EET involves a multimodal approach of endoscopic resection for nodular BE with either endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD). Ablative therapies include radiofrequency ablation (RFA) or cryotherapy, among others. EET is the procedure of choice for patients with LGD, high-grade dysplasia (HGD), and T1a esophageal adenocarcinoma based on abundant data showing treatment efficacy and durability with an acceptable safety profile (1, 2).

However, existing data are largely based on procedures performed by expert endoscopists at high-volume centers, and it is unclear to what degree treatment outcomes are affected by the quality of endoscopic therapy. As with other advanced endoscopic therapies, EET for early esophageal neoplasia involves a discrete skillset that must be mastered, and mastery of these skills is currently poorly quantified.

In this review article, we will discuss the current status of EET in BE including recommended treatment guidelines. In addition, we will explore the current programs available for training endoscopists in EET, how to measure competency in EET, and will review data on the effect of individual endoscopist and center procedural volume on efficacy and safety measures. Finally, we will conclude with a summary of quality metrics for EET in the treatment of BE, drawing on data from a recently performed consensus effort to develop these metrics. Review of these data demonstrates that although quality indicators for EET exist, few practitioners currently track these data. Most training in these procedures is via gastroenterology training programs in an apprentice style, and due to lack of standardization of this training, wide variability in both practices and quality of training may exist.

Current Status of Endoscopic Eradication Therapy (EET) in BE

Endoscopic eradication therapy in (EET) is a proven and effective treatment modality for BE patients with dysplasia and early neoplasia and is preferred over esophagectomy (3, 4). EET consists of EMR of any nodular areas followed by treatment of residual BE with ablative modalities, preferably RFA, based on a large body of high quality evidence supporting its safety and efficacy (1, 2). A recent pooled analysis showed that focal EMR followed by RFA results in high BE eradication rates with 93% of complete eradication of neoplasia (CE-N) and 73% of complete eradication of dysplasia (CE-D) (5). With combined therapy, recurrence of EAC was 1.4%, dysplasia was 2.6%, and intestinal metaplasia was 16.1%. For non-nodular BE, eradication rates with ablation alone were 78% for complete eradication of intestinal metaplasia (CE-IM) and 91% for complete eradication of neoplasia (6). After successful ablative therapy, the recurrence of neoplasia was 0.7% and recurrence of intestinal metaplasia was 13%. EET in BE also has an acceptable safety profile with the most common complication being post-ablation stricture with a pooled estimate of 5.6% (7). EET is not recommended for BE patients with no dysplasia due to low rates of progression to EAC.

In addition to EMR and RFA, a plethora of additional eradication modalities, as well as adjunct endoscopic imaging platforms, have been developed wholly or in part to aid in

endoscopic management of neoplastic BE. Currently commercially available ablation modalities include liquid nitrogen spray cryotherapy, nitrous oxide balloon cryotherapy, argon plasma coagulation (APC), multi-, bi- or monopolar electrocoagulation, and laser modalities, either in conjunction with a photosensitizing agent or as monotherapy. While all of the above listed modalities have documented efficacy in ablating BE and inducing neosquamous epithelium, there is in general a paucity of head-to-head data comparing them. Among the imaging modalities, previously described techniques include narrow band imaging, optical coherence tomography/volumetric laser endomicroscopy, confocal endomicroscopy, elastic scattering spectroscopy, and autofluorescence imaging. While several modalities have shown promise in improving dysplasia detection in BE, none is recommended currently for routine use (3).

Given the recent proliferation in both the treatment and adjunct imaging modalities in BE, it is perhaps unsurprising that training in them is not standardized, and that evidence of competency is scarce. Currently in the U.S., the title of expert is often self-bestowed, sometimes accompanied by a vague reference to how many such procedures have been performed at the facility or by the clinician. Clearly, numbers of procedures performed is an inadequate benchmark for competency, in that a bad endoscopist may perform his or her 100th ablation with the same lack of expertise as his or her 10th. Only recently have attempts been made to standardize training in EET or to provide quality benchmarks in these therapies. As we will review below, these attempts to deliver quality in training and to judge quality in performance are hampered by a paucity of data with which to set standards or to develop curricula for training.

Current Guidelines Regarding EET

Current guidelines recommend EET for management of neoplastic Barrett's mucosa over surgery, as EET has lower associated morbidity and mortality and is more cost effective (8-10). However, these parameters may be only applicable when EET is performed at high-volume centers by experienced endoscopists. It is recommended that the endoscopist have adequate training in both recognizing subtle mucosal irregularities and endoscopic resection techniques, in addition to having expertise in at least one enhanced imaging modality (11). This is because the first step to effective EET is to resect all visible or nodular areas detected on high-definition endoscopy. In addition to being an effective treatment modality, resection also provides more accurate staging information compared to targeted biopsies (12, 13). Endoscopic resection is also the recommended therapy for T1a and T1b sm1 esophageal adenocarcinoma. While endoscopic submucosal dissection may provide data on the lateral margins of the lesion, the technical difficulty restricts the use of this procedure to select centers and is associated with more adverse events (14). In a recent randomized controlled trial, EMR showed equal efficacy to ESD for neoplasia remission and recurrence rates in BE patients with HGD and EAC (14). EMR can be performed with either the cap and snare technique or with band ligation followed by resection, and both techniques show comparable depth of resection and complication rates (15, 16).

Following endoscopic resection, any residual BE needs to be eradicated with ablative therapy. Compared to step-wise endoscopic resection for treatment of residual Barrett's, RFA

has been shown to have equal efficacy and a decreased rate of strictures (17). For flat HGD or intramucosal cancer without visible lesions, endoscopic ablation is the recommended mode of therapy. While all ablation modalities may reduce the risk of progression to EAC compared to surveillance in HGD/intramucosal carcinoma, RFA has a better safety profile and maybe more efficacious in treating buried glands (18, 19).

Endoscopic ablation is now also recommended for patients with confirmed LGD, according to recently published British Society of Gastroenterology (BSG) and American College of Gastroenterology (ACG) guidelines (3, 11, 20) for BE management. This recommendation is based on a recent multicenter trial (2) that randomized patients with LGD to EET or surveillance. Those in the treatment arm achieved CE-D and CE-IM in 98% and 90% respectively with the most common complication being strictures in 12% of the cases. Therefore, EET is safe and effective in treating LGD.

Training in Esophageal Endoscopic Mucosal Resection (EMR) and Radiofrequency Ablation (RFA)

According to recently published guidelines (11), training in endoscopic eradication therapy should initially consist of knowledge acquisition, followed by learning resection and ablation skills in animal models, prior to training in human subjects. Despite these suggestions, training in EET continues to be largely apprentice-based, taking place as part of standard GI fellowship or surgical residency/fellowship training. A limited number of esophageal fellowships exist in the U.S. These fellowship positions are generally filled by the institutions that offer them, without a centralized match process.

In addition to training in EET available as part of subspecialty training programs, intensive programs in esophageal EMR and RFA are offered by organizations such as the RFA-Academia, which is a European training program to teach RFA to endoscopists. In the United States, the American Society of Gastrointestinal Endoscopy (ASGE) offers training programs in Barrett's endotherapy and upper gastrointestinal EMR, which are described below.

The ASGE STAR Certificate Program in Endotherapy is an integrated course consisting of a pretest, an online curriculum of didactics (including guideline review, technology review and key articles), instructional videos, and then another pre-test. Following this work, the trainee attends a weekend-long course, consisting of case-based video sessions and hands-on training in the skills to be acquired. In a recent course, these skills included RFA, EMR, and cryotherapy. Attendees first practice these skills with instruction from clinicians who have published research in these areas. The next day, the attendees complete a one-on-one skills assessment and a post-test, with feedback from the instructors. Those who pass this assessment will be given a Certificate of Completion, which presumably can be used as proof of readiness to perform these procedures clinically. Those participants who do not pass are given feedback as to the specific areas in need of remediation, and options for further training.

Despite the obvious face validity of the approaches described above, little data exist documenting the utility of specific measures in training clinicians in the performance of EET. One European study aimed to identify the most important learning points of endoscopic resection in the esophagus in a structured training program (21). Participants in this program were practicing gastroenterologists with expertise in oncology of the upper gastrointestinal tract. The four-day training program consisted of lectures, live demonstrations, hands-on training on animal models, followed by practical training on human participants at each individual endoscopist's training site. Participants were trained both in endoscopic cap resection and multiband mucosectomy techniques. All steps of training were also provided to an endoscopy nurse and pathologist from each center that worked with the endoscopist. The first 20 endoscopic resections of each endoscopist were videotaped and reviewed by an expert who provided feedback. Based on this, a number of learning points deemed to be essential to endoscopic resection were identified by both the participants and the experts providing feedback on the resection videos. Finally, three expert endoscopists ranked the learning points to compile a list of 10 recommended tips (Table 1) considered crucial to training in endoscopic resection. These tips include conceptual items, such as knowing the management of bleeding and of perforation, as well as logistical/operational factors, such as marking out the areas to be resected with electrocautery, performing a test suction prior to the application of a band for ligation, and keeping endoscopic devices such as snares and APC close to the tip of the endoscope for better control. For RFA, while there are two studies (22, 23) assessing learning curve issues, there are no objective data identifying specific training parameters to be satisfied prior to undertaking these therapies.

Assessment of Competency

Assessing competency for endoscopic procedures and therapies is important to deliver necessary diagnostic and therapeutic procedures in an efficacious, standardized, and safe manner. Proficiency in endoscopy requires meeting technical, cognitive, and integrative competencies (24). Currently there are little data on assessing competency for endoscopic eradication therapy. The most recent BSG guidelines recommend a minimum of 30 supervised cases of endoscopic resection and 30 cases of endoscopic ablation to acquire competence in technical skills, management pathways, and associated complications. Additionally, the authors recommend that at least 15 EMRs be performed per annum at any given site to maintain proficiency in the technique. However, the authors note that these recommendations are based on expert opinion in the absence of data to inform them.

No similar guidelines on case volumes necessary for competency are endorsed in the United States. Recently published guidelines by the ACG (3) specifically declined to set numerical thresholds for independent performance of EET, citing the paucity of data to guide such recommendations. The sole recommendation from this publication was that endoscopists who perform endoscopic ablative therapy also be versed in providing EMR, since the two technologies are so often used sequentially to manage these patients.

Does Case Volume Matter?

Higher surgical and endoscopic procedural volume has been shown to improve treatment outcomes and decrease complications (25). For instance, improved adenoma detection rate has been found to be associated with a larger endoscopist case volume (26, 27). EET is comprised of repeated sessions until CE-IM or CE-D is achieved. In terms of the optimal delivery of EET, there appears to be a correlation between positive outcomes and increasing procedural volumes at both the endoscopist and the center level.

Higher volume centers have been defined as those treating more than 15 HGD cases per year (28). In a study of 148 institutions enrolled in the U.S. RFA Registry that assessed the effect of case volume on outcomes with EET (22), center volume did not affect rates of CE-IM or CE-D. However, in this study volume was associated with a significantly lower number of treatment sessions to achieve CE-IM, with differences persisting after adjusting for factors such as BE length, baseline dysplasia, and need for EMR prior to RFA. The “learning curve” effect of case volume flattened after a center's threshold level of 30 patients, suggesting that this might serve as an appropriate threshold volume above which better outcomes might be expected (Figure 1). In this study, CE-IM rates were not affected by whether the procedures were performed at a community versus an academic center. Center volume was also not associated with an increased number of complications such as strictures, bleeding, perforation, or hospitalizations. However, another smaller retrospective study of single endoscopist case series found no differences between the number of procedures to CE-IM, procedure duration, or complications between the initial 25% and later 75%, or the initial 50% and later 50% of cases (23). For EMR, there is a lower complication rate of less than 3% associated with high-volume centers (29-31) although the outcomes may be related to higher endoscopist volumes according to one study (32).

The number of cases of RFA performed at the provider level also impacts treatment efficacy based on recent data from three tertiary care medical centers (33). Both the number of patients treated with RFA (Figure 2) and the number of total RFA cases performed by an individual endoscopist were associated with increased rates of CE-IM. Compared to the lowest tertile of endoscopist RFA volume, those in the middle (OR 1.54) and highest tertiles (OR 2.34) had higher odds of achieving CE-IM. For EMR, one multicenter study assessed the safety and efficacy of the first 120 endoscopic resections of early neoplasia performed by six endoscopists who participated in a formalized training program (34). There was no difference in resection quality, time of procedure, and complications for the first 10 cases compared to the last 10 cases for each endoscopist. However, there was a significant morbidity of all these training procedures, with 6 perforations and 11 bleeds in the 120 procedures, indicating that 20 cases may not be sufficient to reach the flat part of the learning curve.

Another recent study (32) from a national administrative database in England, showed that in 11051 patients who underwent upper gastrointestinal EMR for cancerous and non-cancerous lesions, endoscopist procedure volume was an independent predictor of 30-day mortality. However, over the initial 8 cases, average 30-day and 90-day mortality were similar between high-volume and low-volume endoscopists showing similar clinical

outcomes in the early stages of learning EMR (Figure 3). The requirement for emergency intervention after EMR was also greater with low volume endoscopists. When EMR was done to treat non-cancerous lesions, after a cut-point of 2 cases, there was a significant reduction in 30-day (1.8% to 0.5%; $p < 0.01$) and 90-day (3.6% to 1.3%; < 0.01) mortality in cases performed by high-volume endoscopists. When procedures were undertaken for esophageal cancer, a cut point of 4 cases resulted in a 15-fold decrease in 30-day mortality. In cancer cases, the proficiency gain curve for urgent re-intervention within 14 days was at a cut-point of 1 case, while the need for elective re-intervention with repeat EMR or surgery for presumed positive resection margin or failed initial EMR was substantially longer at 43 cases.

In addition to treatment outcomes, the efficacy of BE management depends on accurate BE assessment and diagnosis. A single tertiary care experience showed that assessment of dysplastic BE at a specialized BE unit led to increased detection of mucosal abnormalities by 52% and EAC by 36% (35). While factors such as use of advanced imaging techniques at BE referral centers may explain the increased neoplasia detection rates, endoscopist expertise and high case volume also likely contribute to more accurate BE diagnosis with detection of subtle lesions missed by less experienced endoscopists. However, there are no studies that have shown a direct correlation between case volume and improved detection of subtle lesions in BE.

Quality Metrics in EET

Quality metrics are increasingly relevant in gastroenterology to ensure high quality healthcare delivery to BE patients by encouraging practices consistent with recommended guidelines. In addition, quality metrics are likely to impact healthcare reimbursements by government-based and private insurers in the future. A recent consensus conference sponsored by the American Gastroenterological Association (AGA) (36) proposed quality indicators using a modified Delphi method. These quality indicators encompass management and treatment goals for patients with Barrett's esophagus. These indicators all garnered at least 80% agreement by a group of 25 international experts on BE.

Out of eight quality indicators, two statements focused on treatment and management of BE and early cancer. The first quality indicator pertaining to treatment stated that in patients with dysplastic BE or EAC, endoscopic resection should be performed of any raised or suspicious lesions. Endoscopic resection has been shown to be superior to endoscopic ultrasound and superficial biopsies in achieving more accurate histologic grading and local tumor staging (37, 38). With EMR, up to 50% of BE patients with early neoplasia who were referred for EET had a change in the initial pathologic diagnosis in one study (39, 40) with improved interobserver agreement between pathologists (41). Endoscopic resection also provides durable therapy with significant decrease in esophagectomy rates (42, 43). The second quality indicator suggested that in BE patients with neoplasia, the goal of endoscopic therapy is to completely eradicate all BE and any additional areas of dysplasia to achieve complete reversion to neosquamous epithelium. This recommendation is based on evidence that treatment of residual BE after EMR or other EET resulted in a lower rate of metachronous lesions and longer recurrence-free survival (44).

A majority of the eight candidate items were based on moderate quality evidence. The expert group also identified a set of statements that were based on low quality evidence, but had >80% consensus agreement. Of these, statements pertaining to EET recommended that no more than two-thirds of the esophageal circumference be treated with endoscopic resection in a single session due to an increased risk of stricture formation. In addition, RFA was considered an acceptable modality of EET in patients with flat HGD. Following EET, in patients with HGD and/or T1a EAC endoscopic surveillance was recommended at 3, 6, 12, 18, and 24 months and yearly thereafter with both targeted and random biopsies of the neosquamous epithelium.

A second expert panel derived quality indicators specifically for EET in BE, using the RAND Appropriateness Method. These 33 experts considered pre-procedure, intra-procedure and post-procedure domains, to derive 13 “appropriate” quality indicators (Table 2). These quality indicators include such important outcomes as the proportion of patients attaining CE-IM and CE-D. The indicators also propose benchmark thresholds for success. For instance, the proposed threshold for success for CE-IM by 18 months from initiation of endoscopic therapy for a patient with dysplastic BE was 70%, and for CE-D was 80%. These findings were presented in abstract form at DDW (45) and are under review in manuscript form.

In summary, quality indicators derived from expert consensus and existing evidence are designed to serve as guidelines to clinicians who treat BE patients to standardize healthcare delivery. They will also serve as useful benchmarks for training in EET, and to understand competency of individual practitioners as well as institutional EET programs. It is likely that these quality metrics will increasingly be used as part of initiatives seeking to pay for quality, as opposed to fee-for-service models.

Conclusion

EET is a safe and effective treatment of BE with dysplasia and early neoplasia. EET involves a combination of endoscopic resection and ablation techniques. These procedures are complicated and involve knowledge of patient selection, identification of lesions to be treated, the procedural skills of optimal endoscopic resection and ablation techniques, and experience with managing complications. Professional societies like the ASGE offer programs in both the cognitive and procedural training of Barrett's endotherapy. However, there is limited evidence to guide BE endotherapy training. Similarly, assessment of competency does not commonly occur in clinical practice, and suggestions for necessary case volumes to achieve competency are based on scant data, largely comparing high volume endoscopists to low-volume endoscopists. Despite these drawbacks, treatment outcomes and minimization of adverse events likely depend on the quality and standardization of EET. In an effort to quantify quality and set benchmarks for effectiveness, quality metrics specific to EET have been developed. While these quality metrics have been defined, they are not widely reported or applied. Similarly, there is no standardized EET training curriculum or competency testing required by endoscopists performing these therapies, but implementing training programs will likely improve overall quality and decrease variability in EET for BE. Future work should concentrate on the development of

both standardized, widely applied curricula for learning EET skills, as well as standardized assessment of competency in these skills.

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Abbreviations

BE	Barrett's esophagus
EAC	Esophageal adenocarcinoma

LGD	Low-grade dysplasia
EET	Endoscopic eradication therapy
EMR	Endoscopic mucosal resection
ESD	Endoscopic submucosal dissection
RFA	Radiofrequency ablation
HGD	High-grade dysplasia
CE-N	Complete eradication of neoplasia
CE-D	Complete eradication of dysplasia
CEIM	Complete eradication of intestinal metaplasia
APC	Argon plasma coagulation
BSG	British Society of Gastroenterology
ACG	American College of Gastroenterology
ASGE	American Society for Gastrointestinal Endoscopy
AGA	American Gastroenterological Association

Highlights

- Endoscopic eradication therapy (EET) has been established as a safe and effective treatment of Barrett's esophagus with dysplasia and early neoplasia.
- There is limited data on training pathways for EET and competency assessment for providers performing these procedures.
- Quality metrics specific to EET have been recently defined but are not well adopted and likely will play a role in setting benchmarks for EET training and for healthcare reimbursement in the future.

Figure 1. Mean Number of Sessions Required to Achieve Complete Eradication of Intestinal Metaplasia (CE-IM) by the Center's Total Case Experience Prior to Patients' First RFA Treatment. Reprinted with permission (22).

Figure 2. Correlation between the number of patients treated by radiofrequency ablation (RFA) by each endoscopist and rate of complete remission of intestinal metaplasia (CRIM). Reprinted with permission (33).

Figure 3. Thirty-day and 90-day mortality curves for low volume and high volume endoscopists show similar clinical outcomes during the early component of learning EMR. Reprinted with permission (32).

Table 1
Top 10 ranked learning points identified by participants and experts from a formalized endoscopic resection program (21)

Rank	Learning Point
1	Do not compromise inspection and delineation of the lesion – allow sufficient time for inspection and use a high-definition endoscope
2	Place electrocoagulation markings to delineate the area to be resected to create a pre-procedural plan
3	Know the management of bleeding
4	Optimize the endoscopic view by repeatedly cleaning out the stomach, esophagus, and the target area
5	Use an endoscope with a separate water-jet channel
6	Always perform a test suction prior to the endoscopic resection
7	Keep instruments (snare, injection needle, argon plasma coagulation [APC] probe) close to the tip of the endoscope
8	In case of piecemeal endoscopic resection, lift the edges of the previous endoscopic resection prior to subsequent resections
9	Know the management of perforation
10	Pin the specimens down onto cork or paraffin to optimize orientation and cutting in the pathology laboratory

Table 2
Appropriate quality indicators using the RAND UCLA Appropriateness Methodology
and suggested threshold benchmark (45)

Quality Indicator	Threshold (range)
Pre - Procedure	
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	90 (75, 100)
Centers where EET is performed should have available high definition white light endoscopy (HD-WLE) and expertise in mucosal ablation and EMR techniques	N/A
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.	>98 (85, 100)
Intra - Procedure	
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 (75, 100)
The rate at which presence or absence of visible lesions is reported in patients with Barrett's esophagus referred for EET	90 (60, 100)
The rate at which the Barrett's esophagus segment is inspected using high definition white light endoscopy (HD-WLE)	95 (0, 100)
The rate at which complete endoscopic resection (defined as en bloc resection or piecemeal) is performed in patients with Barrett's esophagus with visible lesions	90 (80, 100)
Among patients undergoing EET who have not yet achieved CE-IM, the rate at which a defined interval for subsequent EET is documented	90 (0, 100)
The rate at which CE-N is achieved by 18 months in patients with Barrett's related dysplasia or intramucosal cancer referred for EET	80 (70, 95)
The rate at which CE-IM is achieved by 18 months in patients with Barrett's related dysplasia and intramucosal cancer referred for EET	70 (50, 80)
Post - Procedure	
Among patients who achieve CE-IM, the rate at which a recommendation is documented for endoscopic surveillance at a defined interval	90 (50, 100)
During endoscopic surveillance after EET, the rate at which biopsies of any visible mucosal abnormalities are performed.	95 (50, 100)
The rate at which an anti-reflux regimen is recommended after EET	90 (50, 100)
The rate at which adverse events are being tracked and documented in individuals post EET	90 (50, 100)