Externally removable stents in the treatment of benign recalcitrant strictures and esophageal perforations in pediatric patients with esophageal atresia

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Background: We investigated whether removable stents, such as self-expandable plastic stents (SEPSs) and fully covered self-expandable metal stents (FCSEMSs) could provide an alternative treatment for recalcitrant strictures and esophageal perforations after esophageal atresia (EA) repair.

Objective: The primary aim of our study was to evaluate technical feasibility. Secondary aims were to evaluate safety and procedural success.

Design: Retrospective study.

Setting: Tertiary-care referral center.

Patients: A total of 24 children with EA.

Interventions: Retrospective review of all children with EA who underwent dilation and esophageal stent placement from January 2010 to February 2013 at our institution.

Main Outcome Measurements: Healing of perforation and stricture resolution at 30 and 90 days.

Results: A total of 41 stents (SEPSs 14, FCSEMSs 27) were placed in 24 patients with EA during the study period, including 14 who had developed esophageal leaks. Procedural success of esophageal stent placement in the treatment of refractory strictures was 39% at 30 days and 26% at 90 days. The success rate was 80% for closure of esophageal perforations with stent therapy after dilation and 25% for perforations associated with surgical repair. Adverse events of stent placement included migration (21% of SEPSs and 7% of FCSEMSs), granulation tissue (37% of FCSEMSs), and deep ulcerations (22% of FCSEMSs).

Limitations: Retrospective study with small sample size.

Conclusion: SEPSs and FCSEMSs can be placed successfully in small infants and children with a history of EA repair. The stents appear to be safe and beneficial in closing esophageal perforations, especially post-dilation. However, a high stricture recurrence rate after stent removal may limit their usefulness in treating recalcitrant esophageal anastomotic strictures. (Gastrointest Endosc 2014;80:246-52.)

Abbreviations: EA, esophageal atresia; FCSEMS, fully covered self-expandable metal stent; SEPS, self-expandable plastic stent.

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Esophageal atresia (EA) is the most common reason to have an esophageal anastomosis in children.[1] Recalcitrant strictures after esophageal repair in this population are a rare but difficult problem, and patients can require frequent dilations because of stricture formation.[2] Recalcitrant strictures can be particularly difficult to treat if the gap between both ends of the esophagus was long, because this can lead to a high-tension anastomosis.[1,2]

Traditional stricture treatment in children with EA usually starts with balloon or mechanical dilations.[3] Other endoscopic treatment options have been limited to triamcinolone acetonide or mitomycin C application.[3] More recently, both self-expandable plastic stents (SEPSs) and fully covered self-expandable metal stents (FCSEMSs) have been reported to be an alternative or adjunctive means of preventing stricture formation by providing a continuous means of dilating the esophagus for prolonged periods of time. However, the use of removable stents to definitively treat benign esophageal strictures in adults has yielded mixed results, and pediatric data on the subject of stricture resolution after stent placement has been limited by small sample sizes.[4]

Esophageal perforations or leaks in children with EA are traditionally managed with bowel rest, external drainage, parenteral nutrition, antibiotics, and nasal esophageal tube to suction. If closure does not occur, patients have traditionally required surgical repair. At our institution, we typically initiate treatment by placing a nasal esophageal tube to low-strength wall suction, while the patient is maintained with nothing by mouth and treatment with antibiotics. The patient then undergoes fluoroscopic contrast studies weekly until the leak resolves. Patients with persistent leaks for more than a month are considered candidates for surgical repair. Post-anastomotic surgical leaks in general are drained externally. Post-dilation leaks are generally treated with external drainage if there is evidence of fluid or air collection on radiographs. Several studies of adults with esophageal perforations have suggested that esophageal stent placement may be useful to promote leak closure, especially if the stent is placed early when the leak first develops.[5-8] To date, there has been no pediatric literature on this subject.

The Esophageal Atresia Treatment Program at Boston Children's Hospital is a referral center for children with unrepaired EA, previously repaired EA with recalcitrant strictures, and long-gap EA. Long-gap EA frequently is repaired by using an autologous conduit created from colon, stomach (including a gastric tube), or jejunum.[9-11] An alternative to this is the Foker process, which is a method of placing traction via an open thoracotomy on the proximal and distal esophageal segments in order to induce sufficient esophageal growth to allow for a primary repair.[12-14] Known potential adverse events of the Foker process include high tension anastomoses. We retrospectively looked at our experience as a tertiary-care referral center that provides endoscopic treatment for this pediatric population. Specifically, we sought to evaluate the technical feasibility, efficacy, and safety of removable stents for treating recalcitrant esophageal strictures and esophageal perforation.

Take-home Message

- A high stenosis recurrence rate on stent removal may limit the usefulness of stents in treating recalcitrant anastomotic esophageal strictures in pediatric patients with esophageal atresia. Esophageal stent placement appears to be an especially promising approach to the treatment of post-dilation esophageal leaks in this population.
- Careful monitoring of pediatric patients with indwelling stents may be important to minimize adverse events.

METHODS

We received institutional approval (institutional review board-P00004344) to review the records of all patients who underwent placement of an externally removable stent at our institution's Esophageal Atresia Treatment Program from January 2010 to February 2013. The primary aim of our study was to evaluate technical feasibility of placing stents in our pediatric population. Our secondary aim was to assess safety as well as the efficacy of stent placement in the treatment of recalcitrant strictures and/or esophageal leaks.

All patients in our study had been diagnosed at birth to have EA and had subsequently developed strictures after anastomotic repair. We categorized primary indications for stent placement as refractory stricture, postoperative anastomotic leak (perforation), and post-dilation esophageal leak (perforation). Refractory stricture was defined as an inability to successfully remediate the lumen to a diameter of 10 to 12 mm over 5 sessions at 2-week intervals. All dilations and stents were placed by the same endoscopist (M.M.). Because of patient size, airway stents were placed in most patients. The self-expandable plastic stents used in the study were Polyflex airway stents (Boston Scientific Corporation, Natick, Mass). The FCSEMSs used were AERO fully covered tracheobronchial stents (Merit Medical Systems, South Jordan, Utah) or ALIMAXX-ES fully covered esophageal stents (Merit Medical Systems).

All stents were placed under endoscopic and fluoroscopic guidance over a guidewire. Proper stent placement was confirmed by endoscopy and fluoroscopy. After placement, serial chest radiographs were obtained every 24 to 48 hours to evaluate for stent migration. All children were hospitalized for the duration of stent placement. Stent removal was accomplished by repeat endoscopy by using rat tooth forceps.

TABLE 1. Clinical characteristics of patients with esophageal atresia and esophageal stents

Patients, no.	24
Male, no.	11
Age at time of placement, mean (range)	22 mo (3 mo-12 y)
Weight at time of placement, mean (range), kg	10.6 (3.9-55.2)
Total stents, no.	41
No. of stents per patient, mean (range)	1.7 (1-7)
Indications for stent placement, no.	
Esophageal perforation	14
Refractory strictures	23

TABLE 2. Technical characteristics of stents used in our esophageal atresia patient population

Stent type, no.	
SEPS	14
FCSEMS	27
Airway stent	32
Esophageal sent	9
Stent diameter, no. (%), mm	
8	1 (2%)
10	19 (46%)
12	13 (32%)
14	6 (15%)
16	2 (5%)
Stent length, no. (%), mm	
30	5 (12)
40	21 (51)
50	5 (12)
60	1 (2)
70	9 (22)
Duration of stent placement, mean (range), d	
Refractory strictures	9.7 (2-30)
Stent perforation	9.9 (3-22)

SEPS, Self-expandable plastic stent; *FCSEMS,* fully covered self-expandable metal stent.

TABLE 3. Adverse events during study period after stent placement

Adverse event	SEPS (n = 14)	FCSEMS (n = 27)
Stent migration, no. (%)	3 (21)	2 (7)
Respiratory distress, no. (%)	1 (7)	0
Granulation tissue overgrowth, no. (%)	0	10 (37)
Stent-induced ulceration, no. (%)	0	6 (22)
Pain and retching, no. (%)	4 (23)	7 (26)

SEPS, Self-expandable plastic stent; *FCSEMS,* fully covered self-expandable metal stent.

Pertinent clinical data were recorded from patient charts, endoscopy, and surgical and radiology reports. Patient information recorded included sex, age, weight, stent duration, and number of stents placed per patient. Technical stent information collected included stent type, stent diameter and length, successful stent placement, and stent removal. Adverse events documented were pain, nausea, retching, respiratory distress, stent migration, tissue ulceration, and granulation tissue. Adverse events were grouped based on the type of stent (SEPS vs FCSEMS).

Procedural success for stricture resolution was recorded for each patient. Stricture resolution was defined as no additional therapy required after stent removal at $\geq$30 days and at >90 days. For the subset of patients with esophageal perforation, procedural success was defined as closure of the leak at the time of stent removal. This was confirmed with a fluoroscopic contrast study at the time of stent removal. All patients with post-dilation leaks had stents placed at the time of the leak. All patients with post-anastomotic leaks had a minimum of 1 month of conservative management before stent placement.

RESULTS

Clinical characteristics

We summarized the clinical characteristics of our patients in Table 1. A total of 24 patients (11 male) with an underlying diagnosis of EA had a total of 41 stents placed in the esophagus during the study period. Patients ranged in age at the time of stent placement from 3 months to 12 years and weighed 3.9 to 55 kg. From 1 to 7 stents were placed per patient. Twenty-three of 24 patients had stents placed for refractory strictures. Esophageal leaks resulted from either an esophageal dilation (n = 10) or post-surgical anastomosis (n = 4). All patients with esophageal perforations received antibiotics during the stent

TABLE 4. Procedural outcomes of esophageal stent placement for esophageal strictures

Patient	EA type	Type of EA repair	No. of stents placed	Stricture resolution for ≥30 d after final stent removal	Stricture resolution for ≥ 3 mo after final stent removal	Clinical course after stent removal
1	Long gap	Foker	6	No	No	Stricture resection
2	Long gap	Foker	1	Yes	No	Stricture resection
3	Type C	Thoracotomy	2	No	No	Further dilations
4	Long gap	Jejunal interposition	7	No	No	Stricture resection
5	Long gap	Foker	1	No	No	Further dilations
6	Type C	Thoracotomy	1	Yes	Yes	No further intervention necessary
7	Type C	Thoracotomy	1	Yes	No	Further dilations
8	Type C	Thoracotomy	1	No	No	Further dilations
9	Type C	Thoracotomy	1	Yes	Yes	No further intervention necessary
10	Type C	Thoracotomy	1	Yes	Yes	No further intervention necessary
11	Type C	Thoracotomy	1	Yes	Yes	No further intervention necessary
12	Long gap	Foker	2	No	No	Stricture resection
13	Long gap	Foker	1	No	No	Stricture resection
14	Long gap	Foker	2	No	No	Stricture resection
15	Long gap	Foker	1	No	No	Further dilations
16	Type C	Thoracotomy	1	No	No	Stricture resection
17	Type C	Thoracotomy	2	No	No	Stricture resection
18	Long gap	Foker	1	No	No	Stricture resection
19	Long gap	Jejunal interposition	1	Yes	No	Further dilations
20	Long gap	Foker	1	Yes	No	Further dilations
21	Long gap	Foker	1	Yes	Yes	No further intervention necessary
22	Type C	Thoracotomy	1	No	No	Stricture resection
23	Long gap	Foker	1	No	No	Jejunal interposition

EA, Esophageal atresia.

placement period. Three of the 14 patients were undergoing concomitant external chest tube drainage.

Stent characteristics

The technical characteristics of the stents are summarized in Table 2. A total of 32 of 41 stents placed were designed for the airway. Fourteen were SEPSs and 27 were FCSEMSs. The most common stent diameter used was 10 mm (46%), and the most common length was 40 mm (51%). The mean duration of stent placement was 9.7 days, with a range of 2 to 30 days for refractory strictures and 9.9 days, with a range of 3 to 22 days for esophageal perforations.

Adverse events

Adverse events that occurred during the study period after stent placement are shown in Table 3. Stent migration occurred in 3 of 14 SEPSs and 2 of 27 FCSEMSs. One stent placed for esophageal perforation migrated into the pleural space and required surgical closure of the esophageal perforation. Granulation tissue developing at the edge of the stent occurred in 10 of 27 of the FCSEMSs (37%) and

TABLE 5. Procedural outcomes of esophageal stent placement for esophageal perforation

Patient	Type of esophageal leak	Stent duration, d	External drainage	Leak sealed with stent	Patient outcome
1	Post-dilation	8	No	Yes	No further intervention necessary
5	Post-dilation	17	No	Yes	No further intervention necessary
6	Post-dilation	8	No	Yes	No further intervention necessary
8	Post-dilation	7	No	Yes	No further intervention necessary
10	Post-dilation	7	No	Yes	No further intervention necessary
12	Post-surgical	8	No	Yes	No further intervention necessary
12	Post-dilation	3	No	Yes	No further intervention necessary
13	Post-surgical	14	No	No	Surgical closure
14	Post-surgical	6	Yes	No	Surgical closure
17	Post-dilation	7	No	Yes	No further intervention necessary
18	Post-dilation	12	No	No	Endoscopically closed with clips
20	Post-dilation	13	No	Yes	No further intervention necessary
21	Post-dilation	7	Yes	No	Endoscopically closed with clips
24	Post-surgical	22	Yes	No	Surgical closure

none of the SEPSs. Deep esophageal ulceration from the edge of the stent occurred in 6 of 27 patients (22%) who had FCSEMSs placed. In 1 patient, the ulceration was so deep that it formed a second stricture. No patients developed esophageal ulceration after placement of SEPSs. Severe respiratory distress prompting early stent removal occurred in 1 of 14 patients in the SEPS group and in none of the FCSEMS group. Pain and retching occurred in 4 of 14 patients (23%) in the SEPS group and in 7 of 27 patients (26%) in the FCSEMS group.

Treatment outcomes

Procedural outcomes of esophageal stent placement in our refractory stricture population are shown in Table 4. All children had successful placement and retrieval of all stents. The rate of stricture resolution for $\geq$30 days after final stent removal was 39% (9/23), with a 90-day success rate of 26% (6/23). The procedural outcomes for esophageal stent placement in our esophageal perforation group are shown in Table 5.

Nine of 14 patients (64%) had successful closure and healing of their esophageal leaks after stent therapy. Subdivided by etiology of perforations, there was a closure success rate of 80% (8/10) in post-dilation–induced perforations and a closure success rate of 25% (1/4) in post-surgical perforations. In the 2 patients in the post-dilation perforation group, perforations were closed successfully with endoscopic clips at the time of stent removal, avoiding the need for open surgery.

DISCUSSION

Our study demonstrates the technical feasibility of stent placement and retrieval in young children and infants with anastomotic strictures with EA. Overall, we found good procedural success, especially in the treatment of post-dilation esophageal leaks. We also found that both SEPSs and FCSEMSs had an acceptable safety profile. However, we found that SEPSs were more likely to migrate, whereas FCSEMSs were more likely to cause granulation tissue in the esophagus.

We note that ours is the first formal investigation of esophageal stent placement in the setting of esophageal leaks in children, and we believe our results suggest that stents may prove a promising therapy for sealing esophageal leaks that develop after dilation in children with EA. We did not formally compare stent placement to our standard treatment of nasal esophageal tube to low-strength wall suction; therefore, we can make no conclusion regarding which treatment is superior. However, we note that there appears to be a comfort benefit to the patient and their parents, because it is not necessary to use a nasal esophageal tube. Esophageal stent placement for post-anastomotic leaks appears not to be beneficial, but given our small sample size this may warrant further investigation.

There has been a recent systematic review on temporary stent placement in esophageal leaks in adults that suggests the pooled success rate across all studies is

TABLE 6. Stent literature on benign esophageal strictures

Author	Stent type	Sample size	Reported success*	Stricture type
Studies in adult populations				
Repici[24]	SEPS	15	80%	Mixed benign
Dua[20]	SEPS	38	32%	Mixed benign
Barthel[19]	SEPS	8	12%	Anastomotic
Pennathur[23]	SEPS	9	22%	Mixed benign
Fiorini[21]	FCSEMS	10	50%	Mixed benign
Kim[22]	FCSEMS	55	33%	Mixed benign
Bakken[18]	FCSEMS	10	20%	Mixed benign
Studies in pediatric populations				
Broto[16]	SEPS	10	50%	Caustic
Zhang[17]	FCSEMS	8	75%	Caustic
Best[4]	FCSEMS	7	86%	Mixed benign

SEPS, Self-expandable plastic stent; *FCSEMS,* fully covered self-expandable metal stent.
*Reported success defined as no recurrent stricture.

85%, with no difference between SEPSs and FCSEMSs.[15] Our success rate of 80% for post-dilation leaks appears comparable, whereas our success rate of 25% for post-surgical leaks was relatively poor. In most of our patients, 1 week of stent placement with either SEPSs or FCSEMSs was sufficient to promote leak closure. However, further study of esophageal stent placement to treat esophageal leaks in this population is needed before this approach can be fully recommended.

In addition, our study illustrates that close monitoring of all children undergoing stent therapy is important. One patient in our study with an existing esophageal perforation had stent migration outside of the esophagus into the pleural space. This event occurred within 2 weeks of placement and required surgical closure of the perforation. This patient had not had a chest radiograph in 1 week and was asymptomatic. We note that our institution now uses a protocol that involves near-daily chest radiographs after stent placement to confirm proper stent location, which we acknowledge may add unnecessary cost and patient radiation exposure. However, we would also note that this practice may be especially important in younger children, who cannot adequately verbalize discomfort or new symptoms that may herald stent migration.

We did find that adverse events differed according to type of stent deployed, and each may be associated with its own risk profile for EA treatment. For example, 37% of patients with FCSEMSs, as compared with none with SEPSs, had granulation tissue build up around the stent. Six patients in the FCSEMS group also had deep esophageal ulceration from the edge of the stent. One of these patients developed recurrent stricturing at that site. We found that both granulation tissue and ulceration were more likely to occur with longer stent duration. This prompted a change in our practice to reduce the length of time stents remained inserted. In all cases, granulation tissue was observed to have regressed on subsequent endoscopies.

Our pediatric cohort did demonstrate a high stricture recurrence rate after stent removal. The success rate for stricture resolution after temporary stent placement at 1 month was 39% and 26% at 3 months. The majority of patients had at least 1 stent session. We had 2 outliers, with 6 and 7 stent sessions, respectively, who had a history of multiple ($>$ 6) thoracotomies with many chest adhesions and were believed to be at great surgical risk. Both ultimately underwent successful stricture resections.

We note that stent duration and stent type did not correlate with success of treatment. In contrast with our results, a few other studies have examined stricture resolution after stent therapy in children and have reported success rates ranging from 50% to 86%.[4,16,17] We would note that these studies mostly involved small heterogeneous populations of mostly caustic strictures, which may be more amenable to stent therapy than anastomotic strictures associated with EA repair (Table 6).[4,16,17] The adult literature on stricture resolution with stent placement has a broad range of success rates for stricture resolution and reflects both retrospective and prospective study designs. The reported success rate ranges from 12% to 80%, although most report lower success rates (Table 6).[18-24] It is interesting to note that the Barthel et al[19] study, which looked primarily at anastomotic strictures, had the lowest

success rate (12%). Results from our study of children with anastomotic strictures seem consistent with those of this report.

Our study is limited by its retrospective approach and by our small study size. In addition, we had no strict protocols on type of stent used and duration of time that stents remained inserted. We initially tried keeping stents indwelling for a minimum of 14 days. This goal was largely adopted from Best et al.[4] However, after encountering stent placement adverse events of ulceration, granulation tissue, and migration, we increasingly began to use a maximum placement duration of 7 days. We first started using SEPSs in our practice and then changed to using self-expandable metal stents, given the relative ease of placement as well as an increasingly noted migration rate with SEPS. However, after adverse events occurred that were associated with self-expandable metal stents, we erred on the side of placing either stent with a goal of optimizing stent indwelling time. Although we theorized that SEPSs could stay in longer because of less tissue injury, we were cognizant of the risks of stent migration that appear higher in this group.

Nevertheless, ours represents the largest study to date of treatment with esophageal stents in children and involves a study cohort that is younger than those described in previously published works and that is more homogeneous. Indeed, because we have sought to extrapolate findings from previous reports and our own experiences to develop clinical protocols, we have come to theorize that not all benign strictures behave similarly and that stricture etiology may contribute to the stricture difficulty. In turn, we believe our data show that it may be useful to carefully define benign strictures and to tailor therapy accordingly.

In conclusion, esophageal stent placement appears to be technically feasible and reasonably safe in pediatric patients with EA. We would note that longer stent duration may be associated with more adverse events, and close monitoring is important while stents are in place. Esophageal stent placement appears to be an especially promising approach to the treatment of esophageal leaks in this population. On the other hand, a high stenosis recurrence rate on stent removal may limit the usefulness of stents in treating recalcitrant esophageal strictures. In the future, prospective, multicenter studies will be required if we are to optimize indications and protocols for esophageal stent placement in pediatric patients after EA repair.

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