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Endoscopic therapy and surveillance versus esophagectomy for early esophageal adenocarcinoma: A review of early outcomes and cost analysis

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ABSTRACT

Background: Endoscopic therapy is considered to be comparable to esophagectomy with respect to oncologic outcomes in early (cT1) esophageal adenocarcinoma (EC). The current study aims to compare early outcomes and financial costs, associated with endoscopic versus surgical therapy for early esophageal adenocarcinoma.

Methods: Retrospective review of patients undergoing either endoscopic or surgical therapy for cT1 EC between 2010 and 2015.

Results: Age, BMI, and Charlson Comorbidity Scores were similar in patients undergoing endoscopic therapy (N = 20) and esophagectomy (N = 23). For patients undergoing endoscopic therapy a median of 6 endoscopic interventions, were performed per patient (range 2–18). Esophagectomy was associated with a median hospital stay of 9 (8–13) days and greater procedure specific morbidity compared to endoscopic therapy. Costs related to endoscopic therapy were significantly lower compared to esophagectomy ($22,640 vs. $53,849, P < 0.001).

Conclusions: Endoscopic treatment is associated with decreased morbidity and financial costs when compared to esophagectomy.

Introduction

The incidence of esophageal adenocarcinoma is increasing in Western countries[1] secondary to an increase in cancer-specific risk factors, including gastroesophageal reflux disease, obesity, Barrett's esophagus, and smoking.[2] In patients diagnosed with Barrett's esophagus, early esophageal adenocarcinoma can be found during surveillance endoscopy.[3] The yearly incidence of esophageal adenocarcinoma may be as high as 7–19% of patients presenting with Barrett's mucosa containing high-grade dysplasia.[4]

The current management for high-grade dysplasia and T1a esophageal adenocarcinoma typically involves endoscopic treatment. There is also some evidence supporting selective endoscopic treatment for T1b esophageal adenocarcinoma.[4] If endoscopic treatment is chosen, endoscopic mucosal resection (EMR) of any nodular or suspicious area is undertaken followed by ablation of any remaining Barrett's metaplasia. Since recurrence of Barrett's metaplasia is not uncommon after endoscopic treatment, and residual Barrett's mucosa has been documented underneath intact squamous epithelium, frequent follow-up endoscopies, including biopsies, are mandatory to detect disease recurrence in a stage amenable to repeated EMR or salvage esophagectomy.[5]

Esophagectomy for T1a or T1b (sm1) esophageal adenocarcinoma should be considered in patients with poor differentiation, lymphovascular invasion, or incomplete resection by EMR.[4] Due to an increased incidence of lymphatic spread associated with T1b (sm2-3) esophageal adenocarcinoma, neoadjuvant chemoradiotherapy and esophagectomy are still recommended in current guidelines for T1B

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(sm2-3) disease.[4] Multifocal tumors, long-segment Barrett's mucosa harboring multiple high-grade dysplastic areas, large tumors and tumors adjacent to a hiatal hernia may also be considered for esophagectomy.[6]

Endoscopic therapy is associated with lower morbidity and fewer functional sequelae compared to esophagectomy.[4] Overall costs of these treatments is yet to be comprehensively studied and reported. The importance of such analysis is increasingly relevant in the setting of greater scrutiny and accountability for the use of increasingly limited healthcare resources.

The aim of the current study was to determine financial costs associated with endoscopic and surgical therapy for early (cT1) esophageal adenocarcinoma. Secondary aims were to compare treatment-related morbidity associated with these interventions.

Materials and methods

Patient population

Patients who underwent either surgical or endoscopic treatment for early (cT1, N0, M0) esophageal adenocarcinoma at Virginia Mason Medical Center, with the index procedure performed during the period January 1, 2010 to December 31, 2015, were eligible for inclusion in this study. To ensure comparability between treatment groups, only those patients who were deemed medically fit to undergo esophagectomy, regardless of ultimate management, were included. Exclusion criteria included: patients who received neoadjuvant therapy, and patients who were lost to follow-up. Data for each patient group was recorded within prospectively maintained and IRB-approved databases.

Patients, who started with endoscopic therapy and were found to be at increased risk for incomplete resection or failure to follow-up, were repeatedly presented at the tumor board by their managing gastroenterologists. If appropriate, those patients crossed over for esophagectomy. The associated cost data was not included in one of the predefined groups but outlined individually.

Treatment planning

All patients were discussed at a multidisciplinary tumor board meeting. For those patients undergoing consideration for surgical intervention, staging investigations included: upper gastrointestinal endoscopy, contrast enhanced computer tomography (CT) of the thorax, abdomen and pelvis, positron emission tomography-CT, and endoscopic ultrasound with or without fine needle aspiration. Staging investigations performed prior to endoscopic therapy included: upper gastrointestinal endoscopy, contrast enhanced computer tomography (CT) of the thorax, abdomen and pelvis, and, in selected patients, PET-CT and endoscopic ultrasound with or without fine needle aspiration. All patients, regardless of the final treatment strategy, were reviewed by a senior surgeon and an experienced interventional gastroenterologist before commencing therapy. The pathology of the tumor, risk of lymphatic spread, as well as advantages and disadvantage of each therapeutic option were thoroughly discussed. The final decision with regard to treatment approach, however, rested with the patient having been adequately counseled regarding the tumor board's recommendation.

Surgical treatment

All surgical patients underwent a transthoracic esophageal resection via either an Ivor Lewis approach with intrathoracic anastomosis or left thoracoabdominal incision with cervical anastomosis. Upper gastrointestinal continuity was restored in all cases using a gastric conduit. Perioperative patient management followed a standardized multidisciplinary care pathway.[7]

Endoscopic treatment

Endoscopic therapy principally included endoscopic mucosal resection (EMR) to remove all visible neoplastic lesions utilizing either the Duette® Multi-Band Mucosectomy Device (Cook Medical Inc., Winston-Salem, NC) or the cap mucosectomy kit (EMR Kit, Olympus America Inc., Center Valley, PA). After that, residual Barrett's esophagus mucosa was treated with ablative techniques or completion mucosectomy depending on the length of the Barrett's segment. Follow-up according to an institutional Barrett's esophagus treatment algorithm included four-quadrant biopsies according to the Seattle protocol every three months for the first year, biannually in the following year, and subsequently annually.

Cost analysis

For the esophagectomy group, treatment costs were calculated from: the index admission, readmissions within 30 days of primary hospital discharge, and outpatient endoscopic interventions performed within 12 months of surgery. In accordance with institutional practice, a single diagnostic EMR prior to esophagectomy was permitted and was not included in the final analysis of treatment costs.

For the endoscopy group, total costs included any therapeutic endoscopy performed for the treatment of esophageal cancer. However, similar to the esophagectomy group, the initial staging endoscopy (±EMR) was not included in the final cost analysis. Up to three surveillance endoscopies, for which cost data was available, were included in the final cost analysis. This typically included initial follow-up endoscopies performed within 9–12 months after completion of the therapeutic component of patient's endoscopic treatment. This time period was chosen in order to be comparable to the esophagectomy group, who routinely underwent endoscopic examination of the upper gastrointestinal tract within 12 months after surgery.

The cost accounting system used at our institution has been previously described.[8] The Alliance Decision Support System allows individual identification and tracking of all costs associated with patient treatment (Alliance Decision Support MedAssets, Inc., Atlanta, GA). The costs model consists of two main modules: direct, and indirect costs. The Alliance cost module consists of seven direct cost components. These are costs directly related to the departmental output and include: the physician salaries, room and board expenses, and drugs and medical supplies for the patient. Indirect costs represent institution expenses incurred from the overhead departments (for example, gastrointestinal laboratory facility fees) which support the producing departments (for example, the surgical department in case of an esophagectomy). Yearly cost progression during the study period was found to be 5%. Therefore, costs were adjusted according to the specific year they were generated to resemble the 2016 cost level.

Statistical analysis

SPSS software version 23 (IBM Analytics, Armonk, NY, USA) was used for data analysis. Continuous variables following a normal distribution were compared with the Student's *t*-test and presented as mean ± standard deviation (SD). Nonparametric continuous variables were compared with the Mann-Whitney *U* test and presented as median and interquartile range (IQR). Categorical variables were compared using the chi-square and Fisher's exact test, as applicable, and presented as numbers and percentages. Pearson

correlation was performed for correlation of total costs and complication frequency and complication grade for the esophagectomy group, and correlation of total costs and number of endoscopies for the endoscopy group. A two-sided P value of less than 0.05 was considered statistically significant.

Results

Twenty-three patients who underwent esophagectomy and 20 patients who underwent endoscopic therapy for early esophageal adenocarcinoma were identified as being eligible for inclusion in the current study (Fig. 1). Three additional patients who underwent esophagectomy after failing endoscopic management (≥2 unsuccessful EMRs) were excluded from the final cost analysis. The reasons for therapeutic crossover in these patients were: failure of repeated EMR in two patients, and evidence of submucosal tumor extension at the time of second EMR, with tumor board recommendation for esophagectomy in one patient. All patients, who underwent endoscopic therapy, had clinical stage T1a, while 15 patients in the esophagectomy group had T1b disease (P < 0.001). Patient groups were well matched for all other baseline characteristics (Table 1).

Table 1
Patient characteristics.

	Esophagectomy n = 23	Endoscopy n = 20	*P* value
Sex (M/F)	17/6 (74%/26%)	16/4 (80%/20%)	0.73
Age (years)[1]	68 ± 10	65 ± 10	0.38
BMI[1]	30 ± 6	32 ± 8	0.41
ECOG Performance Status[2]	0 (0–2)	1 (0–1)	0.47
ASA II/III	9/14 (39%/61%)	13/7 (65%/35%)	0.09
Age adjusted CCI[2]	5 (2–8)	4.5 (2–9)	0.41
Cardiac comorbidity	4 (17%)	3 (15%)	1.0
Pulmonary comorbidity	5 (22%)	8 (40%)	0.33
Chronic renal insufficiency	1 (4%)	0 (0%)	1.0
Current or former Smoker	16 (70%)	15 (75%)	0.96
Current or previous alcohol consumption	11 (48%)	7 (35%)	0.59
Clinical T-stage			
T1a	5 (22%)	20 (100%)	<0.001
T1b	15 (65%)	–	
T1 (not further defined)	3 (13%)	–	
Pathological T-stage			
T0	5 (22%)	–	
T1a	1 (4%)	–	
T1b	11 (48%)	–	
T2	3 (13%)	–	
Pathological N-stage			
N0	18 (78%)	–	
N1	2 (9%)	–	
N2	2 (9%)	–	
N2	1 (4%)	–	

ECOG, Eastern Cooperative Oncology Group Performance Status. ASA, American Society of Anesthesiology score. CCI, Charlson Comorbidity index. [1]Values are mean ± standard deviation. [2]Values are median and (interquartile range).

Surgical treatment

Esophagectomy was performed by either an open Ivor Lewis or left thoracoabdominal approach in 11 (48%) and 12 (52%) patients, respectively. Mean operative time was 6.93 ± 0.73 h, with a median of 200 ml (IQR 150-263) blood loss (Table 2).

Twelve (52%) out of 23 patients experienced 30 perioperative complications (Table 2) including five patients who suffered nine severe complications according to the Accordion classification system (Table 2). Severe complications were those defined as requiring an intervention with or without general anesthesia or any organ failure. There was no in-hospital or 90-day mortality in the esophagectomy group. Median Intensive Care Unit (ICU) and hospital length of stay was one (1–2) and nine (8–13) days, respectively. Three (13%) patients required a combined total of six hospital readmissions within 30 days of initial discharge that were included in the cost analysis. All primary hospital readmissions occurred within one week of hospital discharge, with two patients requiring further readmissions within 30 days of initial discharge. Five (22%) patients required endoscopic dilations within the first year after esophagectomy that were included in the cost analysis.

Endoscopic treatment

A median of six endoscopies (range 2–18), were performed in patients who received endoscopic therapy. In total, 16 (80%) patients required five or more endoscopic mucosal resections (EMR) to achieve satisfactory disease excision (Table 3). Additional interventions that contributed to the final cost analysis included twelve (60%) patients who received 1–4 sessions of radiofrequency ablation, while the remaining eight patients received no radiofrequency ablation. Two (10%) patients received 1–4 sessions of cryoablation, while other thermal ablations (e.g., Argon beam ablation) were performed in six (30%) patients. Endoscopic dilations due to stricture formation were required in five (25%) patients, after endoscopic therapy with one patient, requiring a total of 15 dilations (Table 3). Endoscopic biopsies were performed in every patient with five (25%) patients receiving ≥5 diagnostic

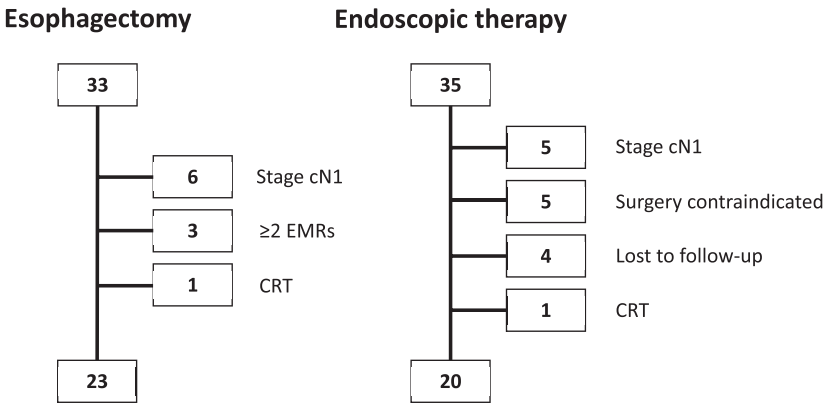

Fig. 1. Patient selection and exclusions.

Table 2
Short-term outcomes of esophagectomy.

	N = 23
Operative time (hours)	6.93 ± 0.73
Blood loss (ml)	200 (150–263)
Surgical procedure	
Two stage	11 (48)
Left thoracoabdominal	12 (52)
ICU LOS (days)	1 (1–2)
LOS (days)	9 (8–13)
Complications (Accordion classification)	
Mild	
Pneumothorax	2 (9%)
Ileus	1 (4%)
Delirium	1 (4%)
Moderate	
Atrial fibrillation/flutter	5 (22%)
Pneumonia	4 (17%)
Chyle leak	1 (4%)
Other GI complication	1 (4%)
Urinary infection	1 (4%)
Deep vein thrombosis	1 (4%)
Pulmonary emboli	3 (13%)
Wound infection	1 (4%)
Delirium	1 (4%)
Severe	
Pleural effusion	1 (4%)
Pneumothorax	1 (4%)
Respiratory failure	2 (9%)
Anastomotic leak	3 (13%)
Gastric conduit perforation	1 (4%)
Sepsis	1 (4%)
Death (in hospital or 90 day mortality)	0 (0%)
30-day readmissions, reason:	3 (13%)*
Pneumonia	1
Pulmonary embolism	2
Endoscopic dilations within <1yr	5 (22%)

ICU, intensive care unit. LOS, length of stay. GI gastrointestinal. *Includes two patients who required multiple readmissions. Accordion classification: Mild, requiring minor bedside intervention, physiotherapy and permitted drugs; Moderate, requiring pharmacological intervention other than that permitted for mild complications; Severe, invasive procedure with or without general anesthesia required or organ failure.

biopsies over the course of their endoscopic treatment. Endoscopic ultrasound was used in nine (45%) patients and fine needle aspiration was performed in three (15%) patients (Table 3).

Seventy-two percent of all endoscopic procedures were performed under general anesthesia, with sedation required for all remaining procedures. Same-day discharge was achieved after 98% of endoscopic procedures. Inpatient admission was required on two occasions: in one case for severe pain following endoscopic radiofrequency ablation, and in another case for concern regarding esophageal perforation, which was ultimately excluded after a normal contrast swallow and extended routine monitoring. Hospital admission within 30 days of an endoscopic procedure was required in two patients. The first patient presented with pain secondary to a displaced esophageal stent, which was subsequently removed. A second patient presented with suspected upper gastrointestinal bleeding one day following EMR and ablative therapy, although no active bleeding was seen on repeated endoscopy.

Table 3
Frequency of endoscopic procedures.

	Patient number	<5 procedures required	≥5 procedures required	Range
Total endoscopies performed	**20**	**6 (30%)**	**14 (70%)**	**2–18**
Total diagnostic procedures	**20**	**16 (80%)**	**4 (20%)**	**0–5**
Biopsy only	20	16 (80%)	4 (20%)	1–10
Endoscopic ultrasound	9	9 (45%)	0 (0%)	0–2
Fine needle aspiration	3	3 (15%)	0 (0%)	0–1
Total therapeutic procedures	**20**	**4 (20%)**	**16 (80%)**	**2–17**
Endoscopic mucosal resection	18	3 (15%)	16 (80%)	0–6
Radiofrequency ablation	12	12 (60%)	0 (0%)	0–4
Cryoablation	2	2 (10%)	0 (0%)	0–3
Other thermal ablation	6	6 (30%)	0 (0%)	0–1
Other endoscopic procedures				
Dilation	5	4 (20%)	1 (5%)	0–15

Cost comparison

Median treatment costs for patients undergoing esophagectomy were significantly greater than costs incurred for patients receiving endoscopic therapy only ($53,849, 95% confidence interval (CI): 50,541-88,784 vs. $22,640, 95%CI: 18,754-46,705, $P < 0.001$). This difference persisted when only T1a cancers were compared ($P = 0.025$). The minimum cost associated with esophagectomy in the current study was approximately four times greater than for endoscopic therapy ($40,410 vs. $9236). Interquartile range was $46,28**5** - $76,096 for esophagectomy, and $14,750 - $34,400 for endoscopic treatment.

In comparison, the maximum cost incurred for surgical and endoscopic therapy in two patients was $247,808 and $127,508, respectively. In the esophagectomy group, there was a strong correlation of total costs and number of complications, ($r = 0.92$, 95% CI: 0.81–0.96, $P < 0.001$. Fig. 2A). Similarly, complication severity was correlated with increased costs ($r = 0.62$, 95%CI: 0.28–0.82, $P = 0.002$. Fig. 2B). In the endoscopy group, total costs correlated strongly with the number of endoscopies performed ($r = 0.93$, 95% CI: 0.82–0.97, $P < 0.001$. Fig. 2C).

In three patients, who were not included in the groups above, repeated endoscopic therapy was followed by esophagectomy after repeated tumor board presentation. The total costs, including costs associated with endoscopic therapy and esophagectomy, were $59.973, $69.386 and $53.172. Of note, crossover to esophagectomy resulted in total costs ranging within the 95% confidence interval of esophagectomy only.

Discussion

The aim of the present study was to compare early outcomes and costs for endoscopic and surgical therapies for early esophageal adenocarcinoma. Despite the requirement for a greater number of interventions, the costs associated with endoscopic treatment modalities were significantly lower when compared to esophageal resection. Furthermore, the rate of early complications associated with endoscopic therapies was minimal compared to patients undergoing esophagectomy.

The study population presented in the present analysis was homogenous in a sense that all patients were deemed physically fit to undergo esophageal resection. No patient had advanced disease (all patients were classified cT1cN0cM0), and no patient received neoadjuvant chemoradiotherapy. Therefore, patient characteristics are less likely to play a major role explaining the difference in total costs. As expected, total costs correlated with the amount and severity of complications in the esophagectomy group. For the endoscopy group, total costs were related to the number of procedures performed. The number of procedures performed per patient was related to the ability to adequately resect neoplastic regions and length of associated Barrett's mucosa as well as complications resulting from endoscopic therapy. The highest number

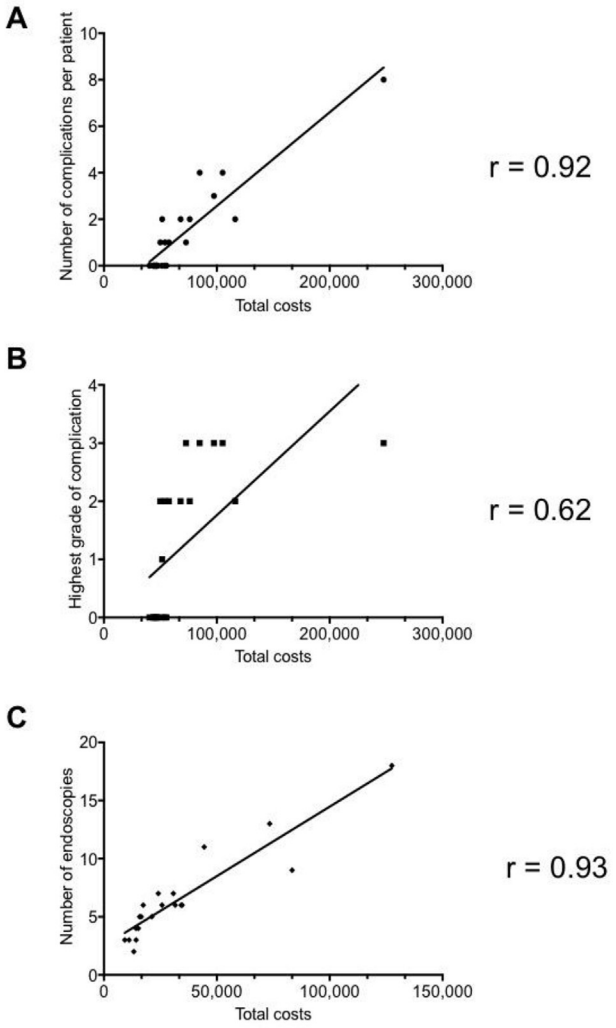

Fig. 2. Cost correlation analysis for (A) number ($P < 0.001$) and (B) severity ($P = 0.002$) of complications in patients undergoing esophagectomy, and (C) number of endoscopies in patients receiving endoscopic therapy ($P < 0.001$).

of procedures in the current series was encountered in a patient who developed an esophageal stricture following endoscopic therapy. This patient had a total of 18 endoscopies performed, which included 15 endoscopic dilations. Total costs for this specific case amounted to $127.508 and was the highest cost incurred for treatment by any patient in this group. By comparison, the lowest cost of endoscopic therapy was less than $10,000 and encompassed three endoscopies, combining a total of seven interventions, including: two biopsies, one EMR, two ablative therapies, one EUS, and one dilation.

In addition to morbidity and financial costs, quality of life and fear of cancer recurrence play a major role when deciding between surgical or endoscopic therapy for early esophageal cancer. Rosmolen and colleagues compared dedicated quality of life scores and a Worry of Cancer Scale between patients undergoing endoscopic therapy versus surgical therapy for early esophageal cancer. They found that quality of life indices favored endoscopic treatment over esophagectomy for early esophageal cancer. However, fear of cancer recurrence in the endoscopic treatment group was higher when compared to patients with early esophageal cancer who underwent surgery.[9] Recurrence of invasive cancer and, in rare cases metastatic disease, is recognized following endoscopic management of esophageal cancer and underscores the importance of careful surveillance in this patient group.[10] Furthermore, as is shown in the current study, a proportion of those patients who are initially treated endoscopically will eventually require surgical therapy for a number of reasons including: failure of endoscopic therapy, the finding of lymphovascular invasion, extended segment Barrett's with multifocal disease, concern for patient compliance with follow-up, and patient choice. While esophagectomy is clearly a more morbid and as demonstrated by this study, costly procedure, it does, however, facilitate complete pathological staging and exclusion of all known disease. Definitive surgery may, therefore, alleviate some of the financial and psychological burdens that may be associated with active disease surveillance after endoscopic resection.

In the current study, failure of endoscopic therapy was associated with the inability to completely remove high-grade dysplasia and superficial carcinoma by EMR in two of three patients. Managing interventional gastroenterologists would typically request a reassessment and multidisciplinary tumor board review if concern was raised during endoscopic therapy regarding inability to clear dysplastic or neoplastic epithelium or if other factors arose which led to concern regarding long-term follow-up.

Limitations of the current study include its relatively small sample size and retrospective design. While it was not the aim of this study to determine the effects of therapeutic intervention on quality of life or long-term survival, these outcomes should be addressed as a priority in future studies. Due to the treatment standards during the study period, the endoscopy group comprises only patients with cT1a disease, while the majority of the esophagectomy patients had cT1b disease. The risk of endoscopic treatment failure may be higher with T1b disease, and that cannot be accounted for with this analysis. Costing presented in this study was based on costs incurred within a single hospital and it remains uncertain how these might compare to other institutions and healthcare systems. The inability to capture all costs that are associated with a patient's management over a prolonged and often ongoing period of time is also recognized as a limitation of this study. Specifically, the financial costs of long-term endoscopic surveillance in the endoscopic treatment group could not be completely captured by this study. Primarily for patient convenience, three normal surveillance endoscopies are typically required in our tertiary referral center before the endoscopic follow-up is transferred back to the local care provider. Final treatment costs that are often spread between different hospitals and providers are therefore hard to accurately determine.

In conclusion, endoscopic treatment of early esophageal adenocarcinoma is associated with decreased financial costs when compared to esophagectomy. Potential treatment failure and requirement for prolonged surveillance should, however, be considered when helping patients make decisions about their individual care.

Conflicts of interest

The authors have no conflict of interest to declare.

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