ORIGINAL ARTICLES—ALIMENTARY TRACT

Adherence to Biopsy Guidelines for Barrett's Esophagus Surveillance in the Community Setting in the United States

JULIAN A. ABRAMS,[*,‡] ROBERT C. KAPEL,[§] GUY M. LINDBERG,[‖] MOHAMMAD H. SABOORIAN,[‖] ROBERT M. GENTA,[‖,¶] ALFRED I. NEUGUT,[*,‡,#] and CHARLES J. LIGHTDALE[*,‡]

[*]Department of Medicine and [#]Department of Epidemiology, Columbia University College of Physicians and Surgeons, New York, New York; [‡]Herbert Irving Comprehensive Cancer Center, Columbia University, New York, New York; [§]Division of Gastroenterology, Danbury Hospital, Danbury, Connecticut; [‖]Caris Diagnostics, Irving, Texas; and [¶]Department of Pathology, University of Texas Southwestern Medical Center, Dallas, Texas

This article has an accompanying continuing medical education activity on page 710. Learning Objectives—After completing this CME activity, the learner should be able to understand further the epidemiology of Barrett's esophagus and adenocarcinoma, and the impact of adherence to biopsy guidelines for Barrett's esophagus in a community setting.

See CME exam on page 710.

BACKGROUND & AIMS: Current surveillance guidelines for Barrett's esophagus (BE) recommend extensive biopsies to minimize sampling error. Biopsy practice patterns for BE surveillance in the community have not been well-described. We used a national community-based pathology database to analyze adherence to guidelines and to determine whether adherence was associated with dysplasia detection. **METHODS:** We identified 10,958 cases of established BE in the Caris Diagnostics pathology database from January 2002–April 2007. Demographic, pathologic, and endoscopic data were recorded. Dysplasia was categorized as low grade, high grade, or adenocarcinoma. Adherence was defined as ≥4 esophageal biopsies per 2 cm BE or a ratio ≥2.0. Generalized estimating equation multivariable analysis was performed to assess factors associated with adherence, adjusted for clustering by individual gastroenterologist. **RESULTS:** A total of 2245 BE surveillance cases were identified with linked endoscopy reports that recorded BE length and could be assessed for adherence. Adherence to guidelines was seen in 51.2% of cases. In multivariable analysis, longer segment BE was associated with significantly reduced adherence (3–5 cm, odds ratio [OR] 0.14, 95% confidence interval [CI] 0.10–0.19; 6–8 cm, OR 0.06, 95% CI 0.03–0.09; ≥9 cm, OR 0.03, 95% CI 0.01–0.07). Stratified by BE length, nonadherence was associated with significantly decreased dysplasia detection (summary OR 0.53, 95% CI 0.35–0.82). **CONCLUSIONS: Adherence to BE biopsy guidelines in the community is low, and nonadherence is associated with significantly decreased dysplasia detection. Future studies should identify factors underlying nonadherence as well as mechanisms to increase adherence to guidelines to improve early detection of dysplasia.**

To view this article's video abstract, go to the AGA's YouTube Channel.

The incidence of esophageal adenocarcinoma (EAC) has increased rapidly in the Western world during the past 3 decades.[1,2] Barrett's esophagus (BE), the presence of columnar mucosa with intestinal metaplasia in the esophagus, is associated with a 30- to 40-fold increased risk of EAC.[3] The overall 5-year survival for patients with EAC in the United States is ~15%[4] and depends heavily on the stage of diagnosis.[5] Endoscopic surveillance is recommended for patients with established BE, with the goal of detecting high-grade dysplasia or early cancer before the development of advanced EAC.[6]

The presence of dysplasia within Barrett's mucosa is often patchy,[7–10] and thus esophageal biopsies are associated with significant sampling error. A biopsy protocol of random 4 quadrant biopsies every 2 cm results in increased detection of dysplasia.[10–12] As part of its first guidelines for the surveillance of patients with BE, the American College of Gastroenterology (ACG) in 1998 recommended the use of this sampling method,[13] also known as the Seattle biopsy protocol. This technique has remained the standard sampling method for endoscopic surveillance in patients with BE.

Endoscopic surveillance has been shown to result in the detection of adenocarcinoma at earlier stages as well as improved survival in patients with EAC who underwent endoscopic surveillance, as compared with those who did not.[14–20] However, according to several survey studies, only 26%–77% of endoscopists adhere to the Seattle protocol in clinical practice.[21–26] Therefore, we decided to use a national community-based pathology database to analyze adherence to surveillance biopsy guidelines in patients with established BE, to assess for factors associated with adherence to guidelines, and to deter-

Abbreviations used in this article: ACG, American College of Gastroenterology; BE, Barrett's esophagus; CI, confidence interval; EAC, esophageal adenocarcinoma; GEE, generalized estimating equation; OR, odds ratio.

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mine whether detection of dysplasia is associated with adherence to biopsy guidelines.

Methods

Study Design and Database

We identified patients who underwent surveillance endoscopy for previously diagnosed BE by using a database that had been maintained prospectively by Caris Diagnostics (Irving, TX). This database is derived from all patients referred to Caris Diagnostics, a provider of gastrointestinal pathology services for physicians from community-based freestanding endoscopy centers from 34 states throughout the United States.

We used WinSURGE anatomic pathology software (Computer Trust Corporation, Boston, MA) to perform all database queries. An initial free-text search of clinical indications was performed to find upper endoscopy cases between January 1, 2002, and April 30, 2007 in which the term *Barrett* was present. We then further refined that query by doing a free-text search for several terms that would indicate patients undergoing surveillance endoscopy for BE: "follow-up, history, established," and "surveillance." Subsequently, we manually reviewed the results of the refined query to include those upper endoscopy cases performed for surveillance and to exclude those cases without a clear prior diagnosis of BE (eg, rule out Barrett's esophagus). All data were entered into Microsoft Office Excel 2003 (Microsoft Corporation, Redmond, WA), and MySQL (Sun Microsystems, Santa Clara, CA) was used to store the master database.

Demographic information for all patients is present on the pathology requisitions and was entered into the Caris database. Corresponding endoscopy reports, when available, were manually reviewed, and endoscopic data, including length of BE and presence and size of hiatal hernia, were recorded. Individual gastroenterologists and endoscopy centers were assigned unique identification numbers. All pathology and endoscopy data were deidentified before analysis.

This study was approved by the Columbia University Institutional Review Board.

Pathology Review

The number of tissue biopsies listed on the pathology reports reflected the number of biopsy pieces that were counted and recorded before fixation in paraffin. When the specific number of specimen fragments was not clearly recorded or when the term *multiple* was used, the archived case slides were obtained for manual review and counting.

The presence or absence of intestinal metaplasia and dysplasia was noted. The degree of dysplasia for a particular case was defined as the highest degree (low grade, high grade, or adenocarcinoma) present on any of the biopsies.

The diagnosis of dysplasia or carcinoma (low grade, high grade, EAC) required confirmation by at least 2 pathologists. When the diagnosis was indefinite for dysplasia, the case was classified in the low-grade dysplasia group.

Biopsies are interpreted by a group of gastrointestinal pathologists who share a common approach to biopsy evaluation. This relative uniformity is achieved via predetermined approach to specimen handling, diagnostic criteria, terminology, and diagnosis-specific guidelines. In an effort to reduce interobserver variability, Caris Diagnostics guidelines require that all diagnoses of low-grade dysplasia or greater in specimens from BE are confirmed by a second pathologist, and in case of disagreement, that the case is presented to all pathologists during the daily consensus conference. When this study was begun, Caris used 8 pathologists; Caris currently has 23 pathologists on staff at the Irving location (where the cases were derived from).

Assessment of Adherence to Biopsy Guidelines

The 1998, 2002, and 2008 ACG Guidelines for BE Surveillance[6,13,27] all recommend 4 quadrant biopsies taken every 2 cm throughout the length of BE. We therefore calculated a ratio for each case by using the following formula: (Number of esophageal biopsies) ÷ (Length of BE in cm). If the ratio was <2.0, then the case was defined as nonadherent, and if the ratio was ≥ 2.0, then the case was defined as adherent.

Statistical Methods and Analysis

We used Fisher exact test to analyze categorical variables. Student *t* tests were used to compare continuous variables with normal distributions; Wilcoxon rank sum tests were used to compare all other continuous variables. All tests were two-sided.

Generalized estimating equation (GEE) multivariable modeling was performed, adjusted for clustering by individual gastroenterologist. Presumably, adherence to guidelines is correlated with an individual gastroenterologist's practice pattern; GEE modeling allows for multivariable analysis, taking into account the likelihood that the observed data are not independent. Statistical significance was defined as $P < .05$ or a confidence interval (CI) that did not cross 1.00. All analyses were performed by using Stata 9.2 (StataCorp, College Station, TX).

Results

Biopsies were received from 278,259 upper endoscopies between January 2002 and April 2007. There were 10,958 cases of BE surveillance performed in 9418 unique patients. Cases were submitted by 668 individual gastroenterologists from 214 community-based endoscopy centers in 34 states. The mean age was 62.3 years (standard deviation, 12.9), and 64.3% of the patients were male.

Endoscopy reports were available and reviewed for 4069 cases (37.1%) (Figure 1). Of these, the length of BE was recorded in 2448 (60.2%). The precise number of biopsies taken could not be determined for an additional 203 cases, and these were excluded from the analyses of adherence. Of these 2245 cases, 29 (1.3%) had a documented history of dysplasia (indefinite or greater). The median BE length was 3 cm (interquartile range, 2–5), and long segment BE ($\geq$3 cm) was present in 53.3% of these cases. The median number of biopsies per case was 5 (interquartile range, 3–8), and the median ratio of biopsies taken per centimeter of BE was 2.0 (interquartile range, 1.0–3.0). As compared with the excluded cases, subjects assessed for adherence were older (62.5 vs 61.7 years, $P = .02$) and had a higher proportion of men (69.2% vs 63.4%, $P < .001$).

Pathology Results

Intestinal metaplasia was identified in 6633 cases (60.5%). Of these cases, low-grade dysplasia (including indefinite for dysplasia) was detected in 478 (7.2%), high-grade dys-

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