



# Esophageal stent failure: a retrospective cohort study

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**Background:** Esophageal stents are a widely used treatment method for various esophageal pathologies such as malign and benign obstruction and contained perforations of the esophagus. The aim of this study was to identify the risk factors affecting esophageal stent failure rates.

**Methods:** A total of 469 patients receiving esophageal stents were included in this retrospective observational study. The stents were inserted between January 2005 and December 2013 in a single tertiary center. Primary outcome was stent failure, classified as any major complication related to the stent or the need to replace or urgently remove the esophageal stent.

**Results:** Esophageal cancer was found in 331 (70.6%) patients, whereas non-esophageal cancer in 79 (16.8%) and benign esophageal disease in 59 (12.6%) patients. Dysphagia was the most common symptom indicating the stent insertion with 371 (79.1%) patients, perforation being the second most common (N=33, 7.0%). Stent failure rate was 34.3% (N=161), with median time to stent failure of 75 days (24–161 days). Multivariate Cox proportional hazards analysis showed stent location in the middle third of the esophagus to carry a higher risk for stent failure compared to distal esophagus [hazard ratio (HR) =1.818, 95% confidence interval (CI): 1.26–2.63, P=0.002]. Stent length of 12–15 cm was associated with higher risk of stent failure than stent lengths of <12 cm (HR =1.462, 95% CI: 1.01–2.11, P=0.042). Pre-insertion dilatation was also shown to correlate with higher rate of stent failure (HR =1.704, 95% CI: 1.13–2.57, P=0.011).

**Conclusions:** Stent failure is more prevalent when stenting the mid-esophagus, using longer stents or after performing esophageal dilatation prior to stenting.

**Keywords:** Esophageal stent; complications; esophageal cancer (EC); thoracic malignancy; benign esophageal disease

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## Introduction

Esophageal stents offer a minimally invasive means to treat esophageal pathologies, malignant obstruction being the most common indication for insertion (1).

Self-expanding metallic stents (SEMS) have been a mainstay of palliation of malignant esophageal obstruction for over two decades (2,3). They offer rapid relief of dysphagia and a short procedural time (3). A Cochrane

review concluded that SEMS are a safe and effective intervention in the palliation of dysphagia in esophageal cancer (EC) (4). Older versions of fully covered SEMS have been found to have a high migration rate *vs.* partially covered SEMS (5), but trials of newer models show similar performance between fully and partially covered SEMS (6,7). SEMS insertion is the most widely used approach in treatment of malignant tracheoesophageal or bronchoesophageal fistulas with reported closure rates of

85–93% (8,9). SEMS have also been studied as a bridge to surgery in EC during treatment neoadjuvant chemoradiation or chemotherapy, although the effect of this intervention on oncological outcomes is unclear (10–12). Extraesophageal compression by mediastinal tumors is effectively treated with a SEMS, although the amount of relief from dysphagia might be lower than in EC (13). Stents have also been studied in esophageal perforation with good success rate (14). Self-expanding plastic stents (SEPS) have been used in treatment of benign esophageal strictures, postoperative- and iatrogenic esophageal leaks (15–20).

Stent complication rates have been previously reported to be between 23% and 56% with the risk of major complications such as pneumonia, fistula formation, or aspiration up to 22% (21–25). The rates of re-intervention vary between 17% and 47%, the most common re-interventions being food bolus impaction, argon laser coagulation for tumor overgrowth and additional SEMS insertion (22,25). Several risk factors for adverse events related to stenting have been identified, such as chemoradiation therapy before or after stent placement, advanced tumor stage and/or tumor invading the aorta (26–28). Longer stent lengths and larger stent diameter are linked to less complications (28). In the treatment of esophageal perforation and esophageal anastomotic leak post-esophagectomy, stent removal before 28 days was associated with 39% reduced risk of complications (14).

The aim of this study was to identify the risk factors affecting the stent failure rates, and survival of patients who received an esophageal stent. Our hypothesis was that the risk of stent failure is greater in benign indications of esophageal stenting and with smaller stents. To assess these questions, the primary endpoint stent failure (any major complications or non-planned need for removal of the stent) was chosen with the secondary endpoint of overall survival (OS).

## Methods

### *Data collection*

The Helsinki University Hospital (HUU) academic review board granted an institutional study permit for the review of relevant medical records.

Data was collected retrospectively from HUU medical records. All patients receiving an esophageal stent between January 2005 and December 2013 were included. The time period was selected due to availability of electronic medical

records (EMR). A total of 469 patients were identified for this study. We collected the following data from our center's EMR: demographic parameters, patients' primary diagnosis and comorbidities, details of stent insertion, time of death, and details related to stent complications. Due to universal healthcare, the EMR is comprehensive with good follow up data.

The primary outcome was stent failure, defined here as a major complication caused by the stent (perforation, fistula formation, severe pain, stent obstruction or bleeding), tumor overgrowth facilitating a new stent, or any need for non-planned urgent removal of a stent. Migration of the stent was considered a stent failure in the setting of permanent stenting, i.e., in the setting of palliative treatment of malignant esophageal obstruction with a stent. Migration is defined here as a symptomatic relocation of the stent into the hypopharynx or stomach. This composite endpoint was constructed as a means to evaluate any factors that lead to any stent-related harm or major inconvenience to the patient. Follow up lasted until January 2017.

### *Stent-insertion protocol*

The stents were placed under conscious propofol sedation or general anesthesia using the standard technique over guidewires and with the help of fluoroscopy. The stents used were Ultraflex, Polyflex, Wallflex (Boston Scientific Corporation, Marlborough, Massachusetts), MICRO-TECH oesophagus stent (MICRO-TECH, Nanjing, China), Niti-S™ esophageal stent (Taewoong Medical, Gyeonggi-do, South Korea) and ENDOMAXX esophageal stent (Merit Medical Endotek, South Jordan, Utah). Ultraflex is a partially covered SEMS and Wallflex, MICRO-TECH and ENDOMAXX are fully covered SEMS, whereas Polyflex is a SEPS. The location and size of the underlying pathology determined the lengths and diameter of the inserted stent. Dilatation was performed as an adjunct if deemed necessary by the surgeon placing the stent. Stent position was confirmed endoscopically and radiologically. After stent insertion, patients were admitted for observation and optimization of nutritional support and pain management. A non-barium swallow study was done post-insertion to assess for the patency and location of the stent. Patients receiving a stent as part of neoadjuvant treatments for cancer received an upper endoscopy before surgery to assess the possible migration of stent, if the stent was found migrated to the stomach during imaging studies, a removal was done semi-urgently. Follow-up plan

was individualized for patients with perforation or post-operative leakage treated by esophageal stent, depending on the complexity of the lesion.

### Statistical analysis

All statistical analysis was done with R Project (R Core Team, 2016). R: a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria. URL: <https://www.R-project.org/>). Variables are presented as mean and standard deviation for normally distributed variables and as median and interquartile range (IQR) for non-normally distributed variables. Shapiro-Wilks test determined the normality of the variables. Variables were compared using the Mann-Whitney U test for non-normal variables continuous and Student's *t*-test for normally distributed continuous variables. Correlations were measured by Pearson product moment correlation. Categorical variables were compared with  $\chi^2$  test. The survival analysis used was Kaplan-Meier's. Cox multivariate regression analysis was done by selecting the variables on a theoretical basis for the whole study population using ubiquitous patient characteristics (diagnosis type, age & gender) and stent-related variables (stent type, stent size, stent location, pre-insertion dilatation). The same model was used for the sub-group analyses without the diagnosis type as a variable.

### Results

This study included 469 patients. Patient demographics and stent details by the primary diagnosis class are presented in *Table 1*. EC was the most common pathology (N=331, 70.6%), with 181 (54.7%) adenocarcinomas, 135 (40.8%) squamous cell carcinomas and 16 (4.8%) other histologies. Non-ECs (N=79, 16.8%) were comprised of 47 (59.5%) lung cancers, 5 (6.3%) breast cancers, 5 (6.3%) mesotheliomas and 22 (27.8%) various cancers. The benign pathologies (N=59, 12.6%) consisted of 24 (40.7%) iatrogenic perforations, 17 (28.8%) non-iatrogenic perforations, 12 (20.3%) strictures due to prolonged gastroesophageal reflux disease, 4 (6.8%) motility disorders of the esophagus and 2 (3.4%) strictures due to corrosion injury. Overall, the morbidity of the population was high with median Charlson comorbidity index (CCI) score of 7 (IQR, 5–7), including the points added from possible malignant disease. Most of the stents were placed as a permanent palliative treatment modality (N=281, 59.9%).

Median hospital stay was 2 days (IQR, 1–5 days). Partially covered SEMs were the most used stents in the setting of malignant esophageal disease (N=304, 91.8% in EC; N=65, 82.3% in other types of cancer), whereas fully covered SEMs were the most used stent type in benign indications (N=27, 45.8%). Re-stenting was done in 139 (29.6%) patients. Stenting was associated with other procedures (surgical or endoscopic) in 140 cases. These procedures are outlined in *Table S1*. Esophagectomy was performed in relation to the stenting in 55 (11.7%) patients, 43 of these were planned as a definitive treatment for EC, 5 patients had stent inserted for treatment of fistula after a esophagectomy for EC, 3 patients initially received a stent for treatment of iatrogenic perforation during endoscopy for benign disease and later progressed to esophagectomy due to complicated disease course, 2 patients received stent for treatment of bleeding after EMR and then received esophagectomy for treatment of EC, and 2 patients received stenting for treatment of recurrent cancer after esophagectomy. Median time between stenting and the associated procedure was 8 days (IQR, –129 to 77 days). The associated procedure preceded the stenting in 38.9% (N=54) of the cases.

*Table 2* displays the stent failure rates and types of stent failure in the patient groups. Stent failure between EC, non-EC and benign disease groups was statistically significant (37.8%, 19.0% and 35.6%, respectively, P=0.007), whereas stent re-insertion rates were not statistically different between the groups (29.0%, 30.4%, and 27.1%, respectively, P=0.175). Complications related to stenting are also presented in *Table 2*. A total of 115 patients (24.5%) suffered complications and 18 patients had more than one complication related to the stenting. Stent migration (N=53, 11.3%) and esophageal fistula to the trachea, bronchial tree or mediastinum (N=29, 6.2%) were most prevalent amongst complications. No intraoperative deaths related to stent placement were reported. The rate of complications in the EC group was 27.5% (N=91), 13.9% (N=11) in non-EC and 22.0% (N=13) in benign esophageal disease (P=0.037). The stent type (partially covered SEMs, fully covered SEMs or SEPS) did not affect the amount of complications (P=0.937). Patients who were stented as a destination therapy had less complications *vs.* those who received a temporary stent (N=51, 18.1% *vs.* N=64, 34.0%; P=0.001). In the patients who suffered more serious complications (fistula or perforation), the stent treatment time was significantly shorter (194 *vs.* 111 days, P=0.006).

Median time to stent failure was 75 days (24–161 days) in the study population with a 6-month stent failure rate of

**Table 1** Patient demographics by primary diagnosis

Demographics	Esophageal cancer (N=331)	Non-esophageal malignancy (N=79)	Benign (N=59)	P value
Age, median [IQR], years	68 [61, 77]	67 [63, 75]	64 [58, 72]	0.035
CCI, median [IQR]	7 [5, 9]	7 [5, 8]	4 [2, 6]	0.625
Gender (%)				0.240
Male	164 (49.5)	47 (59.5)	28 (47.5)	
Female	167 (50.5)	32 (40.5)	31 (52.5)	
Stent location (%)				0.001
Upper esophagus	8 (2.4)	5 (8.1)	3 (6.8)	
Middle esophagus	107 (32.4)	29 (46.8)	6 (13.6)	
Lower esophagus	215 (65.2)	28 (45.2)	35 (79.5)	
Stent size (%)				0.032
<12 cm	137 (43.1)	37 (61.7)	20 (46.5)	
12–15cm	132 (41.5)	20 (33.3)	20 (46.5)	
>15 cm	49 (15.4)	3 (5.0)	3 (7.0)	
Stent type (%)				0.001
Partially covered SEMS	304 (91.8)	65 (82.3)	22 (37.3)	
Fully covered SEMS	13 (3.9)	9 (11.4)	27 (45.8)	
SEPS	14 (4.2)	5 (6.3)	10 (16.9)	
Indication (%)				0.001
Dysphagia	289 (87.3)	63 (79.7)	19 (32.2)	
Perforation	11 (3.3)	4 (5.1)	18 (30.5)	
Postoperative leakage	10 (3.0)	3 (3.8)	18 (30.5)	
Fistula	7 (2.1)	5 (6.3)	1 (1.7)	
Hemorrhage	3 (0.9)	0 (0.0)	1 (1.7)	
Other	11 (3.3)	4 (5.1)	2 (3.4)	
Iatrogenic injury (%)	15 (4.5)	3 (3.8)	21 (35.6)	0.036

IQR, interquartile range; CCI, Charlson comorbidity index; SEMS, self-expanding metallic stent; SEPS, self-expanding plastic stent.

34.3% (N=161). Patients with benign disease had median time to stent failure of 32 days (18–70 days), whereas EC produced a median time to stent failure of 100 days (31–180 days) and other primary cancers showed a median of 46 days (18–98 days), with statistical significance (log rank P=0.01). The 6-month stent failure rates were 74.6% (N=44), 37.1% (N=123) and 15.2% (N=12), respectively (P=0.007).

Multivariate Cox proportional hazards analysis of the

factors affecting stent failure in the whole study population and within the primary diagnosis groups are found in *Table 3*. In the whole study population, mid-esophageal stenting [hazard ratio (HR) =1.818, 95% confidence interval (CI): 1.26–2.63, P=0.002], stent length of 12–15 cm compared to stent length of <12 cm (HR =1.462, 95% CI: 1.01–2.11, P=0.042), and pre-insertion dilatation (HR =1.704, 95% CI: 1.13–2.57, P=0.011) were found to correlate with a higher risk of stent failure. In patients with

**Table 2** Stent failure rates by type of stent failure

Events	Esophageal cancer (N=331)	Non-esophageal malignancy (N=79)	Benign (N=59)	P value
Stent failure (%)	125 (37.8)	15 (19.0)	21 (35.6)	0.007
Stent re-insertion (%)	96 (29.0)	24 (30.4)	16 (27.1)	0.175
Major complication (%)	91 (27.5)	11 (13.9)	13 (22.0)	0.037
Multiple	12 (3.6)	1 (1.3)	5 (8.5)	0.174
Migration	35 (10.6)	3 (3.8)	6 (10.2)	0.174
Bleeding	9 (2.7)	0 (0.0)	0 (0.0)	0.148
Severe pain	5 (1.5)	0 (0.0)	3 (5.1)	0.065
Fistula	26 (7.9)	2 (2.5)	0 (0.0)	0.023
Perforation	11 (3.3)	0 (0.0)	1 (1.7)	0.264
Stent obstruction	4 (1.2)	2 (2.5)	1 (1.7)	0.678

**Table 3** Cox proportional hazards models

Variables	HR	95% CI	P value
Stent failure—all patients			
Diagnosis (benign vs. malignancy)	1.296	0.73–2.30	0.376
Age	0.989	0.97–1.00	0.164
Gender (male vs. female)	0.798	0.57–1.12	0.192
Stent type (SEMS vs. SEPS)	0.691	0.42–1.13	0.137
Stent location			
Mid vs. lower	1.818	1.26–2.63	0.002
Upper vs. lower	2.070	0.81–5.26	0.127
Stent size			
12–15 vs. <12 cm	1.462	1.01–2.11	0.042
>15 vs. <12 cm	0.940	0.54–1.63	0.825
Dilatation	1.704	1.13–2.57	0.011
Stent failure—esophageal cancer			
Age	0.989	0.97–1.01	0.191
Gender (male vs. female)	0.550	0.38–0.81	0.002
Stent type (SEMS vs. SEPS)	1.009	0.42–2.44	0.985
Stent location			
Mid vs. lower	1.953	1.30–2.94	0.001
Upper vs. lower	1.080	0.25–4.65	0.918

**Table 3** (continued)

Table 3 (continued)

Variables	HR	95% CI	P value
Stent size			
12–15 vs. <12 cm	1.435	0.95–2.17	0.086
>15 vs. <12 cm	0.912	0.51–1.63	0.756
Dilatation	1.372	0.86–2.19	0.186
Stent failure—non-esophageal cancer			
Age	0.943	0.86–1.03	0.213
Gender (male vs. female)	1.192	0.22–6.47	0.839
Stent type	0.130	0.004–3.68	0.232
Stent location			
Mid vs. lower	6.151	0.49–77.91	0.161
Upper vs. lower	9.675	0.42–222.22	0.156
Stent size			
12–15 vs. <12 cm	0.812	0.18–3.57	0.782
>15 vs. <12 cm	6.105	0.57–65.13	0.134
Dilatation	N/A*	–	–
Stent failure—benign disease			
Age	0.959	0.91–1.02	0.156
Gender (male vs. female)	9.049	1.74–47.02	0.009
Stent type	0.898	0.38–2.10	0.804
Stent location			
Mid vs. lower	0.902	0.15–5.36	0.910
Upper vs. lower	2.960	0.40–22.09	0.288
Stent size			
12–15 vs. <12 cm	4.710	0.96–23.15	0.057
>15 vs. <12 cm	N/A*	–	–
Dilatation	0.989	0.27–3.62	0.987

\*, no patients in group. HR, hazard ratio; CI, confidence interval; SEMS, self-expanding metallic stent; SEPS, self-expanding plastic stent; N/A, not available.

EC, male gender was found correlate with a smaller risk of stent failure (HR =0.550, 95% CI: 0.38–0.81, P=0.002) and mid-esophageal stenting carried with it a higher risk of stent failure (HR =1.953, 95% CI: 1.30–2.94, P=0.001). No variables in the model reached statistical significance for non-EC. For benign esophageal disease, male gender correlated with higher risk of stent failure (HR =9.049, 95% CI: 1.74–47.02, P=0.009).

## Discussion

Our study shows that in patients receiving esophageal stents, the stent failure rate is greatest in patients with mid-esophageal stent insertion, longer stents and with pre-insertion dilatation.

Our study shows an overall stent failure rate of 34.3%. To our knowledge, no previous studies have used this composite end-point. In other terms, one third of patients experience a clinically significant harmful event such as a

re-intervention or a notable complication. Although no direct comparison can be made, the rate of complications was similar in our study compared to previous literature (24.5% *vs.* previously reported 23–56%) (22–25). The most common complication in our study was stent migration (N=53, 11.3%), its rate is in accordance to earlier accounts varying from 2% to 17% (24,25). Formation of an esophageal fistula after stenting was noted in 29 patients (6.2%), previous reports place the incidence of this complication between 1% and 7% (2,22,29). EC showed the highest amount of complications (27.5%, N=91), with benign esophageal disease having similar complication rate (22.0%, N=13). The amount of complications is lower in non-esophageal malignancies (13.9% N=11), and these rates differed statistically significantly (P=0.037). This effect is most likely due to the low OS of the non-EC patients, making the appearance of late complications rarer. Previous studies suggest that at least in the setting of esophageal perforation and esophageal anastomotic leaks, treatment times shorter than 28 days are associated with reduced risk of complications (14). In our study, the patients who developed a fistula or perforation in relation to stenting had had an esophageal stent for less time (194 *vs.* 111 days, P=0.006) than the patients who did not develop such complications. This phenomenon is explained most likely by the complication itself causing the surgeon to proceed to stent removal, stent change or surgery, in which the stent was either removed or changed.

In multivariate analysis including the whole study population, stent insertion in the middle esophagus was associated with greater risk of stent failure, upper esophageal stenting showed the same trend, but did not reach statistical significance. This is most likely an issue of statistical power in this group (N=16) judging by the wide CI. Distal esophageal stenting has been shown to be a risk factor for stent migration (30). Another study found that by using stents with larger diameter this effect can be negated, but with possible increase in major stent-related complications such as hemorrhage (24). Our study showed a higher risk of stent failure with stent lengths between 12 and 15 cm compared to stents under the length of 12 cm, contradicting the findings of a previous study (26). Longer stents may be more amenable to food bolus impaction and due to the larger area of esophageal tissue affected, might produce more reactive changes in the esophagus. In sub-group analysis of the EC group the patients' gender was found to associate with outcomes, with male gender being protective of stent failure. This finding is probably associated with

the different prevalence of squamous cell carcinoma of the esophagus and adenocarcinoma of the esophagus in men and women. In EC, mid-esophageal stenting was associated with worse outcomes, as in the whole study population. Our hypothesis is that mid-esophageal stenting carries a higher risk due to the proximity of airway structures and partly as a result of the limited maneuverability of the gastroscope in mid-esophagus. In non-EC, no single variable stood out as statistically significant, and in benign esophageal disease only gender affected stent failure rate, with male gender producing almost a 10-fold risk of stent failure. Stent size approached significance, reflecting the findings in the whole study population.

The limitations of this study include its retrospective nature, increasing the risk of selection bias and the possibility of minor complications related to the stenting remaining unnoticed. The groups in this study were heterogeneous, but a comparative study between these groups is needed in order to have groups that are sizeable enough to make conclusions. The reporting of complications varies between providers in retrospective setting and some stenting-related complications might also remain unnoticed in the setting of end-of-life care setting, where diagnostic interventions are rarely performed.

In conclusion, our study found that esophageal stenting carries and significant risk of additional interventions and complications, defined here as a stent failure. Stenting of the mid esophagus in particular carries a high risk of stent failure. Longer stents (>12 cm) are associated with a higher risk of stent failure compared to shorter stents as is pre-insertion dilatation. Esophageal stent failure is common and the benefits and harms of stenting should be carefully considered prior to insertion.

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## Footnote

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/aoe.2019.06.02>). JR serves as an unpaid editorial board member of *Annals of Esophagus* from Jun 2019 to May 2021. The other authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Helsinki University Hospital (HUH) academic review board granted an institutional study permit for the review of relevant medical records (No. Y2017SK015). Informed consent was waived due to the retrospective nature of the study.

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## Supplementary

**Table S1** Types of operations related to stent insertion

Types of operations	N (%)
Any operation	140 (29.9)
Multiple operations	48 (10.2)
Esophagectomy	55 (11.7)
Primary Stomach conduit	48 (10.2)
Primary Colon conduit	7 (1.5)
Primary Jejunal conduit	1 (0.2)
Resection only	10 (2.1)
Secondary reconstruction	9 (1.9)
Esophagoplasty	5 (1.1)
Esophageal conduit revision (suture, flap)	10 (2.1)
Hiatal hernia operation	6 (1.3)
Explorative laparotomy/laparoscopy	24 (5.1)
Explorative thoracotomy/thoracoscopy	10 (2.1)
Pulmonary resection	9 (1.9)
Pleural and/or mediastinal drainage	25 (5.3)
Decortication	14 (3.0)
Bronchoscopy	34 (7.2)
Tracheal/bronchial stent	26 (5.6)
Laser treatment of tumor	8 (1.7)
Tracheostomy	11 (2.3)
Laser treatment of esophageal tumor	4 (0.9)
PEG insertion	5 (1.1)
Cervicotomy	4 (0.9)
Other	5 (1.1)