

# Patient decision-making and clinical outcomes following endoscopic therapy or esophagectomy for Barrett's neoplasia



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## Bibliography

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## ABSTRACT

**Background and study aims** The objective of this study was to assess patient involvement in decision-making, deci-

sion confidence, and decision regret among patients who had undergone endoscopic eradication therapy (EET) or esophagectomy for Barrett's esophagus (BE) associated neoplasia.

**Patients and methods** Patients with BE high grade dysplasia or intramucosal (T1a) adenocarcinoma who had undergone EET or esophagectomy were invited to complete a survey.

**Results** The cohort included 50 subjects, 70% (35/50) of whom had undergone EET and 30% (15/50) of whom had undergone esophagectomy. Subjects who underwent esophagectomy were more likely to report post-treatment dysphagia (47% vs 14%,  $P=0.03$ ), post-treatment dietary modification (73% vs 6%,  $P<0.0001$ ), and were less likely to view their post-treatment health favorably. However, when asked whether they had selected the right treatment, a high degree of confidence was reported by both groups (mean 9.8 for EET vs 9.3 for esophagectomy on a 0–10 scale,  $P=0.12$ ). In fact, 97% (34/35) of EET patients and 80% (12/15) of esophagectomy patients indicated they would select the same treatment option ( $P=0.08$ ).

**Conclusions** Patients who have undergone EET or surgery for BE neoplasia report a high degree of involvement in the decision-making process. Although EET patients report fewer symptom-specific outcomes, measures of decision confidence and decision regret do not differ between the two treatment groups.

## Introduction

Endoscopic eradication therapy (EET), consisting of mucosal resection and ablation techniques, has emerged as a viable alternative to surgical esophagectomy for definitive therapy of Barrett's esophagus (BE)-associated mucosal neoplasia. In the largest reported series, 1000 consecutive patients with T1 esophageal adenocarcinoma (EAC) underwent EET with a complete response rate of 96%. During a mean follow-up of 56.6 months, only 12 patients required salvage esophagectomy and only two patients died of EAC [1]. An increasing number of patients in the United States now undergo endoscopic therapy rather than surgery, with data from the Surveillance Epidemiology and End Results (SEER) database reporting that the proportion

of patients with high grade dysplasia (HGD) or stage T1 EAC undergoing endoscopic therapy rose from 3% in 1998 to 29% in 2009 [2].

Medical decision making is a critical component of current healthcare delivery, and patients themselves have a central role in this process [3]. Current practice guidelines of the American Gastroenterological Association endorse the concept of shared decision-making between physician and patient when considering endoscopic intervention for BE [4]. Yet there exists a critical gap in understanding how an individual patient newly diagnosed with esophageal cancer arrives at a decision to undergo either endoscopic or surgical therapy.

There are precedent data examining patient decision-making in the selection of cancer treatment options. For instance,

patients with breast cancer may face a choice between less invasive and more invasive treatment options – ranging from breast conserving surgery, to mastectomy, to contralateral prophylactic mastectomy. Patient anxiety over future cancer risk has been identified as a factor influencing patient preference for breast cancer intervention [5]. Data from breast cancer research also provide insight into patient involvement in the decision-making process, decision confidence, and decision regret.

The objective of this study was to assess patient involvement in decision making, decision confidence, and decision regret in patients who have undergone EET or esophagectomy for treatment of BE-associated HGD or T1 EAC, and to identify factors associated with patient selection of endoscopic versus surgical therapy. The hypothesis was that high rates of decision confidence and low rates of decision regret would be present in both treatment groups.

## Patients/Material and methods

Approval to conduct this study was granted by the Vanderbilt University Institutional Review Board. Patients who had undergone either surgical esophagectomy or endoscopic therapy, the latter consisting of endoscopic mucosal resection (EMR) and/or radiofrequency ablation (RFA), both of which were available and performed at our institution, were retrospectively identified from surgical and endoscopic databases. Patients with a pre-intervention diagnosis of BE containing HGD or T1a (intramucosal) EAC were eligible for inclusion.

Eligible subjects were contacted between January and October 2015 and invited to complete a two-part survey during a scheduled clinic or endoscopy visit or via scripted telephone interview. The first component of the survey, derived from published literature in decision making [6], was designed to assess patient involvement in the treatment decision (**Supplementary Appendix 1**). The second component of the survey was designed to identify factors which influenced the subject's treatment decision, to assess the subject's digestive functional status following intervention, and to assess decision confidence and decision regret [7] (**Supplementary Appendix 2**).

Additional clinical and demographic data were extracted from the electronic medical record, including the specialty (surgeon or gastroenterologist) of the initial consulting physician within the institution.

Study data were recorded and managed using the Research Electronic Data Capture (REDCap) tools hosted at Vanderbilt University. REDCap is a secure, web-based application designed to support data capture for research studies. Statistical analysis was performed using JMP software (SAS Institute, Cary, NC, United States). Parametric testing with the Student's *t* test was used for comparison of continuous data. Fisher's exact test was used for comparison of categorical data. The threshold for statistical significance for all analyses was set at a two-sided *P* value of less than 0.05.

## Results

In total, 68 patients who underwent EET for HGD/T1a EAC were eligible for study participation; among these, 35 agreed to participate and completed the surveys. We were unable to contact 25 subjects during the study period, one subject was deceased, and seven subjects were contacted but declined enrollment – for a participation rate of 83% (35/42) among contacted subjects and an overall participation rate of 51% (35/68). A total of 26 patients who underwent esophagectomy for HGD/T1a EAC were eligible for study participation; among these, 15 agreed to participate and completed the surveys. We were unable to contact seven subjects, during the study period, two subjects were deceased, and two declined enrollment – for a participation rate of 88% (15/17) among contacted subjects and an overall participation rate of 58% (15/26).

Overall, 50 subjects were enrolled and completed the survey, 70% (35/50) of whom had undergone endoscopic therapy and 30% (15/50) of whom had undergone esophagectomy. Mean age at time of survey completion was 66 years in the endoscopic treatment group compared to 62 years in the esophagectomy group ( $P=0.17$ ). All patients in the esophagectomy group were at least 1 year post-esophagectomy at the time of survey administration. The majority of patients were male (80% of endoscopic group vs 93% of esophagectomy group,  $P=0.41$ ).

Among the 50 patients surveyed, all lesions were discovered by a gastroenterologist. Eighty percent of the lesions were discovered outside of our health system, and all lesions were confirmed by expert pathology review before treatment. Of the total cohort, 48% (24/50) saw both a surgeon and a gastroenterologist in consultation. Of the 12 patients who had seen a surgeon in initial consultation, eight were treated with EET and four were treated with esophagectomy. In contrast, of the 12 patients who had seen a gastroenterologist in initial consultation, four were treated with EET and eight were treated with esophagectomy. Fifty-two percent (26/50) of patients did not visit with both a surgeon and a gastroenterologist. Of these 26, three met with a surgeon and were treated with esophagectomy, while 23 met with a gastroenterologist and were treated with EET.

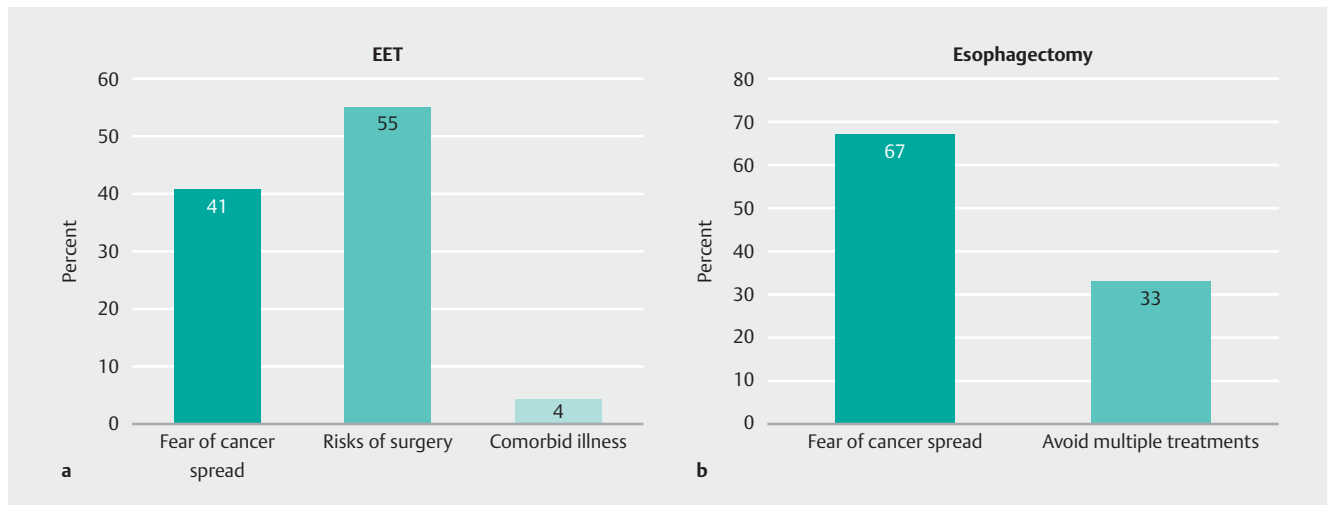
### Patient involvement in decision-making

Seventy-one percent (25/35) of patients who underwent EET reported that esophagectomy was discussed as a treatment option and 80% (12/15) of subjects who underwent esophagectomy reported that EET was discussed as a treatment option.

Sixty-six percent (23/35) of EET patients and 93% (14/15) of esophagectomy patients recall being asked whether they preferred EET or surgery ( $P=0.04$ ).

### Factors involved in patient decision

Among subjects who underwent EET and identified factors influencing treatment choice, risk of surgery was reported by 55% (16/29) as the most important reason for selecting EET rather than surgery (► **Fig. 1a**). Among subjects who underwent esophagectomy, fear of cancer spread was reported by 67%



► **Fig. 1** **a** Most important factor influencing choice for endoscopic eradication therapy over esophagectomy. **b** Most important factor influencing choice for esophagectomy over endoscopic eradication therapy.

(10/15) and desire to avoid multiple treatment sessions was reported by 33% (5/15) of subjects as the most important reasons for selecting esophagectomy rather than EET (► **Fig. 1b**).

Eight percent (4/50) of subjects reported that they had a family member or friend who had undergone endoscopic treatment for BE or EAC, while 12% (6/50) reported they had a family member or friend who had undergone surgery for BE or EAC. No patients in the EET group and 20% (3/15) of patients in the esophagectomy group reported having had the opportunity to speak before treatment with another patient who had undergone similar treatment for this condition. No patients in the EET group and 73% (11/15) of patients in the esophagectomy group responded that they would have liked the opportunity to speak before treatment with another patient who had undergone similar treatment.

### Decision confidence and decision regret

Subjects who underwent esophagectomy were more likely to report post-treatment dysphagia compared to subjects who underwent EET (47% vs 14%,  $P=0.03$ ), and were more likely to report that their ability to eat a normal diet had changed (73% vs 6%,  $P<0.0001$ ) (► **Fig. 2**).

On a five-point ordinal scale ("Compared to how I felt before undergoing treatment/surgery, my current overall health is: much better, somewhat better, the same, somewhat worse, or much worse), subjects who underwent esophagectomy were less likely than those who underwent EET to view their overall post-treatment health favorably compared to pretreatment health ( $P=0.047$ ).

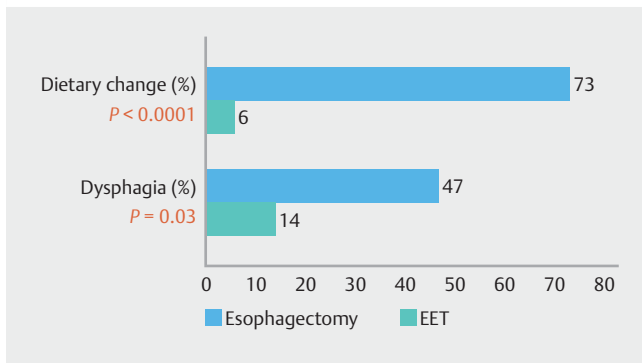
Yet when asked whether they had in hindsight selected the right treatment approach, there was no difference in decision confidence (mean 9.8 for EET vs 9.3 for esophagectomy on a 0–10 scale,  $P=0.12$ ) (► **Fig. 3a**). There was also no difference in decision regret: 97% (34/35) of EET patients and 80% (12/15) of esophagectomy patients indicated they would select the same treatment option (definitely yes or probably yes) if faced again with the same treatment decision ( $P=0.08$ ) (► **Fig. 3b**).

### Discussion

To our knowledge, this is the first study to assess decision confidence, decision regret, and patient involvement in decision making among patients choosing between endoscopic or surgical therapy for BE associated neoplasia. The demographic characteristics of the cohort mirror those of the general population with BE, therefore the study results are likely to be representative of the decision process experienced by patients with BE associated neoplasia evaluated at a tertiary referral center and selecting between endoscopic and surgical therapy.

Although patients with BE neoplasia are evaluated in multidisciplinary fashion at our institution, each consultant discussed treatment options, both EET and esophagectomy, with the patient typically before formal multidisciplinary review. Prior data reported by the study authors in a similar patient population showed a strong correlation between provider specialty and treatment choice [8]. We did not observe a similar degree of specialty bias in our study, though this potential bias may have been attenuated by the size of the cohort.

There are potential advantages and disadvantages to either EET or esophagectomy for treatment of BE neoplasia. EET is less invasive and carries low rates of procedural morbidity; however, it does require a longitudinal commitment to multiple treatment sessions followed by long-term (perhaps indefinite) post-treatment surveillance given recurrence risk. Surgical therapy, on the other hand, is more invasive and has higher up-front morbidity, yet offers the allure of a "one-and-done" cure in a single intervention. In this context, risk of surgery was reported by the majority of patients in the EET cohort as the most important reason for selecting EET rather than esophagectomy. Fear of cancer spread was reported by the majority of patients in the esophagectomy cohort as the most important reason for selecting esophagectomy rather than EET. These findings are consistent with data reported by Rosmolen et al. from a European cohort demonstrating that patients who undergo EET for BE neoplasia are more likely to experience



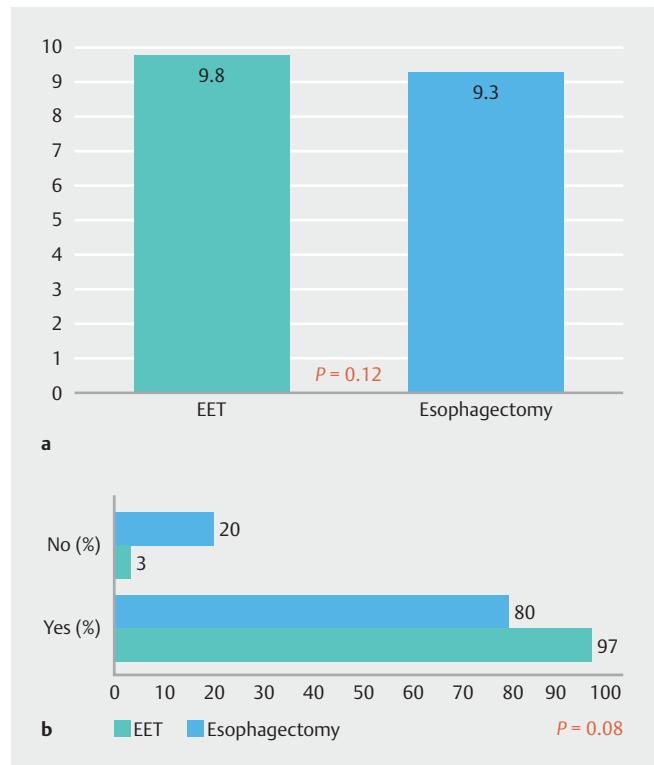
► **Fig. 2** Percentage of patients reporting post-treatment dietary change or dysphagia after undergoing endoscopic eradication therapy or esophagectomy.

fear of cancer recurrence post-treatment than patients who undergo esophagectomy [9].

Curiously, fear of cancer spread was reported by 41% of subjects in the EET arm as a reason for selecting EET rather than esophagectomy. This was not an expected finding, and the reason(s) for this finding may include poor representation of the posed question, misunderstanding of the relative ability of EET or esophagectomy to prevent cancer spread, or a perception that esophagectomy might contribute to cancer spread. Rephrasing this question to reflect the ability of EET to stop progression to cancer, rather than prevent spread of cancer may alter these results. Regardless, the fear of cancer, both its progression and potential spread, looks to play an important role in selection of therapy.

Cost influences medical decision making and may make the one time monetary outlay of esophagectomy more appealing. Depending on insurance type and plan, the upfront cost for esophagectomy is likely higher than for EET, but may prove to be more cost efficient in the long term by eliminating the downstream cost of multiple treatment sessions and indefinite endoscopic surveillance that is inherent with EET. In our cohort, 13.8% of patients choosing EET indicated that medical insurance played a role in their decision making compared to 6.7% of patients choosing esophagectomy. No patient indicated that medical insurance status was the most important factor in the treatment decision. As is often the case in a privately insured medical system, it is unlikely that patients were aware of the overall individual cost at the time of treatment decision. We did not collect specific insurance type as a part of our survey, and did not calculate each patient's out of pocket cost. If individual cost to the patient was more transparent and readily available, it may impact treatment decision.

Subjects who had undergone esophagectomy were more likely to report post-treatment dysphagia, were more likely to report that their ability to tolerate a normal oral diet had changed, and were less likely to view their post-treatment health favorably compared to subjects who had undergone EET. However, high rates of decision confidence were reported with no meaningful difference in comparing subjects who had undergone EET vs esophagectomy (9.8 vs 9.3 on a 10-point scale,  $P = 0.12$ ). Rates of decision regret were also similar: 80% of sub-



► **Fig. 3 a** Decision confidence for treatment choice of EET vs esophagectomy. **b** Decision regret for treatment choice of EET vs esophagectomy.

jects who underwent esophagectomy and 97% of subjects who underwent EET reported they “definitely” or “probably” would select the same treatment choice again ( $P = 0.08$ ). While a difference in this measure might be discernible in a study with larger sample size, on a base level, these findings indicate that the majority of patients are satisfied with their treatment choice, irrespective of modality, and despite apparent differences in symptom-specific outcomes. This may serve as a striking reminder that, despite the emergence of EET in an era in which endoscopists may be conditioned to view the need for surgical therapy as a failure of endoscopic management, the option of surgical intervention may remain a desirable option for some patients.

A retrospective study of this nature may be subject to recall bias. For instance, 93% of esophagectomy patients recall being asked which treatment they preferred; however, a percentage which exceeds the 80% of patients who report that discussion of the alternative treatment option in fact occurred.

Studies of decision regret in patients undergoing therapy for prostate cancer have suggested that physiologic dysfunction plays a significant role in decision regret, such that patients with more physiologic dysfunction are more likely to regret their treatment decision [10]. We suspect that the lack of a significant difference in decision regret among patients undergoing esophagectomy despite worse physiologic outcomes is influenced by the concept of “cognitive dissonance reduction”. In accordance with this theory, individuals tend to reduce or minimize inconsistencies between previous decisions and cur-

rent beliefs or treatment preferences [11]. As a result, subjects would be expected to adjust current beliefs in favor of the treatment which they had received, and thus report a higher degree of decision confidence and a lower degree of decision regret than is commensurate with post-treatment symptoms and health. We expect the effect of cognitive dissonance reduction to be strongest in patients who experienced a relatively worse functional outcome, yet still maintained a high degree of decision confidence and a low degree of decision regret; however, there is likely considerable interpatient variability, and the magnitude of this effect is hard to measure absolutely. A study with responses measured before a treatment decision and monitored prospectively might in theory minimize this source of potential bias.

Participation in our survey was voluntary and our study population included all patients who underwent therapy during the study period. We did not identify any specific predictive factors for survey participation, but we did note that patients who declined to participate in the survey of the EET arm were slightly older than patients who chose to participate (77 years vs 66 years) and were all male. As with any survey, there is the possibility of self-selection bias where more respondents with either strongly positive or strongly negative feelings would be more likely to participate. The lack of variability in decision confidence and decision regret within groups suggests that this effect is small.

Our survey was either administered during a scheduled gastroenterology clinic or endoscopy visit at our institution or by an interviewer identifying himself as affiliated with Vanderbilt University. This distinction opens the possibility that survey responses could be influenced by auspices bias, by which responses are influenced by the organization conducting the survey. It is possible that responses may have differed if the surveyor identified himself as a surgeon, or did not reveal any institutional affiliation.

This was a single-center retrospective experience, in which one physician served as both the treating endoscopist and the clinical consultant for all EET cases. This factor may decrease practice variability in the study, but may lead to a lack of generalizability and external validity. The size of our cohort, particularly the esophagectomy cohort, limits the power of statistical analysis, and it is possible that a larger sample size could influence study findings. A multicenter prospective study would be ideal to further investigate these findings, but this may be a moving target in the midst of a paradigm shift: as rates of esophagectomy for BE HGD/T1a EAC decline, future enrollment of a sizable surgical cohort may prove difficult.

The study instruments were adapted from studies involving breast cancer treatment, but have not yet been validated in the setting of patient decisions for treatment of BE associated neoplasia. Also, health literacy was not formally assessed as a part of our study.

In summary, this retrospective survey of patients who underwent endoscopic eradication therapy or esophagectomy for BE with HGD or T1a EAC at a tertiary referral center identified a high degree of patient involvement in the decision-making process. Despite differences in specific symptom outcomes,

measures of decision confidence and decision regret do not differ statistically between the two treatment groups. Continued attention to patient preferences, dedication to informed, shared decision making, and further prospective study of factors influencing treatment selection should result in desirable treatment outcomes for patients with BE-associated neoplasia irrespective of treatment modality.

## Acknowledgments

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## Competing interests

None

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## Appendix 1

### Involvement in decision making assessment – Retrospective survey #1

#### Endoscopic treatment cohort

Instructions: please choose the one best response for each question

1. Did any of your doctors discuss surgery as an option for you?  
Yes    No    I'm not sure
2. How much did your doctors discuss reasons to have endoscopic therapy with you?  
A lot    Some    A little    Not at all    I'm not sure
3. How much did your doctors discuss reasons not to have endoscopic therapy with you?  
A lot    Some    A little    Not at all    I'm not sure
4. How much did your doctors discuss reasons to have surgery with you?  
A lot    Some    A little    Not at all    I'm not sure
5. How much did your doctors discuss reasons not to have surgery with you?  
A lot    Some    A little    Not at all    I'm not sure
6. Did any of your doctors ask you whether you preferred endoscopic therapy or surgery?  
Yes    No    I'm not sure

#### Esophagectomy cohort

Instructions: please choose the one best response for each question

1. Did any of your doctors discuss endoscopic therapy as an option for you?  
Yes    No    I'm not sure
2. How much did your doctors discuss reasons to have surgery with you?  
A lot    Some    A little    Not at all    I'm not sure
3. How much did your doctors discuss reasons not to have surgery with you?  
A lot    Some    A little    Not at all    I'm not sure
4. How much did your doctors discuss reasons to have endoscopic therapy with you?  
A lot    Some    A little    Not at all    I'm not sure
5. How much did your doctors discuss reasons not to have endoscopic therapy with you?  
A lot    Some    A little    Not at all    I'm not sure
6. Did any of your doctors ask you whether you preferred surgery or endoscopic therapy?  
Yes    No    I'm not sure

## Appendix 2

### Retrospective survey #2

#### Endoscopic treatment cohort

1. Current age      years
2. Gender (circle one)      Male      Female
3. Surgery was offered to me as an alternative to endoscopic treatment:  
Yes      No
4. I have a family member or friend who underwent endoscopic treatment for Barrett's esophagus or esophageal cancer:  
Yes      No
5. I have a family member or friend who underwent surgery for Barrett's esophagus or esophageal cancer:  
Yes      No
6. Reasons I chose endoscopic treatment rather than surgery include (circle all which apply)
  - a) My age
  - b) My other medical condition(s)/illness(es)
  - c) Risks of surgery
  - d) Fear of cancer spread
  - e) My health insurance
7. The most important reason I chose endoscopic treatment rather than surgery was (circle one):
  - a) My age
  - b) My other medical condition(s)/illness(es)
  - c) Risks of surgery
  - d) Fear of cancer spread
  - e) My health insurance
8. Before undergoing treatment, I had the opportunity to speak with another patient who had undergone endoscopic treatment for this condition:  
Yes      No
9. I would have liked the opportunity to speak with another patient who had undergone endoscopic treatment for this condition:  
Yes      No
10. Since undergoing treatment, I have difficulty swallowing:  
Yes      No
11. Since undergoing treatment, my ability to eat a normal diet has changed:  
Yes      No
12. Compared to how I felt prior to undergoing treatment, my current overall health is (circle one):
  - a) Much better
  - b) Somewhat better
  - c) The same
  - d) Somewhat worse
  - e) Much worse
13. On a scale of 0 to 10 where 0 is not at all confident and 10 is extremely confident, how confident are you that the decision about treatment was the right one for you? (circle one response)  
0   1   2   3   4   5   6   7   8   9   10
14. If you had the chance to make the decision again, would you have the same type of treatment (circle one response):
  - a) Definitely yes
  - b) Probably yes
  - c) Not sure
  - d) Probably no
  - e) Definitely no

#### Esophagectomy cohort

1. Current age      years
2. Gender (circle one)      Male      Female
3. I have a family member or friend who underwent endoscopic treatment for Barrett's esophagus or esophageal cancer:  
Yes      No
4. I have a family member or friend who underwent surgery for Barrett's esophagus or esophageal cancer:  
Yes      No

5. Reasons I chose surgery rather than endoscopic treatment include (circle all which apply)
  - a) My age
  - b) My other medical condition(s)/illness(es)
  - c) Fear of cancer spread
  - d) My health insurance
  - e) Desire to avoid multiple treatment sessions
6. The most important reason I chose surgery rather than endoscopic treatment was (circle one):
  - a) My age
  - b) My other medical condition(s)/illness(es)
  - c) Fear of cancer spread
  - d) My health insurance
  - e) Desire to avoid multiple treatment sessions
7. Before undergoing treatment, I had the opportunity to speak with another patient who had undergone surgery for this condition:  
Yes    No
8. I would have liked the opportunity to speak with another patient who had undergone surgery for this condition:  
Yes    No
9. Since surgery, I have difficulty swallowing:  
Yes    No
10. Since surgery, my ability to eat a normal diet has changed:  
Yes    No
11. Compared to how I felt prior to undergoing surgery, my current overall health is (circle one):
  - a) Much better
  - b) Somewhat better
  - c) The same
  - d) Somewhat worse
  - e) Much worse
12. On a scale of 0 to 10 where 0 is not at all confident and 10 is extremely confident, how confident are you that the decision about treatment was the right one for you" (circle one response)  
0 1 2 3 4 5 6 7 8 9 10
13. If you had the chance to make the decision again, would you have the same type of treatment (circle one response):
  - a) Definitely yes
  - b) Probably yes
  - c) Not sure
  - d) Probably no
  - e) Definitely no