CME

Predictors and Outcomes of Fully Covered Stent Treatment for Anastomotic Esophageal Strictures in Esophageal Atresia

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ABSTRACT

Background and Aims: Anastomotic strictures following surgical repair is one of the most common complications in esophageal atresia (EA). The utility of esophageal stenting to treat anastomotic esophageal strictures in pediatrics is unclear. Our primary aim was to evaluate whether esophageal stenting, in conjunction with dilation and other endoscopic therapies, prevented surgical stricture resection (SR). Our secondary aims were to evaluate predictors of successful esophageal stenting and evaluate adverse events from stent placement.

Methods: A retrospective review of pediatric patients with EA complicated by esophageal strictures was performed. The change in stricture diameter in millimeters from the time of stent removal to subsequent endoscopy was defined as delta diameter (ΔD). A receiver operating characteristic (ROC) curve analysis was performed to determine the discriminatory ability of ΔD. Youden J index was used to identify optimal cutoff-point in predicting stent success. A univariate and multivariate analysis were done to assess predictors of success.

Result: Forty-nine esophageal anastomoses were stented to treat esophageal strictures. Stents prevented SR in 41% of patients. ROC curve analysis utilizing Youden J index identified ΔD of $\leq$4 mm (area under the curve = 0.790; 95% confidence interval: 0.655–0.924; $P < 0.001$) as the optimal cutoff point in differentiating stent success. The most common adverse events were erosions/ulcerations, granulation tissue formation, and vomiting/retching.

Conclusion: Stent therapy in preventing SR at the site of EA repair was successful in 41% in our population with good long term follow-up. The most significant predictor of success in this study was the change in luminal diameter ($\leq$4 mm) at initial poststent follow-up.

Key Words: anastomotic stricture, endoscopy, esophageal atresia, esophageal stent, esophageal stricture, esophagus, gastroenterology, long gap esophageal atresia, pediatrics

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What Is Known

- Anastomotic stricture is one of the most common complication at the site of esophageal atresia (EA) surgical repair.
- The success of stent therapy in EA patient with anastomotic stricture has shown variable results.
- There are no reported factors that can predict the success of esophageal stent treatment in EA patients with anastomotic strictures.

What Is New

- Esophageal stenting prevented stricture resection in 41% of pediatric EA patients who underwent esophageal stent treatment.
- The main predictor of successful stent treatment was the change in esophageal diameter from the time of stent removal to the time of first follow-up endoscopy (ΔD). A ΔD of $\leq$4 mm was predictive of success.
- The most common adverse events were erosions/ulcerations, granulation tissue, and vomiting/retching.

Esophageal atresia (EA) with/without tracheoesophageal fistula is a congenital anomaly that occurs in 1 in 3500 births (1–3). Anastomotic strictures following surgical repair is one of the most common complications, with prevalence ranging from 9% to 80% in the literature (4–7). The cornerstone of stricture treatment involves mechanical dilation. When a stricture is difficult to manage with mechanical dilation alone other treatment modalities such as intralesional steroid injection (ISI), externally removable stents, endoscopic electrocautery incisional therapy (EIT), and/or topical mitomycin C are considered (6,8,9). Despite these additional therapies, strictures may ultimately require surgical resection (10). The rationale behind esophageal stenting has always appeared sound. In theory, stents provide the ability to continuously apply dilation forces to the esophagus over a prolonged period of time with the goal of avoiding repeat procedures for frequent intermittent dilations. However, the success of esophageal stents to treat strictures has varied in the literature (11–13). To date, there is no clear

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way to predict successful stent therapy in esophageal strictures. Moreover, there is significant heterogeneity in pediatric stent practice due to the variety of types and sizes of stents used to treat pediatric strictures, since most standard adult esophageal stents are often too large for pediatrics. The primary aim of this retrospective observational study was to assess the utility of stent therapy in EA patients with anastomotic esophageal strictures. Our secondary aims were to evaluate clinical predictors of success and to evaluate adverse events related to esophageal stents.

METHODS

An institutional review board approved a retrospective chart review of all patients who underwent placement of esophageal stents at our Esophageal and Airway Treatment Center between January 2010 and March 2021. We included only patients diagnosed with EA who subsequently developed postoperative anastomotic strictures. Long gap EA (LGEA) was defined as an EA with/without a TEF where the gap length hindered the ability to complete primary repair, one-stage surgical repair (14–16). Most of our patients with LGEA were treated with the Foker procedure for tension induced esophageal growth (17). All the patients required repeated stricture dilations prior to stenting and/or had a stricture diameter that rapidly narrowed within two weeks back to predilation diameter or smaller. For this study, stent treatment success was defined as not requiring an esophageal stricture resection (SR) within 12 months of esophageal stent removal. Patients who did not require a SR, poststent dilation data were collected. The decision to undergo surgical resection was determined by a multidisciplinary team that includes pediatric gastroenterologists, pediatric surgeons, pediatric pulmonologist and pediatric otolaryngologists who manage EA patients regularly who make a collective decision on risk/benefit of medical versus surgical management.

Demographics and clinical characteristics were recorded using frequencies and percentages for categorical data and medians and interquartile ranges for continuous data. Data was collected per patient, per esophageal stricture, and per stent placement. Statistical comparisons of categorical data including rates of adverse events were performed using Fisher exact test, and statistical testing of continuous data were done using the nonparametric Wilcoxon rank sum test. Adverse events were compared between stent type and brand. Bonastents (Thoracent, Long Island, NY) were excluded from the adverse events comparison due to the low sample size. Esophageal leak was assessed during fluoroscopy performed at the time of endoscopy. A leak was defined as an extravasation of contrast that was free flowing beyond the esophageal wall with access into the mediastinum or chest cavity.

The method of measuring esophageal stricture diameter was previously described (8,18). During endoscopy, we used live fluoroscopy with contrast to determine the greatest anastomotic diameter. A radiopaque ruler was used as a size reference. Additionally, the endoscope diameter and/or known width of open and closed biopsy forceps were used to determine diameter of the anastomosis in cases with poor contrast distention. All stents were placed by two experienced endoscopists that use similar placement techniques. A repeat endoscopy with fluoroscopy was done 1–2 weeks following stent removal to measure anastomotic stricture diameter and patency.

Stent Placement/Monitoring

After stricture dilation as previously reported (18), the stent was placed either comparable to final balloon size or 1–2 mm greater. The diameter of the upper and lower esophagus were also noted on fluoroscopy, at the time of the endoscopy, to ensure that the diameter of the flared ends of the stents were not too large for the esophagus. The stent was placed under fluoroscopy with aid of a fluoroscopic ruler to allow for proper positioning of the stent. When possible, the stent was centered across the stricture with a minimum of 2 cm of stent above and below the stricture. We tried to keep the stent at least 2 cm below the upper esophageal sphincter and avoided stent placement across the lower esophageal sphincter to minimize stent migration. All patients were admitted after stent placement for observation. Daily chest X-ray for the first 2 days after stent placement followed by every other day for 7 days. For stents staying in longer than one week, a chest x-ray was obtained biweekly. Discharge from the hospital, was considered if patient's tolerated adequate oral nutrition for at least 3 days.

Statistical Analysis

Delta diameter (ΔD is the change in the anastomotic stricture diameter in millimeters,. It was calculated by subtracting the diameter at the time of stent removal from the diameter at the first subsequent endoscopy. Receiver operating characteristic (ROC) curve analysis was implemented to determine the ability of ΔD in differentiating stent success and stent failure. Results from ROC analysis are summarized using area under the ROC curve (AUC) with corresponding 95% confidence interval. Youden J index was examined to determine the optimal cutoff of ΔD, which maximizes the sum of sensitivity and specificity in predicting stent failure. A Bonferroni-adjusted two-sided $P < 0.013$ (0.05/4) was used for determining statistical significance for the comparison adverse event rates, and $P < 0.05$ was used for all other analyses. Stata (version 16.0, StataCorp LLC., College Station, TX) was used for performing all statistical analyses.

Of note, in this cohort we included 15 patients from our previously published paper in 2014 (19). These patients were included in the manuscript since different treatment outcomes and additional analysis was performed.

RESULTS

Demographics

The clinical characteristics of the study population are summarized in Table 1. A total of 45 patients (25 female) with a total of 49 esophageal strictures were stented. The median age at time of stent placement was 14.5 months [interquartile range (IQR) 8.5, 25] and a median weight at time of placement was 9.3 kg [IQR 6.7, 12.6]. The majority of the patients had the diagnosis of LGEA (N = 32, 71%) followed by EA type-C (N = 13, 29%). Twenty patients had a staged esophageal Foker repair, 10 had primary esophageal repair, 12 had prior stricture repair, 6 had a jejunal interposition, and 1 patient had a gastric pull up.

Stent Characteristics

The total number and stent types are summarized in Table 1. A total of 92 stents were placed in the study period. A combination of self-expandable plastic stents (SEPS) and fully covered self-expandable metal stents (FCSEMS) were used. The SEPS used were N = 10 Polyflex airway stents (Boston Scientific Corporation, Marlborough, MA). The FCSEMS used included biliary stents, N = 43 Wallflex stents (Boston Scientific Corporation, Marlborough, MA); airway stents, N = 19 Aero stents (Merit Medical, South Jordan, UT) and N = 3 Bonastent (Thoracent, Long Island, NY); esophageal stents, N = 9 Alimaxx-ES stents (Merit Medical, South Jordan, UT); and vascular stents N = 8 Viabahn (Gore Medical, Flagstaff, AZ). The median stent diameter used was

TABLE 1. Demographics and characteristics

Variable	n (%) or median (IQR)
Number of patients	45
Number of anastomoses	49
Sex	
Female	25 (56%)
Age at stent placement (mo)	14.5 (8.5, 25)
Weight at stent placement (kg)	9.3 (6.7, 12.6)
Number of stents	92
WallFlex	43
Alimaxx-ES	9
Alimaxx (airway)	19
Viabahn	8
Bonastent	3
Polyflex	10
Stent diameter (mm)	10 (8, 12)
Stent length (mm)	60 (30, 100)
Stent duration (days)	11.5 [IQR 7,17.5]
Diagnosis	
EA-C	13 (29%)
LGEA	32 (71%)
Type of surgery	
EA primary repair	10 (20.4%)
Stricture repair	12 (24.5%)
Foker procedure	20 (40.8%)
Jejunal interposition	6 (12%)
Gastric pull up	1 (2%)

EA = esophageal atresia, IQR = interquartile range; LGEA = long gap esophageal atresia.

10 mm [IQR 8, 12] with a median stent length 60 mm (30, 100). The stent treatment duration was variable with a median of 11.5 days [IQR 7, 17.5].

The Success Of Esophageal Stenting in Preventing Stricture Resection

Stent therapy was successful in preventing the need for SR in 41% of patients within 12 months following stent removal (see Table 2). There was no statistical difference in the treatment success and failure group with respect to starting diameter and number of dilations prestent placement. The median diameter was <4 mm [IQR 2, 8] in the success group versus 3 mm [IQR 2, 5] in the failure group ($P = 0.355$) (see Table 2). The median number of dilations prestent placement was 4 [IQR 2, 6] in both groups ($P = 0.915$). The median total number of dilations following stent removal in the success group was 1 dilation [IQR 1, 2] within 12 months following stent removal, with the majority of these dilations performed within the first 3 months. The number of dilations poststent removal in the failure group was not collected due to SR that was performed at a median duration of 58 days [IQR 24, 87] following last stent removal.

TABLE 2. Comparison of the stent success and failure groups (*compared to prestent)

Stent success group		Stent failure group	
41% (20/49)		59% (29/49)	
	Median (IQR)	Median (IQR)	*P* value
Prestent diameter (mm)	4 (2, 8)	3 (2, 5)	0.355
Poststent diameter (mm)	7 (3, 10)	2 (1, 5)	*<0.001/*0.302
Number of dilations prestent	4 (2, 6)	4 (2, 6)	0.915
Number of dilations poststent:			
• 0–3 m	1 (0, 2)	–	*<0.001
• 3–6 m	0 (0, 0)	–	*<0.001
• 6–12 mo	0 (0, 0)	–	*<0.001
• Total	1 (1, 2)	–	*0.002

IQR = interquartile range.

The Change in Post-Stent Luminal Diameter (ΔD) Is a Predictor of Stent Success

The poststent esophageal stricture diameter determined at the time of first endoscopy after stent removal was improved in the success group, median 7 mm [IQR 3, 10] when compared to prestent diameter ($P = < 0.001$). The failure group had a median diameter similar to prestent diameter, median of 2 mm [IQR 1, 5] ($P = 0.302$) (Table 2). This follow-up endoscopy was done at a median of 14 days [IQR 7.5, 28.5] following stent removal. Based on this observation, the change in esophageal diameter from the time of stent removal to the time of first follow-up endoscopy (ΔD) was evaluated in all patients. A ROC analysis was performed to determine the optimal cutoff of ΔD to differentiate stent success from failure. Youden *J* index found that a reduction in stricture diameter by <4 mm, at the first follow-up endoscopy after stent removal, was an optimal cutoff point to predict treatment success and ultimately prevent SR following stent removal (Fig. 1: AUC = 0.790, 95% confidence interval [CI]: 0.655–0.924; $P < 0.001$) with a sensitivity of 85% and specificity of 69%.

Additional Predictors of Stent Success

Multiple factors including age, sex, number of prestent dilations, stricture diameter at stent placement, stricture length >1 cm at stent placement, EA type, type of surgery, history of SR, duration of stent therapy, number of stents needed, time of stenting from surgical EA repair, and adjunct therapies to stenting (EIT, ISI, and mitomycin C) were assessed as potential predictors for stent success. A univariate analysis showed that none of these

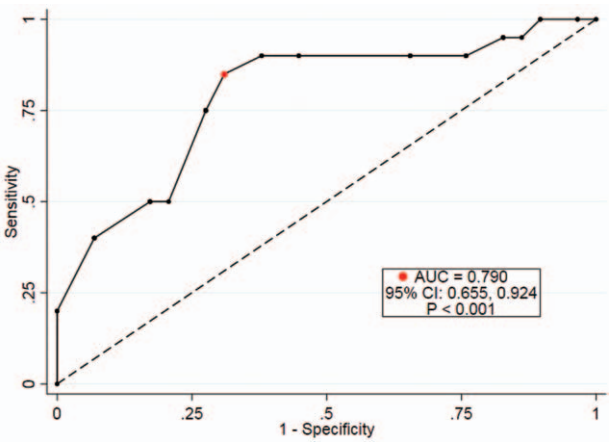

FIGURE 1. (red mark) The optimal cutoff of ΔD to differentiate stent success from failure as determined by the Youden *J* index was a ΔD of <4 mm (sensitivity = 85%, specificity = 69%), at the first follow up endoscopy. The area under the receiving characteristic curve (AUC) = 0.790; 95% confidence interval = 0.655–0.924; $P < 0.001$.

TABLE 3. Univariate analysis to predict stent failure

Variable	Did not require SR (n = 20)	Required SR (n = 29)	*P* value
Age (mo)	21.4 (8.4, 41.3)	11.5 (6.3, 16.8)	0.083
Sex			0.771
Male	8 (40%)	14 (48.3%)	
Female	12 (60%)	15 (51.7%)	
Stricture diameter at stent placement (mm)	4 (2, 8)	3 (2,5)	0.355
Stricture length >1 cm at stent placement	4 (20%)	11 (37.9%)	0.221
Number of dilation prestent	4 (2, 6)	4 (2, 6)	0.915
History of stricture resection	6 (30%)	11 (37.9%)	0.761
Comorbidities			
VACTREL	4 (20%)	3 (10.3%)	0.422
Trisomy 21	1 (5%)	6 (20.7%)	0.216
Diagnosis			0.201
EA-C	8 (40%)	6 (20.7%)	
LGEA	12 (60%)	23 (79.3%)	
Type of surgery			0.608
Primary EA repair	6 (30%)	4 (13.8%)	
Foker	7 (35%)	13 (44.8%)	
Stricture repair	4 (20%)	8 (27.6%)	
Jejunal interposition	3 (15%)	3 (10.3%)	
Gastric pull up	0 (0%)	1 (3.5%)	
EIT	7 (35%)	5 (17.2%)	0.189
ISI	7 (35%)	16 (55.2%)	0.245
MMC	1 (5%)	3 (10.3%)	0.636
Number of stents per anastomosis	1.5 (1, 2)	1 (1, 2)	0.795
Total stenting duration per anastomosis	13.5 (7, 21)	14 (7, 32)	0.364
Time of stenting from surgical repair (days)	123 (38, 692)	64 (34, 115)	0.117

EA = esophageal atresia, EIT = endoscopic incisional therapy, ISI = intralesional steroids, LGEA = long gap esophageal atresia, MMC = mitomycin C, SR = stricture resection.

factors were significant predictors of stent treatment success (see Table 3).

Adverse Events

Across all stent placements, the most common adverse events were erosions and ulcerations (29%), followed by granulation tissue formation (27%), and retching/vomiting (26%). Stent migration was recorded in 9% of stents. Esophageal leak caused as a result of the stent were seen in 3% of patients. When cross comparing adverse events between stent types used, WallFlex stents were significantly less likely than Alimaxx-ES stents to migrate ($P = 0.013$). WallFlex stents were also significantly less likely than Alimaxx (airway) stents to develop granulation tissue in the esophagus ($P = 0.002$) (see Table 4 for reference).

Long-Term Follow-up

Out of 20 patients who met criteria for successful stent treatment to prevent SR, 19 patients maintained long term follow-up, beyond the initial 12 months. The median duration of follow-up was 5 [IQR 2–6] years. None of the 19 patients have required a SR to date. These patients also underwent a median of 0.5 dilations [IQR 0, 1] during this same follow-up period.

DISCUSSION

We report the largest pediatric study to date on esophageal stenting in pediatrics. We found that stents have a moderate success rate (41%) in preventing esophageal SR in a cohort of EA patients. Patients in the success group who avoided SR still needed additional dilations poststent therapy, however these dilations were minimal and limited to the first 3 months poststent in the majority of cases. There are no standard criteria for stent success in the literature and although preventing the need for SR may seem extreme and a last resort at many institutions, it is not the case at our center. It is important to point out that we are a referral center for complex esophageal disease, and SR is a common treatment approach for a recalcitrant stricture. The success group also had good long-term success with a median 5-year follow-up. Other centers have published widely variable outcomes in stenting esophageal strictures, with reported success rates ranging from 0% to 86% (11,20–22). Most of these studies were small in size, as the largest cohort behind our study being 13 patients. No pediatric studies to date have looked at predictors of success, and future study should focus on assessing which patients are most likely to benefit from stenting.

Multiple potential predictors for stent success were assessed, including type of EA and surgery which did not show statistical significance to predict stent success. The success and failure groups had similar prestent stricture characteristics including number of dilations and stricture diameter at time of stenting.

Adjunct maneuvers (including EIT, MMC, and ISI) added to stenting were not associated with statistically improved odds of avoiding SR. We were surprised by this finding, as our clinical experience suggested that EIT for asymmetric strictures with thick scar bands can be anecdotally effective in managing strictures. Although 58% (n = 12) of patients with EIT at time of stenting were successful in avoiding SR, it was not a statistically significant predictor in our analysis potentially due to small sample size. Further studies are needed to answer this question.

TABLE 4. P1 = WallFlex versus Alimaxx-ES, P2 = WallFlex versus Alimaxx (airway), P3 = WallFlex versus Viabahn, P4 = WallFlex versus Polyflex

Adverse event	WallFlex (n = 44)	Alimaxx-ES (n = 15)	Alimaxx (airway) (n = 13)	Viabahn (n = 8)	Bonastent (n = 3)	Polyflex (n = 9)	Cumulative Stents (n = 92)	P1	P2	P3	P4
Erosion/ulceration	12 (27.3%)	8 (53.3%)	5 (38.5%)	0 (0%)	1 (33.3%)	1 (11.1%)	27 (29%)	0.112	0.499	0.174	0.424
Granulation tissue	7 (15.9%)	4 (26.7%)	8 (61.5%)	3 (37.5%)	1 (33.3%)	2 (22.2%)	25 (27%)	0.446	0.002*	0.171	0.64
Leak	2 (4.5%)	1 (6.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3.2%)	0.999	0.999	0.999	0.999
Migration	1 (2.3%)	4 (26.7%)	1 (7.7%)	2 (25%)	0 (0%)	2 (22.2%)	10 (9%)	0.013*	0.407	0.058	0.071
Chest pain	0 (0%)	2 (13.3%)	0 (0%)	0 (0%)	0 (0%)	1 (11.1%)	3 (3.2%)	0.061	0.999	0.999	0.17
Nausea/retching/ vomiting	10 (22.7%)	5 (33.3%)	4 (30.8%)	1 (12.5%)	1 (33.3%)	3 (33.3%)	24 (26%)	0.497	0.715	0.999	0.672
Respiratory distress	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (11.1%)	1 (1%)	0.999	0.999	0.999	0.17

*Statistically significant using the 0.013 significance level (Bonferroni-adjusted).

The most significant predictor of success in this study was the degree to which the stricture recoiled back down in its diameter after stent removal, defined as ΔD at initial poststent follow-up endoscopy. A $\Delta D \geq 4$ mm at an average 2 weeks following stent removal increased the odds of the stricture being refractory and requiring SR. We hypothesize, if a stricture that narrows down significantly despite dilation (which is a short lived esophageal expansion force) and stent placement (which is a longer duration of constant expansion force) suggests that the anastomotic stricture contains significant amount of scar tissue that is beyond ones capabilities for endoscopic treatment and will require surgical correction. To date, this novel finding has not been reported in the literature. This information may play a significant role in poststent management to help set expectations with patients and families, and help physicians plan operative or further endoscopic interventions ahead of time. Additionally, we hope it will detract physicians from trying repeated stenting if the first time failed.

Esophageal stents are relatively safe but requires the technical expertise for proper placement and removal. Various adverse events have been reported with the most common complication being stent migration (23). Stent migration was relatively uncommon in our cohort, which we attribute to the shorter median duration of stent therapy in our cohort, regular monitoring of stent positioning with chest x-rays, a preference for placement of longer stents (which may allow for some migration while still keeping the affected area stented), and avoidance of stent crossing the lower esophageal sphincter. Surprisingly, we have noticed a higher migration rate with the esophageal stents compared to the biliary stents. The reasoning is unclear but likely secondary to the type of anastomosis, as three out of four of the esophageal stents that migrated were placed to treat a jejunal interposition stricture, which accounts for 30% of total stent migrations.

The most common adverse events in this cohort were erosions and ulceration followed by granulation tissue formation, then retching/vomiting/nausea. Erosions and ulceration are potentially troubling since they occur at the edges of stents especially where the stent has a large flair. Ulcerations can lead to perforation as well as stricturing. We hypothesize that our shorter duration of stent time may have prevented the erosions/ulcerations from developing into more serious adverse events. Granulation tissue made stent removal occasionally challenging, but all patients had granulation tissue resolution on their follow-up endoscopy. To proactively address nausea/vomiting, part of our standard therapy is being aggressive with antiemetic treatment. We typically use Ondansetron around the clock or a scopolamine patch as first line treatment. Zhang *et al.* (24) also reported vomiting being a common adverse event as well compared to stent migration in their cohort.

We had three stents that were complicated with an esophageal leak as a result of stenting that required further medical management to treat. Having said that, leak resolution was achieved by follow-up endoscopy.

Limitations for the study include being a single-center retrospective study. Although this is the largest pediatric study to date looking at esophageal stenting for stricture treatment in EA patients, it is still relatively small to adequately power analysis of predictors of success as well as benefits of specific stent brands and types compared to others. Since our cohort purely looked at anastomotic strictures in EA patients, we cannot necessarily apply our results to other types of esophageal strictures. Moreover, we have included EA patients with different types of anastomoses which made our cohort slightly more heterogeneous. However, the univariate analysis did not show that surgical anastomosis type had any statistical difference. Also, there is a wide variability in peri-stent interventions that may aid with stricture resolution.

CONCLUSION

EA patients following surgical repair are at risk for developing anastomotic strictures. Patients exposed to stent treatment had a 41% success rate of avoiding additional esophageal SR surgery, with long term success. Although the success rate is low, the authors' feel stenting is reasonable to attempt prior to surgical SR. If the change in esophageal diameter following stent removal decreases by 4 mm or more, then no further stenting attempts should be performed, and other endoscopic or surgery therapy should be considered. Larger prospective multicenter pediatric studies with control groups are needed to further assess the utility of stents in treating esophageal strictures in EA patients.

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