

# Lifestyle Risk Factors, Quality of Life, and Intervention Preferences of Barrett's Esophagus Patients: A Prospective Cohort Study

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## Abstract

**Background and Aims:** Lifestyle counseling to achieve a healthy weight, quit smoking, and reduce alcohol is a cornerstone in the management of Barrett's Esophagus (BE). However, little is known about whether patients make these recommended lifestyle changes or the impact of non-adherence on their quality of life (QOL). This study characterized the lifestyle risk factors, QOL, and intervention preferences of BE patients as a first step toward developing lifestyle change interventions for this population.

**Methods:** Patients with a confirmed BE diagnosis (N = 106) completed surveys at a surveillance endoscopy visit (baseline) and at 3- and 6-month follow-ups. Patients reported on lifestyle risk factors, adherence determinants (e.g., perceived benefits/barriers, risk, intentions), QOL, and intervention preferences.

**Results:** Most patients (56%) had uncontrolled reflux, were overweight/obese (65.1%), and had low dietary fiber intake (91%). Many (45%) reported poor QOL. Patients' perceived risk of developing esophageal cancer was high, but their behavior change intentions were low. Despite receiving lifestyle counseling from physicians, there were no significant changes in patients' QOL or lifestyle risk factors over time. Nonetheless, patients indicated strong interest in internet (62.6%) and multimedia programs (57.9%) addressing acid reflux and weight control.

**Conclusion:** BE patients reported uncontrolled reflux, poor QOL, and multiple lifestyle risk factors that did not change over time. Despite low levels of intention for making lifestyle changes, patients were interested receiving more information about controlling acid reflux, suggesting a potential teachable moment and opportunity for web-based and multimedia multiple behavior interventions that seek to control acid reflux symptoms through weight loss and a high fiber diet.

## Keywords

Barrett's esophagus, physical activity, dietary behavior, quality of life, gastroesophageal reflux disease

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## Introduction

Barrett's Esophagus (BE) is a condition of the distal esophagus in which the normal squamous epithelium is replaced by intestinal-type mucosa comprised of columnar epithelium with goblet cells.<sup>1</sup> BE results from repeated injury to the esophageal mucosa secondary to long-standing, uncontrolled gastroesophageal reflux disease (GERD).<sup>2</sup> Men are 2 to 3 times more likely to develop BE than women,<sup>3,4</sup> and Caucasians are 2.6 and 2.9 times more likely to develop BE than Hispanics and

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Blacks, respectively.<sup>5</sup> Other risk factors for BE include obesity, tobacco use, and a family history of the disease.<sup>6</sup> In the last decade, the prevalence of BE in the United States has risen by 6-fold annually,<sup>7</sup> and BE patients have a 30-40 fold increased risk of developing esophageal adenocarcinoma (EAC) compared with the general population.<sup>8</sup> EAC is one of the most rapidly rising cancers in the Western world with an estimated 300-500% increase in incidence over the last 40 years.<sup>9</sup> Although reasons for the increase are not entirely understood, rising rates of GERD, BE, and EAC parallel the epidemic increases in obesity.<sup>10</sup> Most EAC patients present with advanced disease; even with multi-modal therapy, survival rates are poor.

Progression of GERD to BE and EAC follows a sequence in which the normal squamous epithelium progresses from metaplasia to low-grade dysplasia (LGD), high-grade dysplasia (HGD), and ultimately cancer.<sup>11</sup> Although the role of lifestyle factors in the clinical pathogenesis of EAC is controversial,<sup>12,13</sup> overweight/obesity and dietary behavior (e.g., increased fat intake, and low fruit and vegetable (F&V) and fiber intakes) are hypothesized to 1) increase GERD symptoms,<sup>14</sup> 2) impact mucosal integrity and healing,<sup>15</sup> and, 3) contribute to metabolic dysregulation.<sup>16</sup> In particular, central obesity is associated with higher levels of adiponectin and leptin from adipocytes, which has been proposed as a link between obesity, BE, and EAC.<sup>17</sup> Smoking and alcohol consumption have also been identified as risk factors for EAC,<sup>18</sup> whereas physical activity (PA) is considered a protective factor.<sup>19</sup> Thus, obesity and lifestyle behaviors (i.e., poor diet, insufficient PA, smoking, alcohol consumption) are lifestyle risk factors that may not only exacerbate acid reflux, but also modulate individual susceptibility for the progression of BE to EAC.<sup>12</sup>

Acid reflux damages the esophageal lining and produces symptoms of regurgitation, and heartburn which can significantly diminish quality of life (QOL).<sup>20</sup> In fact, BE patients report worse QOL relative to the general population.<sup>21</sup> Thus, one of the first priorities in treating BE is to control acid reflux symptoms.<sup>1</sup> Overweight/obese patients often display increased intra-abdominal pressure and hiatus hernia,<sup>22</sup> which results in increased reflux of gastric acid into the esophagus and impaired clearance of acid from the distal esophagus. Because this disruption exacerbates reflux symptoms, weight reduction (e.g., through lower caloric/fat intakes, higher intakes of F&Vs and whole grains, and PA<sup>23</sup>) is a cornerstone in the management of GERD and BE.<sup>24</sup>

The American College of Gastroenterology (ACG) encourages physicians to advise BE patients to achieve and maintain a healthy weight, quit smoking, and avoid foods/drinks that may exacerbate GERD symptoms (e.g., chocolate, peppermint, fatty foods, coffee, tea, sodas, alcohol) and ultimately promote dysplastic

changes in the esophageal lining that may lead to EAC.<sup>25</sup> Whereas a variety of benefits could be gained from adhering to these lifestyle recommendations including improved health and better QOL,<sup>26</sup> the cost of non-adherence could be high (i.e., uncontrolled reflux, poorer QOL, further dysplastic changes, possible progression to cancer). Surprisingly, very little is known about QOL after a BE diagnosis or whether patients make and maintain recommended behavioral changes after receiving lifestyle counseling from their physicians. According to the Health Belief Model (HBM)<sup>27</sup> adherence determinants include perceived benefits and barriers for making behavioral changes, the perceived severity of the illness and risk of future illness/disease progression, and a person's intentions and self-efficacy for making needed lifestyle changes.<sup>28</sup> However, these factors have yet to be examined in the context of BE.

As BE patients may have several lifestyle risk factors that may exacerbate their GERD symptoms and potentially increase their risk for EAC,<sup>18</sup> their diagnosis represents a unique opportunity and potential teachable moment for multiple behavior interventions (MBIs). In MBIs, individuals are exposed to strategies for changing 2 or more behaviors, either simultaneously or sequentially.<sup>29</sup> Indeed, as risk behaviors including poor diet, sedentary lifestyle, and smoking often cluster together,<sup>30</sup> intervening on multiple behaviors may be more efficient and result in more synergistic and lasting change than intervening on a single risk behavior alone.<sup>31</sup> Success in changing one risk behavior may also increase confidence or self-efficacy to improve other behaviors for which individuals have low motivation for change.<sup>29</sup>

Although MBIs have demonstrated success at increasing PA, improving diet, and reducing weight in other health contexts,<sup>32,33</sup> their efficacy has not been examined in the context of BE. As respecting and responding to patient preferences, needs, and values is a hallmark of patient-centered care,<sup>34</sup> more research is also needed to elicit BE patient preferences regarding program topics, format (e.g., individual, group), delivery channels (e.g., web-based, clinic-based), and timing (e.g., at diagnosis, after endoscopy). Thus, as a first step toward the development of MBIs for this population, this study examined the lifestyle risk factors, QOL, and intervention preferences of BE patients following their surveillance endoscopy visit (baseline) and at 3- and 6-month follow-ups. Consistent with the HBM, effects of different adherence determinants on lifestyle changes were also explored.

## METHODS

### Study Design

This prospective cohort study was approved by the Institutional Review Board of the Icahn School of

Medicine at Mount Sinai (#09-0923). Eligibility criteria included: 1) having newly diagnosed, confirmed BE, 2) able to read and speak English, 3) able to provide informed consent, and 4) being over age 18. Patients were recruited from the practices of four gastroenterologists who specialized in treating BE. Patients were identified from the electronic health record (EHR), approached for study participation at their surveillance endoscopy visit at our institution, and asked to complete a baseline survey. In accordance with ACG recommendations, physicians at our institution routinely counsel patients to stop smoking avoid alcohol, achieve a healthy weight, and avoid specific foods that exacerbate their reflux symptoms; however, no specific training is provided to physicians around giving lifestyle counseling. Follow-ups were mailed 3 and 6 months later, and participants received a \$10 gift card for each completed survey.

### Measures

Surveys comprised validated measures of QOL and lifestyle risk factors (e.g., weight status, dietary intake, PA, smoking, alcohol use). Adherence determinants, demographic/medical variables and intervention preferences were also assessed. All measures were administered at each assessment unless otherwise specified.

### QOL

The 27-item Functional Assessment of Cancer Therapy – General Population (FACT-GP) survey assesses physical, functional, emotional, and social well-being.<sup>35</sup> Total scores range from 0-108, with higher scores indicating better well-being over the past month. A reference value of 85.9 (SD = 15.1) for the general population has been reported, providing a benchmark against which the impact of disease on QOL can be evaluated.<sup>36</sup>

### Lifestyle Risk Factors

**Weight Status.** BMI was computed from self-reported weight in kilograms divided by height in meters squared. Patients were categorized as underweight (BMI < 18.5), normal weight (BMI 18.5–24.9), or overweight (BMI 25–29.9) or obese (BMI ≥ 30) based on established clinical guidelines.<sup>37</sup>

**Dietary Intake.** The 17-item National Cancer Institute Multifactor Screener provides general estimates of F&V, fat, and fiber intake over the past month.<sup>38,39</sup> Because the survey was mailed, the use of dietary recalls or lengthy food frequency questionnaires was not possible. However, using established cutoffs, respondents who consumed ≥ 5 servings of F&Vs, obtained < 35%

of caloric energy from fat, and consumed 25-30 grams of fiber per day met national guidelines.<sup>40</sup>

Given the nature of BE, it is important to assess dietary factors associated with both weight loss and reflux management. Because consumption of citrus, carbonated beverages, caffeine, and tomatoes/tomato products may exacerbate reflux, we included 12 items from the NCI Diet History Questionnaire II (DHQ)<sup>41</sup> to assess frequency of consumption of these specific foods on a 9-point Likert scale from 0 (never) to 8 (4 or more times per day). A cut-point of ≥ 3 (3 to 4 times a week) was established to determine foods consumed with moderate to high frequency.

**PA.** The 3-item Godin Leisure-Time Exercise Questionnaire (GLTEQ) assesses the frequency of mild, moderate, and strenuous leisure-time bouts of PA of at least 15 minutes in duration in a typical week. The Leisure Time Index (LTI), which corresponds to MET values for mild, moderate, and vigorous activity, is calculated by weighting and summing the frequencies of these behaviors (3x mild + 5x moderate + 9x strenuous).<sup>42</sup> Patients scoring ≥ 24 are regarded as active, and those scoring ≤ 23 as insufficiently active.<sup>42</sup> Weekly minutes of moderate and vigorous PA were also compared to national PA guidelines, which recommend achieving 500-1000 MET-minutes per week.<sup>43</sup>

**Smoking.** Participants were asked if they had ever smoked more than 100 cigarettes in their lifetime, and, if so, if they were still smoking or had quit (and when). Based on this, they were classified as current, never, and former (quit > 6 months ago) smokers, or recent quitters (quit < 6 months ago).

**Alcohol Use.** The 10-item Alcohol Use Disorders Identification Test (AUDIT) assesses current/past alcohol intake.<sup>44</sup> Response options range from 0 to 4 resulting in a total possible score of 40. Higher scores indicate greater alcohol intake. Individuals scoring above 8 are considered frequent drinkers with established cut-points for hazardous (8–15), problem (16–19), and alcohol dependent (≥ 20) drinkers.

### Adherence Determinants

The Adherence Determinants Questionnaire (ADQ)<sup>28</sup> is based on the HBM and assesses elements of patients' adherence to their medical treatment plan. It has been used to assess adherence to a variety of prevention behaviors including eating a low fat, high-fiber diet<sup>45</sup> and smoking cessation.<sup>46</sup> All the MDs whose patients we recruited provided lifestyle counseling to manage acid reflux by achieving a healthy weight, avoiding alcohol and foods that exacerbate reflux symptoms, and

stopping smoking, as part of their standard of care. In this study, patients rated their degree of agreement on a 5-point Likert-type scale (1 = strongly disagree to 5 = strongly agree) with 21 statements about this specific treatment plan. Adherence determinants included: perceived benefits (4 items), perceived efficacy (3 items), perceived severity of BE (2 items), perceived risk of developing EAC (3 items), intentions (4 items) and barriers (5 items). Internal consistency reliability (Chronbach's alpha) for each of the subscales was satisfactory, ranging from .60 to .78.

### Demographic and Medical Variables

Pathologic diagnosis (metaplasia, LGD, or HGD) was abstracted from the EHR. At baseline, patients reported on their age, race/ethnicity, sex, and education. At each assessment, they also completed the 23-item Mayo Clinic Gastroesophageal Reflux Questionnaire (GERQ) to report on GERD symptoms and medication use over the past month.<sup>47</sup>

### Intervention Preferences

At baseline, participants rated their interest in receiving information on a variety of educational topics (e.g., controlling GERD symptoms) and intervention delivery modalities (e.g., in person, web-based, multimedia) on an 11-point Likert scale (0 = "not at all interested" to 10 = "extremely interested"). Frequencies of those indicating strong interest ( $\geq 7$  out of 10) were tallied. Participants also rated preferences regarding intervention format (e.g., individual, group), and timing of delivery on a similar scale.

### Data Analysis

Descriptive statistics (means (M), standard deviations (SDs), and ranges) were computed for the major study variables. Percentages of BE patients meeting national guidelines for diet and PA were calculated. Pearson correlations were conducted to examine associations between lifestyle risk factors and QOL. To evaluate trends in lifestyle risk factors over time, the generalized estimating equation analysis method was employed. P values  $\leq 0.05$  were considered statistically significant. Cases with missing follow-up data were excluded from the longitudinal analyses. Final sample size was determined by logistical and budgetary constraints.

## RESULTS

### Baseline Demographic and Medical Characteristics

Of the 130 eligible patients approached, 119 consented and 106 completed the baseline survey (see Figure 1). No significant differences were observed between survey responders and non-responders on the basis of gender, age, or race. Retention was good; 89 (84%) patients completed the 3 month survey and 81 completed the 6 month survey (78%).

As Table 1 shows, BE patients were predominantly male (72.6%), Caucasian (97.3%) and older aged (M = 60.3 years, SD = 11.8). Most had pathologically confirmed metaplasia (49.1%) or LGD (29.2%), and 54 (57.4%) reported a hiatal hernia. A large proportion (89.3%) had chronic acid reflux (i.e., heartburn and/or acid regurgitation), with an average duration of 12.3 years (SD = 10.6 years). Fifty-six percent reported uncontrolled reflux (i.e., they experienced heartburn or acid regurgitation "several times a week" or "daily").

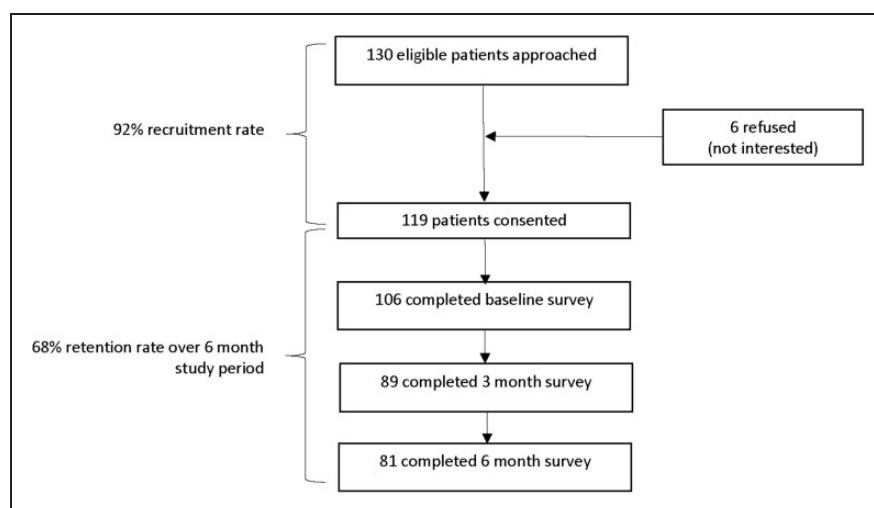


Figure 1. Recruitment Flowchart.



**Table 1.** Baseline Demographic and Disease Characteristics of the Study Sample (N = 106).

Characteristics	N	%
Age: Mean (SD)	60.3 (11.8)	
Gender		
Male	77	72.6
Female	29	27.4
Race		
White/Caucasian	100	97.3
Black/African American	4	3.8
Hispanic	2	1.9
Education		
High school diploma	17	16.0
Some college	17	16.0
College degree	14	13.2
Trade or business school	6	5.7
Some graduate school	8	7.6
Graduate degree	44	41.5
Employment		
Working full time	45	42.5
Working part time	5	4.7
Retired	50	47.2
Unemployed	3	2.8
Homemaker/Housewife	3	2.8
Marital status		
Married	99	93.4
Living with significant other	7	6.6
Smoking status		
Non-smoker	65	61.3
Former smoker	36	34.0
Current smoker	5	4.7
Recent quitter	0	0
BE stage		
Metaplasia	52	49.1
Low grade	30	28.3
High grade	23	21.7
BMI: Mean (SD)	26.7(5.2)	
Underweight = < 18.5	2	2.0
Normal weight = 18.5–24.9	28	26.4
Overweight = 25–29.9	44	41.5
Obese > = 30	25	23.6
Did not report	7	6.6
Alcohol status		
No drinking problem	91	85.8
Hazardous drinker	9	8.5
Problem drinker	4	3.8
Alcohol dependent	1	1.0
Acid regurgitation and heartburn		
Acid regurgitation only	5	4.9
Heartburn only	18	17.5
Acid regurgitation and heartburn	69	67.0
No acid regurgitation or heartburn	11	10.7
Antacid consumption		
Reflux medication only	2	2.1
PPI medication only	59	62.8
Reflux and PPI medication	33	33.1

With regard to reflux medications, 35 patients (33.0%) took antacids (e.g., Pepcid, Zantac), 92 (87%) took proton-pump inhibitors (PPIs; e.g., Nexium, Prevacid, Prilosec), and 33 (31.1%) took both. Among those reporting heartburn, 16% had not taken reflux medication and 15% said their heartburn was not made better by taking medication. Among those reporting acid regurgitation, 21.2% did not take any reflux medication, and 17.6% reported their acid regurgitation was not made better by taking medication.

### Lifestyle Risk Factors

At baseline, 75.5% of patients had one, and 35.8% had two or more lifestyle risk factors. The most common were being overweight/obese (65.1%) and not being sufficiently physically active (54.7%).<sup>43</sup> Although 13.3% of participants were frequent drinkers, 38.5% did not drink at all. Forty-one patients (38.7%) had a smoking history. Of these, five (12.2%) were current smokers, and 36 (87.8%) were former smokers. With regard to dietary intake, at baseline, patients obtained an average of 32.7% of their daily calories from fat and consumed 4.2 servings of F&Vs and 17.2 grams of fiber per day. Across study time points, approximately 23%, 64%, and 91% of patients did not meet guidelines for consumption of fat, F&V, and fiber respectively. There were no statistically significant changes in lifestyle risk factors over the study period (see Table 2).

PA was significantly negatively correlated with BMI across study time points and positively correlated with F&V intake at 6 months. F&V and fiber intakes were also significantly positively correlated across time points. F&V consumption was significantly positively associated with intentions ( $r = .19$ ) at baseline and perceived benefits at 3 months ( $r = .21$ ); it was negatively associated with perceived barriers at 6 months ( $r = -.29$ ). PA was also negatively associated with perceived severity of BE at 3 months ( $r = -.22$ ).

Consumption of foods that could potentially exacerbate reflux symptoms was generally low (1–2 times per week or less) and stable over time, with the exception of caffeinated coffee consumption ( $M = 3.33$  cups per week,  $SD = 2.76$ ). At baseline, 57.5% of patients consumed caffeinated coffee 3 cups or more times per week; this increased to 63.3% at the 6 month follow-up. However, the difference was not significant (see Table 3).

### Associations between Lifestyle Risk Factors, Adherence Determinants, and QOL

At baseline, perceived benefits, efficacy, and risk of developing EAC were generally high ( $M \geq 3.9$  out of 5), with patients reporting few barriers to adherence

Table 2. Descriptive Statistics for the Major Study Variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	Mean (SD)	Range	P-Value for Trend	Percent Meeting Guidelines
<b>1. BMI</b>																	
Baseline	-													26.72 (5.15)	16.00–54.00	.53	28.30%
3 months	-													27.12 (4.27)	16.00–38.00		23.80%
6 months	-													27.54 (4.55)	16.00–38.00		22.20%
<b>2. PA</b>																	
Baseline	-.25*	-												28.12 (23.38)	0–110.00	.59	45.30%
3 months	-.027*	-												24.14 (20.81)	0–104.00		39.50%
6 months	-.029*	-												27.10 (22.31)	0–104.00	.73	45.00%
<b>3. Fat Intake</b>																	
Baseline	0.08	-0.15	-											32.67 (3.35)	22.00–41.00		79.50%
3 months	-0.01	-0.07	-											32.51 (3.54)	22.00–41.00		77.10%
6 months	0.02	-0.11	-											32.97 (3.37)	22.00–41.00	.76	73.80%
<b>4. F&amp;V Intake</b>																	
Baseline	-0.10	0.14	-0.14	-										4.23 (1.61)	1.00–9.00		34.90%
3 months	-0.06	0.14	-0.17	-										4.17 (1.48)	1.00–9.00		36.50%
6 months	-0.16	0.24*	-0.03	-										4.35 (1.53)	1.00–8.00	.94	37.20%
<b>5. Fiber Intake</b>																	
Baseline	-0.14	0.16	-0.19	0.78*	-									17.22 (6.52)	9.00–37.00		11.36%
3 months	-0.14	0.15	-0.17	0.76*	-									17.22 (5.98)	9.00–36.00		7.87%
6 months	-0.21	0.22	-0.05	0.73*	-									16.90 (5.97)	8.00–35.00	.85	8.20%
<b>6. Alcohol Use</b>																	
Baseline	-0.09	0.03	0.13	-0.05	-0.13	-								3.80 (4.40)	1.00–22.00		86.70%
3 months	-0.06	0.07	-0.07	-0.03	-0.10	-								3.40 (4.10)	1.00–21.00		89.50%
6 months	-0.02	0.02	-0.02	-0.14	-0.03	-								3.50 (4.40)	1.00–28.00	.68	89.90%
<b>7. QOL</b>																	
Baseline	-0.30*	0.17	-0.03	0.08	-0.08	0.16	-							85.31 (14.77)	36.23–106.83		55.2%
3 months	-0.12	0.15	-0.05	-0.10	-0.10	0.13	-							84.35 (14.56)	36.23–105.67		58.8%
6 months	-0.08	0.22	-0.17	0.13	-0.08	0.06	-							83.42 (14.38)	36.23–105.67	.58	50.0%
<b>8. Perceived Benefits</b>																	
Baseline	-.17	.01	-.09	.15	.13	.06	.09	-						4.21 (.66)	2.75–5.00		
3 months	-.20	.05	.02	.21*	.19#	-.04	.08	-						4.11 (.64)	2.75–5.00		
6 months	-.18	.05	.01	.12	.02	.06	.15	-						4.19 (.66)	2.75–5.00	.19	
<b>9. Perceived Efficacy</b>																	
Baseline	-.05	.04	-.01	-.09	.08	.02	.01	.67*	-					4.19 (.71)	2.33–5.00		
3 months	-.20	.05	.09	.04	.20#	.01	.08	.61*	-					4.13 (.76)	2.00–5.00		
6 months	-.11	-.06	.02	-.01	.10	-.05	.09	.69*	-					4.18 (.69)	2.33–5.00	.18	
<b>10. Perceived Severity</b>																	
Baseline	.16	-.07	.06	.04	.11	.10	-.27*	.10	.29*	-				2.93 (.89)	1.00–5.00		
3 months	.07	-.23*	.01	-.07	.04	.03	-.36*	-.03	.27*	-				2.86 (.91)	1.00–5.00		
6 months	-.11	-.07	.14	-.12	.09	.03	-.41*	-.05	.23*	-				2.93 (.91)	1.00–5.00		

(continued)

Table 2. Continued.

	1	2	3	4	5	6	7	8	9	10	11	12	13	Mean (SD)	Range	P-Value for Trend	Percent Meeting Guidelines
<b>11. Perceived Risk</b>																	
Baseline	-.12	.09	-.04	-.10	.06	.07	.15	.35*	.65*	-.04	-	-	-	3.92 (.76)	1.00-5.00		.67
3 months	-.07	-.05	.19	-.13	-.07	.05	.28*	.61*	.15	-	-	-	-	3.86 (.77)	1.00-5.00		
6 months	-.04	-.10	-.03	-.13	-.18	-.01	.22*	.48*	.64*	.03	-	-	-	4.00 (.76)	1.00-5.00		
<b>12. Intentions</b>																	
Baseline	.02	.02	.10	.19*	-.10	-.06	-.01	-.41*	-.73*	-.23*	-.62*	-	-	2.37 (.59)	1.25-5.00		.43
3 months	.04	.01	-.03	.11	-.10	-.03	-.01	-.33*	-.70*	-.27*	-.70*	-	-	2.41 (.61)	1.25-5.00		
6 months	-.07	.10	.13	.16	.03	.07	.01	-.39*	-.58*	-.24*	-.62*	-	-	2.32 (.57)	1.00-5.00		
<b>13. Perceived Barriers</b>																	
Baseline	.15	-.07	.03	-.06	-.01	.09	-.10	-.38*	-.27*	.01	-.14	.03	-	2.50 (.71)	1.00-3.80		.89
3 months	.07	-.04	.02	-.11	.06	.03	-.14	-.26*	-.15	.09	-.01	-.09	-	2.39 (.75)	1.00-3.80		
6 months	.13	-.12	-.06	-.29*	-.01	-.05	-.28*	-.44*	-.26*	.17	-.19	-.04	-	2.52 (.75)	1.00-4.00		

Note: BMI = Body Mass Index; QOL = Quality of life, assessed using FACT-GP Total Score; PA = Physical Activity, assessed using Godin Leisure Time Index; F&V = Fruits and Vegetables; Fat intake refers to percent of calories from fat; Fiber Intake is in grams; F&V Intake is in servings per day.

For fruit and vegetable intake, percentages refer to those consuming five or more fruit and vegetable servings per day. Percentages of those meeting guidelines for fiber intake are based on 25-30 grams consumed per day as recommended by the Food and Nutrition Board of the Institute of Medicine. For dietary fat intake, those meeting national guidelines consumed 20-35% of their energy from fat; for physical activity, those meeting national guidelines reported >500 MET minutes of leisure time activity per day.

( $M = 2.50$  out of 5). However, intentions to adhere to the treatment plan by making lifestyle behavioral changes were low ( $M = 2.37$ ,  $SD = .59$ ), and there were no changes in adherence determinants over time (see Table 2). The only lifestyle risk behavior that was associated with adherence determinants was F&V consumption. Specifically, at baseline, F&V consumption was with significantly positively associated with intentions, and at 3 months, it was positively associated with perceived benefits of adherence and negatively associated with perceived risk of developing EAC. At 6 months, it was negatively associated with perceived barriers.

With regard to QOL, 55.2% of patients scored above population norms for QOL at baseline (average FACT-G Total score was  $M = 85.3$ ,  $SD = 14.8$ ), and there were no significant changes in QOL over time. We looked at group differences in the outcomes based on degree of dysplasia and because there were no differences, we analyzed all the data together. The only lifestyle risk factor that was significantly correlated with QOL at baseline was BMI ( $r = -.30$ ). Across study time points, greater perceived severity of BE was associated with poorer QOL ( $r = -.26$  to  $-.41$ ). Individuals who perceived more barriers to adherence with their treatment plan also reported poorer QOL at 6 months ( $r = -.28$ ).

Given that adherence determinants, lifestyle risk factors, and QOL did not significantly change over the study period, examination of baseline adherence determinants associated with changes in lifestyle risk factors and of baseline risk behaviors associated with changes in QOL was not possible.

### Intervention Preferences

As Table 4 shows, 93.5% of BE patients expressed strong (7 or more out of 10) interest in learning more about controlling acid reflux symptoms. Between 63.6% and 88% were interested in learning more about weight loss, eating better to stay healthy, and becoming more physically active. Sixty-nine patients (64.5%) reported strong interest in all 4 of these topics, and 98% were interested in at least two topics. Over a quarter (27.1%) wanted this information either immediately after a BE diagnosis or after endoscopy, but 71.8% were willing to receive it at "anytime". Most patients (69.3%) preferred group-based programs where they either participated with their spouse/partner (22.8%) or other BE patients (46.5%), over one-on-one, individual-based programs (30.7%).

In terms of delivery channel, few patients were interested in clinic- (15.9%) or telephone-based (27.1%) programs. Mail-based programs ranked in the middle (37.4%), and multimedia and internet-based programs ranked the highest, with 57.9% and 62.6% of patients expressing strong interest, respectively. Almost all

**Table 3.** Dietary Intakes of Foods That May Exacerbate Reflux Symptoms (NCI Multifactor Screener).

	Baseline (N = 106)		3 Months (N = 89)		6 Months (N = 81)		ANOVA (N = 81)  F (p)
	Mean (SD)	Percent ≥3–4 Times a Week	Mean (SD)	Percent ≥3–4 Times a Week	Mean (SD)	Percent ≥3–4 Times a Week	
1. Soft drinks, soda, or pop	1.47 (1.76)	25.5%	1.38 (1.62)	19.8%	1.48 (1.66)	21.5%	.09 (.92)
2. Fresh tomatoes	1.73 (1.35)	27.4%	1.75 (1.35)	26.7%	1.89 (1.48)	27.8%	.32 (.73)
3. Tomato-based cooked foods (e.g., spaghetti sauce, chili, pizza, or salsa)	1.58 (1.03)	16.0%	1.57 (.98)	16.3%	1.65(1.06)	15.2%	.14 (.87)
4. Foods containing garlic or onions	2.27 (1.42)	39.6%	2.13 (1.34)	16.3%	2.23(1.38)	35.4%	.27 (.76)
5. Hot peppers or other spicy foods	.77 (1.08)	5.7%	.70 (1.00)	5.8%	.82(1.11)	8.9%	.29 (.76)
6. Chocolate candy	1.60 (1.40)	14.2%	1.66 (1.33)	16.3%	1.47(.97)	12.7%	.51 (.60)
7. Mint (spearmint, peppermint, etc.) or foods containing mint flavorings	.76 (1.52)	8.5%	.95 (1.76)	8.1%	.80(1.33)	6.3%	.38 (.68)
8. Caffeinated coffee	3.33 (2.76)	57.5%	3.57 (2.64)	61.6%	3.61(2.65)	63.3%	.30 (.74)
9. Decaffeinated coffee	1.70 (2.22)	29.2%	1.71 (2.22)	27.9%	1.72(2.20)	27.8%	.01 (.98)
10. Regular hot or cold tea (with caffeine)?	1.75 (1.99)	27.4%	1.55 (1.85)	23.3%	1.85(2.11)	27.8%	.51 (.30)
11. Citrus fruits (e.g., oranges, grapefruit, tangerines, tangelos, etc.)	1.08 (1.28)	22.3%	.97 (1.14)	9.3%	.92(1.21)	8.9%	.45 (.64)
12. Orange juice or grapefruit juice	.80 (1.28)	7.5%	.84 (1.32)	8.1%	.91(1.34)	11.4%	.16 (.85)

Note: Raw scores range from 0 (never) to 8 (4 or more times per day). A value of 3 (3–4 times per week) was used as a cut point to indicate more frequent consumption. ANOVAs examined mean differences over time. None were significant.

**Table 4.** BE Patient Intervention Preferences at Baseline (N = 106).

	Percent
<b>How interested are you in learning about these topics?*</b>	
Controlling acid reflux symptoms	93.5
Weight loss	71.0
Eating better to stay healthy	88.8
Increasing PA	63.6
Stopping smoking	2.8
Stopping drinking alcohol	2.8
<b>There are many ways to get information on these topics. How interested are you in the following:*</b>	
Clinical based programs	15.9
Telephone based program with a health educator	27.1
Mailed pamphlets or newsletters	37.4
A DVD I can watch on my TV or home computer	57.9
Interactive internet based programs	62.6
<b>When would this information be most helpful?</b>	
Right after a BE diagnosis	18.4
After endoscopy	8.7
Anytime	72.0
<b>Would you prefer to participate in such programs:</b>	
Alone (e.g., individual counseling)	32.5
With other BE patients	18.2
With your spouse or partner	49.3

Note: \*Percentages are based on the number of BE patients who indicated they were either extremely or very interested in a particular topic of intervention or mode of intervention delivery.



patients had computers (96.3%) and internet access (94.4%).

## DISCUSSION

This is the first study to document the lifestyle risk factors, QOL, and intervention preferences of BE patients. Overall, we found that a large proportion of patients had chronic (89.3%) and uncontrolled (56%) acid reflux. Approximately 31.0% of patients with heartburn and 38.8% of those with acid regurgitation either did not take reflux medication or reported their symptoms were not made better by taking medication. Most patients (75.5%) had at least one lifestyle risk factor, and over a third had multiple risk factors, with the most common being overweight/obesity and insufficient PA. Despite the fact that all BE patients received lifestyle counseling and 45% were below population norms for QOL at baseline, they did not make any significant lifestyle changes during the 6-month study period. Moreover, across study time points, approximately 23.0%, 64.0%, and 91.0% of patients did not consume recommended intakes of fat, F&V, and fiber respectively. The finding regarding fiber is particularly concerning given that a meta-analysis found that dietary fiber intake is inversely associated with risk of BE and EAC.<sup>48</sup> Other studies have found that high dietary fiber intake is associated with decreased reflux symptoms in the context of GERD.<sup>49</sup> Despite reporting poor QOL and multiple lifestyle risk factors, patients reported interest in learning more about controlling acid reflux and addressing BE lifestyle risk factors (i.e., through weight loss, eating a healthy diet, and engaging in PA). They were also amenable to participating in digitally delivered (i.e., via multimedia or the internet) lifestyle behavioral interventions. Taken together, these findings suggest that the diagnosis of BE may signify a potential teachable moment and that patients may benefit in terms of better QOL from web-based MBIs that seek to control acid reflux symptoms through weight loss and a high fiber diet.<sup>50</sup>

Even though patients reported high levels of perceived benefit of engaging in a healthy lifestyle, high levels of perceived risk for developing EAC, and were interested in learning more about strategies for controlling acid reflux symptoms, losing weight, and becoming more physically active, their behavior change intentions were low. The Transtheoretical Model may help to reconcile these seemingly disparate findings.<sup>51</sup> It is possible that patients were still in the precontemplation stage, in which people do not intend to take action in the near future and are often unaware that their behavior is problematic or produces negative consequences. At the same time, the finding that patients were still interested in receiving new information about lifestyle risk reduction suggests that a BE diagnosis may represent a teachable

moment and opportunity for healthy lifestyle interventions aimed at controlling reflux symptoms and ultimately reducing cancer risk. Indeed, such interventions could help motivate further contemplation and possibly behavior change in this population.

It is also notable that receiving lifestyle counseling from their physicians was not sufficient for BE patients to make recommended lifestyle changes. One possibility is that patients were not convinced that making these changes would actually mitigate their cancer risk. Even though physicians are uniquely positioned to encourage patients to adopt healthy lifestyle behaviors, most are not formally trained to perform lifestyle counseling.<sup>52</sup> As we did not observe patient-provider discussions in the clinic nor did we assess the quality of counseling in this study, we are unable to gauge whether some physicians may have been better than others at counseling BE patients. Beyond providing physicians with more evidence-based training for encouraging lifestyle behavior changes, it may also be useful for counseling to emphasize the effects of lifestyle changes on more concrete, proximal outcomes (e.g., control of reflux symptoms) as opposed to more distal outcomes (e.g., QOL or cancer risk). Providing partial support for this idea, research in the context of GERD has found that standardized comprehensive counseling that provided education and emphasized symptom relief resulted in significant improvements in patient QOL relative to providing education alone.<sup>53</sup>

Another possibility is that patients may have been convinced about their cancer risk but did not have enough information or support to make needed lifestyle changes. Given clinic demands, most physicians have very limited time to follow-up with patients to address barriers and ensure they are making progress on their behavior change goals. Thus, behavioral counseling by the physician alone may not be sufficient and interventions that provide structured support and skills training may be needed to help BE patients achieve lasting behavioral changes and meaningful improvements in QOL. Providing support for this idea, a structured weight loss program that was delivered over a 6-month period that encouraged GERD patients to make behavioral changes through a variety of behavioral strategies (e.g., behavior shaping, goal setting, self-monitoring, feedback and reinforcement, social support, problem-solving, and relapse prevention) resulted in weight loss and a significant decrease in GERD symptoms.

Many patients (69%) reported a strong preference for participating in group-based lifestyle risk reduction programs with either other BE patients or their spouses/partners. This novel finding suggests a new avenue for intervention development incorporating natural sources of support. One benefit of such an approach is that the social support obtained from the group could have a

positive effect on one's self-esteem and self-efficacy for making and maintaining behavioral changes.<sup>54,55</sup> Social networks can provide coping resources such as emotional, informational, and instrumental support. In addition, heightened awareness among spouses may be a catalyst for lifestyle changes in both partners.<sup>56</sup> Additional work is needed to understand the impact of a BE diagnosis on spouses' perceptions of their own disease risk and behaviors as well as their efforts to support/motivate the patient to make and maintain healthy lifestyle behavioral changes.

Stress reduction approaches may play an important role in the management of BE via influencing sleep patterns, food intake, weight gain, abdominal obesity and the effects of weight loss interventions.<sup>57</sup> Although this was beyond the scope of this study, it represents a promising avenue for future research. Likewise, given that most patients were interested in participating in lifestyle behavioral interventions at any time, future studies should explore the effects of timing on patient receptivity and impact on behavioral outcomes. Finally, with respect to program delivery, patients preferred internet and multimedia methods of delivery, which could enhance efficiency, reduce cost, and expand the potential reach of MBIs targeting this population.

Strengths of this study include the use of validated measures and a prospective cohort design. The study sample was large, and although most of our participants were Caucasian males, this is reflective of the overall BE population,<sup>3</sup> which bolsters generalizability. Patients were newly diagnosed with BE and undergoing their first surveillance endoscopy, allowing us to examine the potential influence of lifestyle counseling received at diagnosis on behavior change over time. However, results should be interpreted with caution. Not all patients reported heartburn or acid regurgitation. This may be due to limitations in our measure of reflux symptoms, which did not ask about cough. It is possible that some patients had chronic cough but did not recognize this as acid reflux. Others may not have received a formal reflux diagnosis before their BE diagnosis. Additionally, some patients with chronic reflux do not feel it due to damage of the nerve endings. On a related note, severity of reflux symptoms and frequency of reflux medication and PPIs were not assessed. More comprehensive self-report measures of reflux symptoms, severity, and medication use are needed.

Overall, BE patients reported poor QOL, uncontrolled reflux, and multiple lifestyle risk factors that did not change over time. Despite low levels of intention for making lifestyle changes, patients were interested in receiving more information about controlling reflux symptoms, losing weight, and becoming more physically active, suggesting a potential teachable moment and opportunity for MBIs.

Structured group-based programs with other BE patients and dyadic programs that incorporate spouses are two potentially promising approaches for incorporating support for recommended lifestyle changes beyond the clinic. Likewise, internet and multimedia technology could expand reach of lifestyle programs and may be more cost-effective than in-person interventions, although these options must be carefully evaluated. Overall, our findings provide important preliminary data that can be used to translate lifestyle behavioral change research into care for BE patients.

### **Ethics approval and consent to participate**

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This prospective cohort study was approved by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai (#09-0923). Informed consent was obtained from all individual participants included in the study.

### **Consent for publication**

Not applicable.

### **Availability of data and material**

The datasets used and/or analyzed during the current study are available from the corresponding author on request.

### **Competing interests**

The authors declare that they have no competing interests.

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### **Authors' contributions**

HB had the initial idea for the study and contributed to acquisition of data. SA and HB were involved in the conception and design of this study. SA, JA, and HB were involved in data collection and the conduct of the study. XZ and HB conducted the analyses. XZ, SA, JA, MO, and HB were involved in interpretation of the data. XZ wrote the first draft of the manuscript with support from HB. All authors revised the manuscript for intellectual content and approved the final manuscript.

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### Conflict of Interest Statement

Dr. Mohamed Othman received honoraria from Abbvie, Olympus, Boston Scientific, ConMed, and Lumendi and commercial research funding from US Biotest. All other authors have no conflicts of interest to disclose.

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