Adherence to Surveillance Guidelines in Nondysplastic Barrett's Esophagus.

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ABSTRACT

Introduction: Surveillance patterns in Barrett's esophagus (BE) are not well characterized. Guidelines published between 2002-2008 recommended surveillance esophagogastroduodenoscopy (sEGD) at three-year intervals for nondysplastic BE (NDBE). We assessed guideline adherence in incident NDBE in a VA-based study.

Methods: At a single VA center, we identified incident cases of biopsy-confirmed NDBE between 1/2006-12/2008. We excluded patients age ≥76 years and those who developed BE-associated dysplasia or cancer during follow-up. All sEGDs through 10/2014 were documented. Our primary criteria classified cases as guideline *adherent* if a sEGD was performed within 6 months of each expected three-year surveillance interval; in cases with ≥2 sEGDs, one sEGD >6 months and ≤1 year outside an interval was allowed if the average interval was between 2.5 and 3.5 years. Comorbidity, primary care (PC) encounters, presence of long segment BE (LSBE), endoscopist recommendations, and Charlson comorbidity index (CCI) were assessed.

Results: We identified 110 patients (96.4% male, 93.6% Caucasian) with mean age 58.9 ± 8.5 years at index EGD. Median follow-up was 6.7 years (range 3.7-8.6). 33 (30.0%) cases were guideline *adherent*; 77 (70.0%) cases were *non-adherent*, including 52 (47.3%) with irregular surveillance and 25 (22.7%) with no surveillance. 40 cases (14 *adherent*) had 1 sEGD, 36 (18 *adherent*) had 2, 8 (1 *adherent*) had 3, and 1 *non-adherent* case had 4. *Adherent* cases were significantly older (61.5 vs 57.9 years, p=0.04), and tended to have more LSBE (33.3% vs 20.8%, p=0.16). There were no differences between *adherent* and *non-adherent* cases in annual PC encounters (72.7% vs 66.2%, p=0.66), CCI ≥4 (15.2% vs 15.6% p=0.95), biopsy-positive sEGDs (75.8% vs 76.6%, p=0.92), and any recommendation for subsequent surveillance (81.8% vs 77.9%, p=0.65). A logistic regression model using age, CCI, and LSBE showed an independent association between adherence and older age (p=0.03).

Conclusions: In a single-center VA cohort, sEGD of NDBE was mostly *non-adherent* to guidelines. *Adherent* cases were older at baseline with a trend towards more LSBE. A larger study is needed to identify medical and social factors associated with adherence or non-adherence to surveillance.

INTRODUCTION

Barrett's esophagus is a premalignant condition of the esophagus associated with an increased risk of esophageal adenocarcinoma [1-3], and for which endoscopic surveillance is recommended. The guidelines from major gastrointestinal societies published between 2002 and 2008 specify a 3-year surveillance interval for non-dysplastic Barrett's esophagus (NDBE) [4-6]. In part because of recent data indicating a lower-than-expected risk of adenocarcinoma arising from Barrett's epithelium [7], more recent guidelines have extended the surveillance interval to 3-5 years. [8, 9]

While most endoscopists practice endoscopic surveillance for NDBE [10], there is considerable variation in surveillance patterns and adherence to guideline recommendations [10-16]. Particularly in community practice, adherence to surveillance guidelines is low. [14] One multicenter study demonstrated overutilization of endoscopic surveillance in NDBE as measured by patient report [17], whereas a previous VA-based multicenter study showed that regular surveillance was practiced in only 23% of patients who had at least 6 years of follow-up. [18]

Most of the previous studies are limited by reliance on surveys and questionnaires, or by a lack of pathology. In addition, clinical factors (such as severe comorbidity and patient age) that might explain deviation from surveillance guidelines are not available. We conducted a single-center VA-based study to assess electronic medical record-based adherence to guideline recommendations in biopsy-proven incident NDBE. The primary

aim was to quantify adherence to surveillance guidelines; the secondary aim was to identify factors associated with adherence.

METHODS

This study protocol was approved with a waiver of informed consent by the Indiana University Institutional Review Board and by the Research Committee at the Richard L. Roudebush VA Medical Center in Indianapolis, IN. We searched the Indianapolis VA's electronic medical record (Computerized Patient Record System [CPRS]) and a linked, independent endoscopy database (ProVation, Inc.) to identify all incident cases of NDBE diagnosed between January 2006 and December 2008. Within the ProVation software, search queries specifying upper endoscopy with endoscopic findings of BE and maneuvers including "Barrett's biopsies" or "esophageal biopsies" were utilized to identify all potential BE cases. Within the CPRS, ICD-9 and CPT codes were used to identify potential incident BE cases. Codes included ICD-9 code 530.85 for Barrett's Esophagus, and CPT codes 43235, 43236, 43239, 43241-43251, and 43255-43258.

Patient records from ProVation and CPRS were merged using SAS 9.2 to identify the total number of unique patients during the study period. Pathology reports for these patients were then manually reviewed. Patients were included for analysis if they had biopsy-confirmed, incident diagnosis of BE during the study period and were younger than 76 years of age at the time of diagnosis.

We excluded prevalent cases of Barrett's esophagus, including those diagnosed outside our center, as well as patients with any grade of dysplasia or adenocarcinoma diagnosed at time of index procedure through the 1st surveillance endoscopy, and patients with no further VA encounters after the index diagnosis.

We abstracted data on patient demographics, symptoms, comorbidities, and number of primary care (PC) encounters. Data were also collected on procedural characteristics including presence or absence of long-segment BE (LSBE), endoscopist recommendations for timing of subsequent surveillance, and biopsy results from surveillance exams. The Charlson-Deyo comorbidity index (CCI) score was calculated for each patient.

Index and surveillance endoscopies:

The index endoscopy refers to the first documented upper endoscopy procedure at the Roudebush VA Medical Center with findings of an irregular z-line or BE, and during which biopsies of the z-line or esophagus were taken with confirmation of BE. Surveillance intervals are defined as 3-year periods between surveillance EGDs (sEGD) for BE. This interval was chosen based on the 2002-2008 ACG and ASGE guidelines [4-6], which best corresponded to the time frame of our incident cases. We assumed that surveillance practices during the follow-up period most likely reflected these guidelines, and that these practices had not yet been significantly impacted by updates to the guidelines in 2011 and 2012, which increased acceptable intervals to 3-5 years. [8, 9] Surveillance at our center was largely performed using a recall database, where patients

were contacted based on an endoscopist's recommendation at the time of a sEGD and pathology review; these recommendations were unlikely to have been modified by updates to the guidelines.

All sEGDs had the indication of "follow-up" or "surveillance" of BE, and required esophageal biopsies to be taken during the same procedure. If a procedure was performed for an alternate indication but fell within the expected surveillance interval in the absence of another sEGD within that interval, and if esophageal biopsies were taken, this procedure was considered to be the sEGD corresponding to that interval.

If sEGD was aborted prior to biopsies being taken, or if biopsies were not taken due to severe esophagitis, only the subsequent exam with biopsies was counted towards surveillance. If biopsies during sEGD were incomplete or yielded indeterminate biopsy results and necessitated a shorter interval follow-up EGD, only the initial sEGD with biopsies was counted towards surveillance.

Based on guideline recommendations to repeat the EGD 1 year following the index diagnosis of BE [5, 6], we allowed for a single confirmatory endoscopy within 15 months of BE index diagnosis (the 1-year confirmatory endoscopy along with a 3-month "buffer" period), and did not count this confirmatory endoscopy towards surveillance. In cases without a confirmatory endoscopy, if the first sEGD occurred earlier than 6 months from the expected 3-year surveillance interval, we only assessed guideline adherence from this point forward to prevent biasing towards over-surveillance.

Patient follow-up

Follow-up was conducted from the date of index diagnosis to the date of the last outpatient VA encounter through November 1, 2014. The total surveillance period was determined using the date of the confirmatory endoscopy (or the date of the index endoscopy in cases without a confirmatory endoscopy) along with the date of the last outpatient VA encounter. Follow-up was assessed by review of CPRS at our center, and VistaWeb to account for other VA centers where the patient may have received medical care.

Determining guideline adherence

For our primary set of criteria, a case was considered *adherent* to guidelines if each sEGD was performed within 6 months (on either side) of the expected three-year surveillance interval, and surveillance was not yet overdue by more than 6 months. In cases with more than one sEGD that did not satisfy the preceding criterion, a single sEGD up to 1 year outside of the expected interval was accepted as adherent if the total number of years per sEGD (total surveillance period/ total number of sEGDs) was ≥ 2.5 and ≤ 3.5. Any case not meeting these criteria was considered to be guideline *non-adherent*. Among cases that were guideline *non-adherent*, we sub-classified cases as having *no surveillance* or *irregular* surveillance.

We also examined adherence to a secondary, more lenient set of criteria as a type of sensitivity analysis, where a case was considered non-adherent if a single sEGD was

performed more than 1 year outside of an expected three-year interval, was more than 1 year overdue, or if two or more sEGDs were performed more than 6 months outside of the expected surveillance interval. All other cases were then considered to be guideline-adherent.

Data analysis

Descriptive analyses were conducted using means and standard deviations for continuous variables and proportions for categorical and binary variables. Bivariate analysis was performed to test the association of patient and procedural factors with guideline-adherence. To determine factors independently associated with adherence / non-adherence, logistic regression analysis was performed to model the association between patient and procedural factors with guideline-adherence. A bivariate p-value of 0.10 or less and clinical judgment were used to select candidate variables for the multiple logistic regression equation.

RESULTS

A total of 110 patients (96.4% male, 93.6% Caucasian) were included in the analysis (**Figure 1**), with mean age 58.9 ± 8.5 years at index EGD. Median total follow-up was 6.7 years (IQR 1.3, range 3.7-8.6) years. Median duration of the surveillance period was 6.3 years (IQR 1.6, range 3.7-8.6). Patient and index procedure characteristics are described in **Table 1**.

Using the primary adherence criteria, 33 (30.0%) patients were determined to be guideline-adherent; 77 (70.0%) cases were non-adherent, including 52 (47.3% overall) with irregular surveillance and 25 (22.7% overall) with no surveillance. A total of 85 patients had at least one sEGD performed during the surveillance period, while 45 patients had at least two sEGDs and 9 had at least three (**Figure 2).**

Differences between adherent and non-adherent patients are shown in **Table 2**. In bivariate analysis, adherent patients were older (61.3 vs 57.9 years, $p<0.001$), and tended to have more LSBE (33.3% vs 20.8%, $p=0.16$). There were no differences in proportions with at least an annual PC encounter, CCI score of ≥ 4, sEGDs with biopsy-positive BE, or in recommendation given by the endoscopist for timing of subsequent sEGD. There were also no significant associations between guideline-adherence and any patient characteristic, including symptoms at time of index EGD and individual comorbid conditions.

The recommended intervals for future surveillance provided by the endoscopist performing each sEGD are shown in **Figure 3**. Following the index EGD, the recommendation was to perform follow-up EGD within 1 year in 77.3% of cases, likely reflecting the guideline recommendations to have a confirmatory EGD 1 year after index BE diagnosis. For subsequent surveillance, the endoscopists recommended sEGD at 3-year intervals for the majority of cases, which followed 2002-2008 guidelines. The observed recommendations did not reflect updated guidelines from 2011 and 2012, as a

minority of endoscopists recommended surveillance at 3-5 year intervals. This lag between updated surveillance guidelines and application to practice suggests that the updated guidelines had not been widely adopted during the surveillance period, or had not yet impacted surveillance practices.

A logistic regression analysis of the association between guideline-adherence and age, CCI group, and presence of LSBE showed an independent association between adherence and older age (p=0.03; OR 1.06; CI 1.01-1.12). CCI group (p=0.24) and presence of LSBE (p=0.12) were not associated with adherence. Age and presence of LSBE were included in the model based on results from bivariate analysis, and CCI group was included due to its perceived impact on real-life surveillance practices.

In sensitivity analysis, we assessed adherence using the more lenient secondary criteria and found that the proportion of adherent cases remained in the minority at 41.8%. In addition, while it is unlikely that the ASGE 2012 guidelines [9] had a significant impact on surveillance practices during the study period, we applied these guidelines in conjunction with the primary criteria to any surveillance interval that potentially could have been modified to reflect the updated guideline recommendations; under these conditions adherence was 46.4%.

DISCUSSION

In this single-center VA-based study of 110 incident cases of biopsy-confirmed Barrett's esophagus, we compared actual surveillance practices with surveillance recommendations based on the 2002-2008 guidelines. We found that the minority of cases (30%) were guideline-adherent. This remained true even when using a more lenient set of criteria for quantifying adherence, which intended to allow for greater flexibility in scheduling, patient compliance, and other factors that might have delayed surveillance.

Over the past decade, a limited number of studies on endoscopic surveillance of BE indicate that most gastroenterologists perform surveillance to some degree. [8, 10, 14, 16, 19] In a survey of mostly U.S. community gastroenterologists, 86% practiced surveillance for NDBE [10], while in a recent European survey of mostly university-based gastroenterologists, 76% practiced surveillance for NDBE. [19] In another large survey of 470 North American AGA members, 79% performed surveillance for NDBE [16] in accordance with the 2011 AGA guidelines. [8]

Considerable variation has been reported in actual surveillance patterns. Surveys of physicians from the UK [12], France [11], and the Netherlands [20] show that surveillance generally follows international guidelines, although it is less consistent in the presence of LGD. [12] In a large UK-based survey on the management of BE, wide variation was reported in surveillance for specific subgroups (those with LSBE or mucosal abnormalities were more likely to be surveyed), surveillance interval, and biopsy

protocol. The majority of gastroenterologists who do not offer surveillance claimed a lack of efficacy and the need for stronger evidence for surveillance as the reason. [21]

Another study suggested that endoscopy is over-utilized for surveillance in BE. In this multicenter study, 235 patients with NDBE were given a survey to collect data including validated measures of quality of life, symptom severity, cancer risk perception, and number of times they underwent surveillance endoscopies. The investigators presumed that all post-diagnosis endoscopies were for surveillance purposes, and found that overutilization occurred in 65% of cases using a cutoff of >1 endoscopy per three year period. A trend towards over-surveillance was seen with private insurance, although no demographic factors, health behaviors, or symptom severity measures were associated with over-surveillance. [17]

Prior VA-based studies have suggested that most veterans do not undergo regular surveillance. El-Serag et al demonstrated that of 4499 patients with a minimum of six years follow-up, only 23.0% had regular surveillance, while 26.7% had irregular surveillance and 50.3% had no surveillance. Study limitations include potential misclassification of BE and surveillance from use of ICD-9 codes for cohort identification and lack of pathology data. [18] In a single VA center without a formal surveillance program, 305 (64.6%) of 472 patients diagnosed with BE did not have surveillance based on review of medical records; 165 patients underwent surveillance with a median surveillance interval of 50 months (range 3-204); 44 patients missed their surveillance by 6 months or more, and 23 missed their surveillance by twice the

recommended interval of 3 years. [22] Our results add further evidence of under-surveillance in the veteran population.

Inconsistencies and limitations in reported surveillance practices among prior studies may be related to reliance on surveys [11, 12, 16-20], variable inclusion criteria for surveillance endoscopies [17, 18, 22], and lack of histologic data [17, 18]. We attempted to circumvent these issues and provide a true estimate of endoscopic surveillance by clarifying the indication of each endoscopy and measuring actual surveillance frequency by reviewing endoscopic records. We minimized the possibility of misclassifying BE cases from over-reliance on coding queries by selecting histologically confirmed cases. Finally, we performed sensitivity analysis by using more lenient surveillance intervals to avoid biasing the results towards under-surveillance; adherent patients remained in the minority, with an absolute difference of 11.8% compared to our primary criteria.

Multiple logistic regression found that older age was independently associated with guideline-adherence. This finding contrasts with that of a previous VA-based study, in which El-Serag et al showed that compared to patients with no surveillance, patients with at least one sEGD were more likely to be under 65 years of age. Guideline-adherent patients were also somewhat more likely to have GERD, obesity, dysphagia, strictures, and less likely to have a high Deyo comorbidity score. [18] Although we hypothesized that guideline non-adherence could be explained by increasing comorbid conditions as reflected by a higher CCI, this hypothesis was not confirmed by the logistic regression.

Despite the low rate of guideline-adherence in our cohort, only a fraction of cases with non-adherence could be attributed to a recommendation made by the endoscopist that deviated from the guidelines. At the time of surveillance, the endoscopist recommended three-year follow-up for subsequent sEGD in the majority of cases, suggesting that the endoscopists generally intended to follow guidelines, but that competing variables − including facility-level factors not included in our logistic model − may have impacted observed surveillance patterns. Facility-level variation across multiple VA facilities has been shown to influence surveillance, including the finding that patients seen at a smaller VA facility (< 87 beds) were more likely to have undergone surveillance. [18]

Our study has important limitations to consider. Given the observational and retrospective nature of this study, we could not account for the contribution of certain unobserved factors including patient refusal or noncompliance with surveillance, surveillance conducted at non-VA facilities, and undocumented comorbid conditions and symptom severity. In addition, while we considered the intention of endoscopists regarding future surveillance based on recommended follow-up intervals, we could not account for facility-level factors, including reliance on a recall database and use of an open-access system, as is our endoscopy unit. Finally, our results are based on a cohort of veteran patients at a tertiary VA center and may not apply to other health-care settings.

In an open-access endoscopy unit such as ours, lack of adherence may reflect inadequate understanding of the surveillance guidelines on the part of the primary care provider. However, while patients are often referred for Barrett's screening by the primary

provider, their role in determining the appropriate surveillance interval at our center is limited. This interval is determined by the endoscopist completing the exam, entered into a recall database, and documented in the medical record. Thus, non-adherent surveillance less likely reflects the primary provider's awareness of guideline recommendations. In fact, the primary provider often relies on the endoscopist to manage this aspect of a veteran's care.

If guideline-adherence is truly uncommon in veterans, the reasons for this were not elucidated by examination of the medical record and require further study. The low incidence of EAC in NDBE may impact decision-making regarding surveillance on the part of both providers and patients. Future studies should aim to assess adherence to surveillance recommendations in the context of updated guidelines, which liberalize surveillance to 3-5 year intervals, and should identify the patient-, provider-, and/or systems-specific reasons for non-adherence with surveillance guidelines.

In summary, guideline-adherence was observed in the minority of patients in our study of veterans with histologically-confirmed BE when considering only true surveillance procedures. In conjunction with prior VA-based studies, our findings may lead to heightened awareness for under-surveillance in the veteran population, and provide the impetus for establishing quality measures to ensure that guideline-driven endoscopic surveillance is considered for all patients with BE.

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Table 1. Patient and Index EGD Characteristics		
Age at index (mean ± st dev)	58.9 ± 8.5	
Length of follow-up (yrs) [median (range)]	6.7 (3.7-8.6)	
Length of surveillance (yrs) [median (range)]	6.3 (3.7-8.6)	
Sex	n	%
Male	106	96.4%
Female	4	3.6%
Race	n	%
White	103	93.6%
Black	7	6.4%
Index procedure		
Indication		
GERD/heartburn	37	33.6%
Abdominal pain/dyspepsia	16	14.5%
Anemia	15	13.6%
Dysphagia	13	11.8%
Follow-up of esophagitis	5	4.5%
GI Bleed	5	4.5%
Diarrhea	4	3.6%
History liver disease/varices	3	2.7%
Nausea ± vomiting	3	2.7%
Weight loss	3	2.7%
Other	6	5.5%
Endoscopic finding		
Long segment BE	27	24.5%
Short segment BE	63	57.3%
Irregular Z-line	20	18.2%
Recommended to repeat EGD in 6 months*	5	4.5%
Recommended to repeat EGD in 1 year*	72	66.1%

*For confirmatory EGD

Table 2. Comparison of Surveillance-Adherent and -Non-Adherent Patients			
	Adherent	**Non-adherent**	**p-value**
Total number of patients	33 (30.0%)	77 (70.0%)	
Mean age (yrs +/- SD)	61.3 (±7.7)	57.9 (±8.7)	**<0.001**
Congestive heart failure	1 (3.0%)	6 (7.8%)	0.35
Chronic pulmonary disease	7 (21.2%)	12 (15.6%)	0.47
Heartburn	17 (51.5%)	38 (49.4%)	0.84
Abdominal pain/dyspepsia	8 (24.2%)	22 (28.6%)	0.64
Dysphagia	10 (30.3%)	14 (18.2%)	0.16
Mean length of follow-up (years)	6.1 (±1.0)	6.5 (±1.2)	0.21
Long segment BE	11 (33.3%)	16 (20.8%)	0.16
Patients with annual PCP encounter	24 (72.7%)	51 (66.2%)	0.66
sEGDs with biopsy-positive BE (overall)	25 (75.8%)	59 (76.6%)	0.92
Any recommendation given by endoscopist for timing of next sEGD	27 (81.8%)	60 (77.9%)	0.65
Charlson-Deyo Comorbidity Index			
0	16 (48.5%)	27 (35.1%)	
1	5 (15.2%)	20 (26.0%)	
2	5 (15.2%)	13 (16.9%)	
3	2 (6.0%)	5 (6.5%)	
4+	5 (15.2%)	12 (15.6%)	
Confirmatory EGD	15 (45.5%)	30 (39.0%)	0.53
Number (%) with positive biopsy result for BE	13 (86.7%)	19 (63.3%)	**0.04**
Number (%) recommended to repeat sEGD in 3 years by endoscopist	15 (100%)	24 (80.0%)	0.07
1st Surveillance EGD	33 (100.0%)	52 (67.5%)	
Number (%) with positive biopsy result for BE	24 (72.7%)	39 (75.0%)	
Number (%) recommended to repeat sEGD in 3 years by endoscopist	28 (84.8%)	35 (67.3%)	
Number of deaths during follow-up	3 (9.1%)	7 (9.1%)	1.00
Median follow-up [years (range)]	6.5 (3.7-6.7)	4.3 (3.9-7.0)	

FIGURE KEY

Figure 1: Patient Inclusion

Figure 2: Overall Endoscopic Surveillance Patterns During Follow-Up Period

Figure 3: Endoscopist Recommendation For Timing of Follow-Up EGD

Figure 1

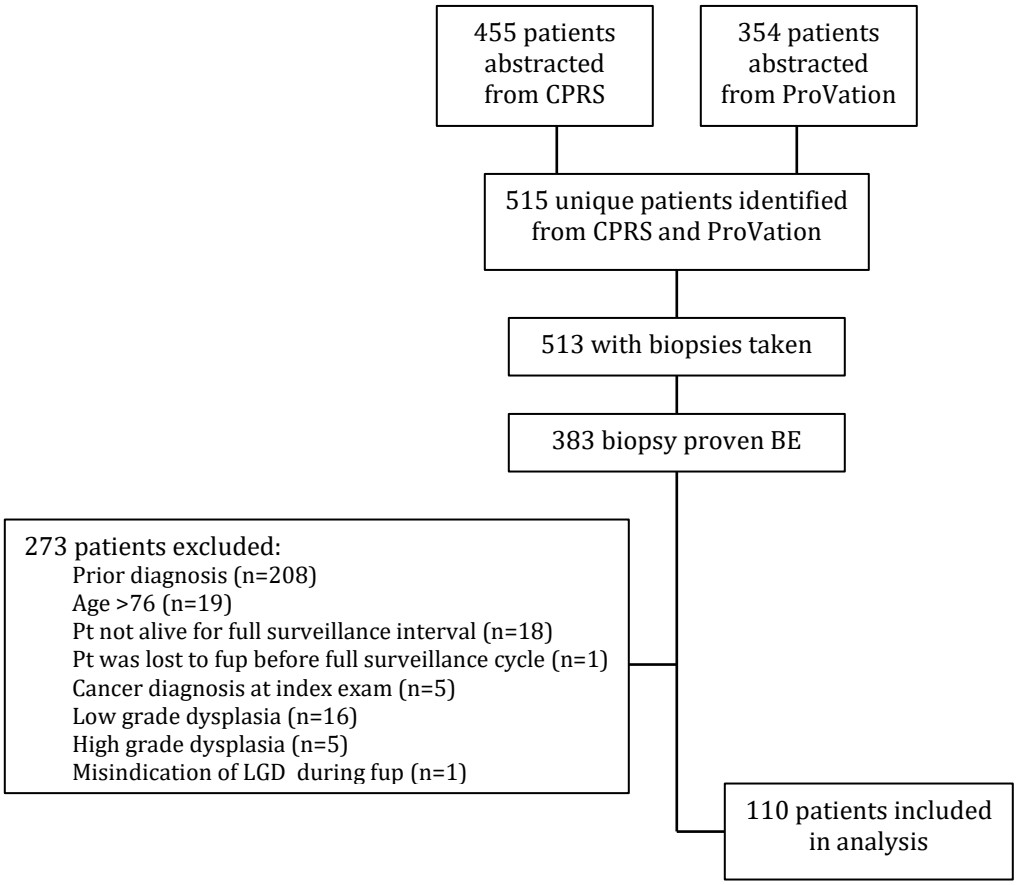

455 patients abstracted from CPRS
354 patients abstracted from ProVation
515 unique patients identified from CPRS and ProVation
513 with biopsies taken
383 biopsy proven BE
273 patients excluded:
Prior diagnosis (n=208)
Age >76 (n=19)
Pt not alive for full surveillance interval (n=18)
Pt was lost to fup before full surveillance cycle (n=1)
Cancer diagnosis at index exam (n=5)
Low grade dysplasia (n=16)
High grade dysplasia (n=5)
Misindication of LGD during fup (n=1)
110 patients included in analysis

Figure 2

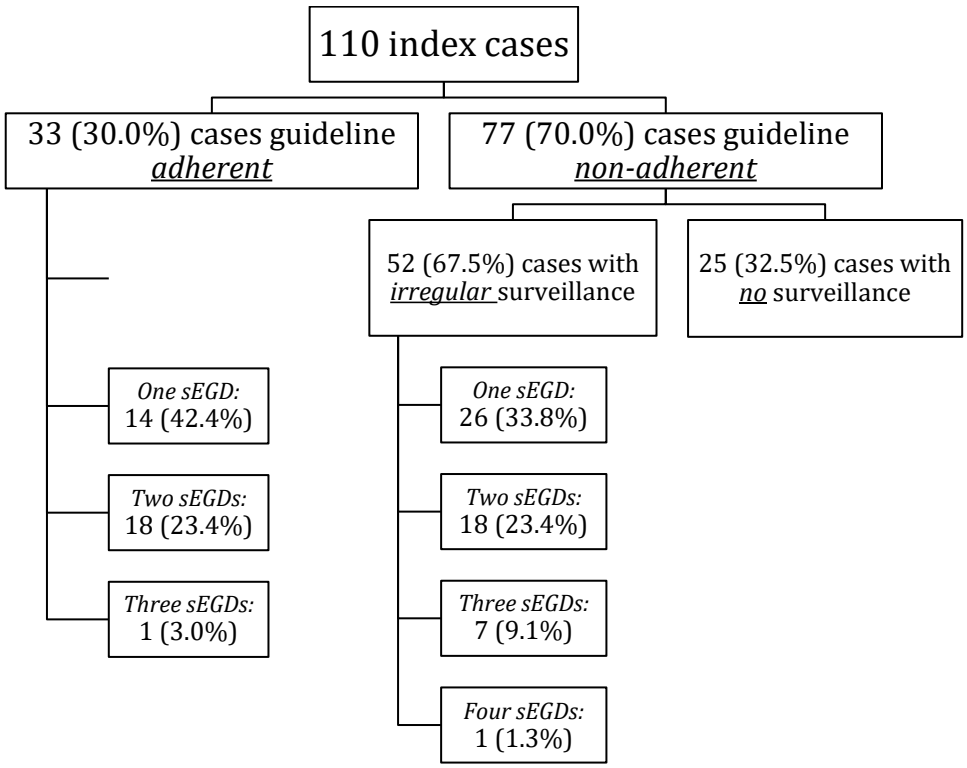
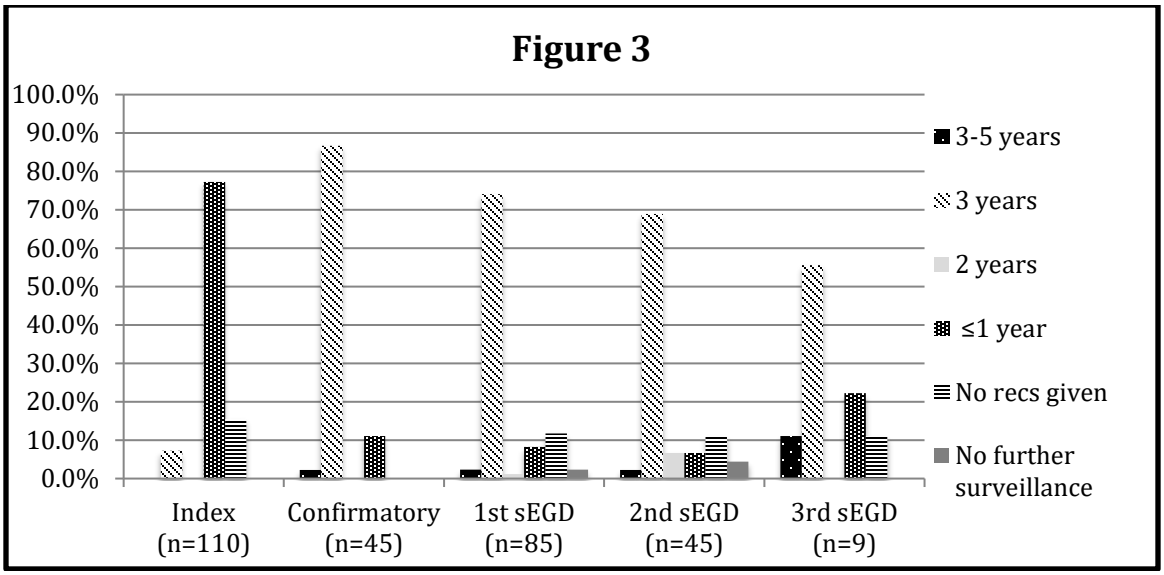

110 index cases
33 (30.0%) cases guideline adherent
77 (70.0%) cases guideline non-adherent
52 (67.5%) cases with irregular surveillance
25 (32.5%) cases with no surveillance
One sEGD: 14 (42.4%)
Two sEGDs: 18 (23.4%)
Three sEGDs: 1 (3.0%)
One sEGD: 26 (33.8%)
Two sEGDs: 18 (23.4%)
Three sEGDs: 7 (9.1%)
Four sEGDs: 1 (1.3%)

Figure 3


100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
Index (n=110)
Confirmatory (n=45)
1st sEGD (n=85)
2nd sEGD (n=45)
3rd sEGD (n=9)
3-5 years
3 years
2 years
≤1 year
No recs given
No further surveillance