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Esophageal Stents for Severe Strictures in Young Children: Experience, Benefits, and Risk

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Abstract The use of esophageal stents has been commonplace in adults for many years and for a variety of indications, including palliative care for malignant lesions involving the esophagus. The use of esophageal stents in the pediatric population, however, was limited by the inability to remove them and the implications this has for the growing child, especially for primarily benign esophageal lesions. With the advent of removable, covered stents, the potential uses for stents in children expanded to include treatment of a wide variety of congenital and acquired esophageal strictures. Stenting offers tremendous potential advantage over more traditional pneumatic or bougie dilation in its ability to provide continuous, radially oriented dilation pressure sustained over a period of time. This review examines the published pediatric literature on stents, discusses the indications for their use, outlines the types of stents available, offers technical guidance for proper placement, and reviews subsequent management and complications.

Keywords Esophageal stricture · Caustic ingestion · Pediatric · Esophageal stent · Polyflex · Aero stent · Allimaxx · Mitomycin c · Covered stent · Removable stent · Esophageal dilation · Nitinol stent · Biodegradable stent · Plastic stent · Esophageal atresia · Stent migration · Tracheobronchial stent

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Introduction

Over the past 23 years, the use of esophageal stents in the management of benign strictures of the pediatric esophagus has evolved significantly. The most profound change in the use of these devices has come about with advances in materials and technology that overcame many of the technical and practical obstacles of earlier years. Nevertheless, esophageal stenting is still a relatively uncommon practice within pediatric gastroenterology, because of the limited indications in this age group and the lack of technical familiarity with stent placement on the part of most clinicians caring for these patients. Additionally, the limited number of pediatric studies that exist are all retrospective in design, have small numbers of patients, and use a wide variety of stenting techniques. It is therefore difficult for the clinician contemplating the use of this therapeutic modality to determine the optimum type of stent, timing of placement, and duration of treatment. The goals of this manuscript are to present the available literature, to review the current types of stents available, and to offer practical advice on the placement and management of these stents.

Review of the Literature

The first published report of esophageal stenting to prevent occurrence of caustic strictures was reported by Fell et al. [1]

in 1966. It was not until 1986, however, that Coln and Chang [2] reported the first clinical series of pediatric patients treated with intraluminal stents. This paper and other early published series of pediatric stents primarily used modified nasogastric tubes to maintain the patency of the esophageal lumen and prevent stricture formation in severe cases of caustic injury. In 1996, Mutaf [3] published the largest series of pediatric caustic ingestions, in which he used a modified polytetrafluoroethylene nasogastric stent/rod during prolonged periods of time (up to 1 year) for treatment of 69 esophageal strictures that had failed at least two previous attempts at dilation. The evolution in stent design took the next step with a 1998 series by De Peppo et al. [4], in which a customized length of Silastic tubing was fitted over a nasogastric tube, which was adjusted to site the Silastic tube at the level of the stricture. These stenting methods still required prolonged time with some form of nasogastric intubation. It was not until 2003 that published reports emerged about the use of covered Polyflex retrievable stents for esophageal stenosis in children, allowing deployment at the level of the stricture alone [5]. By 2005, the use of silicon-coated nitinol stents had reached the pediatric population [6]. Most recently, a case report of the use of a biodegradable esophageal stent was published [7]. These newer generations of stents come in a variety of diameters and lengths and allow for removal after variable durations.

Most of the published literature regarding use of esophageal stents in children involved patients with caustic strictures (Table 1). The only other indication has been for stricture following esophageal atresia repair. Because accidental caustic injury was the most common indication, most children in these series have been young, typically less than 8 years of age. The duration of stenting used in these series was quite variable, ranging from 1 to more than 52 weeks. Most of the more recent studies used stents after several failed attempts at endoscopic dilation. Most patients suffered from some degree of nausea, retching, or chest pain in the days following stent placement, occasionally requiring premature removal of the stent. Migration of the stent was the most commonly cited complication of placement, reported in 0% to 29% of patients.

Results from the pediatric studies of self-expanding covered stents documented complete response, ability to remove the stent without recurrence of dysphagia or need for subsequent dilation, in 50 to 85% of patients [5, 6, 8]. Other patients in the series who tolerated stent placement had improvement but still required further stenting or endoscopic dilation. Treatment failures were essentially the result of premature stent removal due to intolerance or complications.

Overview of the Use of Covered, Removable Pediatric Stents

In general, these newer stents are cylindrical devices composed of a mesh-like lattice of either plastic or metallic

Table 1 Previous series of esophageal stenting in children

Study	Year	Patient no.	Stent type	Age	Indications	Duration, *wk*	Complications
Coln and Chang [2]	1986	7	Silastic NGT	14 mo–8 yr	Caustic, initial	3	Migration (14%) Atelectasis (28%) Airway obstruction (14%)
Wijburg et al. [12]	1989	11	Siliconized NGT	1–19 yr	Caustic, initial	5–6	None
Mutaf [3]	1996	69	PTFE rod	Not reported	Caustic, failed dilation × 2	47	Soft palate injury (1%)
De Peppo et al. [4]	1998	22	Silastic tube affixed over NGT	1.5–12.5 yr	Caustic, within 2.5 mo of ingestion	6	Migration (5%) Severe reflux (14%)
Broto et al. [5]	2003	10	Polyflex	14 mo–21 yr	Caustic × 9, EA × 1, Dilations > 6 mo	3–19	Migration (10%)
Zhang et al. [6]	2005	8	Covered nitinol	2–12 yr	Caustic, Dilations > 12 mo	1–4	Migration (13%), Chest pain/emesis (100%)
Atabek et al. [14]	2007	11	PTFE open stent tied to nasogastric catheter	1–7 yr	Caustic grade 2b, failed dilation × 3	36–56	None
Best et al. [8]	2009	7	Covered nitinol	7 mo–7 yr	EA × 5, Caustic × 1, Congenital anomaly	1	Migration (29%) Dysphagia (29%) Respiratory distress (14%)

EA esophageal atresia, *NGT* nasogastric tube, *PTFE* polytetrafluoroethylene

alloy. They come in variable lengths and diameters and are coated with silicone or polyurethane to prevent in-growth of esophageal tissue into the walls of the stent. The stents are expandable, meaning they have a small initial diameter until they are deployed at the site of stricture, at which point they expand to their designated caliber. They are best placed fluoroscopically, after endoscopic visualization of the stricture. They are deployed over guidewires, to help ensure proper placement across the stricture. They are typically left in place 4 to 6 weeks, providing continuous dilatory force. They are designed to allow for endoscopic removal, either by traction on the upper margin of the stent or of a purse-string suture, which decreases the diameter and collapses the stent. The desired result is stent-free maintenance of adequate esophageal lumen patency to avoid dysphagia, while obviating the need for further dilations.

Stent Characteristics

Two major types of fully covered stents are commercially available in the United States, Europe, and worldwide where distribution systems are available (Table 2). They share some features, but differ markedly in their internal structure and antimigratory features. Other fully covered

Table 2 Description of all commercially available over-the-wire expandable fully-covered stents

Stent type	Diameter, *mm*	Length, *mm*	Flange (single/double)
Polyflex[a]	16	90	Single
Polyflex	16	120	Single
Polyflex	16	150	Single
Polyflex (Fig. 1b)	18	90	Single
Polyflex	18	120	Single
Polyflex	18	150	Single
Polyflex	21	90	Single
Polyflex	21	120	Single
Polyflex	21	150	Single
Alimaxx-Es[b]	12	70	Single
Alimaxx-Es	14	70	Single
Alimaxx-Es (Fig. 1A2)	18	70	Single
Alimaxx-Es	18	100	Single
Alimaxx-Es	18	120	Single
Alimaxx-Es	22	70	Single
Alimaxx-Es	22	100	Single
Alimaxx-Es	22	120	Single
AERO[b]	10	20	Double
AERO	10	30	Double
AERO	10	40	Double
AERO	12	20	Double
AERO	12	30	Double
AERO	12	40	Double
AERO	14	20	Double
AERO	14	30	Double
AERO	14	40	Double
AERO	16	40	Double
AERO	16	60	Double
AERO	16	80	Double
AERO (Fig. 1A4)	18	40	Double
AERO	18	60	Double
AERO	18	80	Double
AERO	20	40	Double
AERO (Fig. 1A3)	20	60	Double
AERO (Fig. 1A1)	20	80	Double

Refer to Fig. 1a and b

[a] Polyflex™ stent, manufactured by Willy Rüsch GMBH Kernen, Germany

[b] Allimax™ esophageal stent and AERO™ tracheobronchial stent, manufactured by Merit Endotek, South Jordan, UT, USA

stents have been offered by endoscopy supply manufacturers, but are not as widely marketed or available.

One of the first commercially developed, expandable, fully covered stents in clinical use was the Polyflex esophageal stent, manufactured in Germany by Rüsch (Willy Rüsch GMBH Kernen, Germany), and distributed in the United States by Boston Scientific (Boston, MA, USA). It is made of polyester braided mesh covered in silicone. A wider proximal flange is its only true antimigratory feature. It has radio-opaque markers in the middle and at the ends to assist in both endoscopy-guided and fluoroscopy-guided delivery. This type of stent enjoys broad coverage in the medical literature both in children [5] and adults. Stent cost is $2000 (USA). The stents come individually packed and must be loaded onto the specialized delivery device, included with the stent, prior to insertion.

The Allimaxx-ES (esophageal stent) (Merit Endotek, South Jordan, UT, USA) is a fully covered, metal (nitinol) device with a proximal thread loop to collapse the proximal flange (Fig. 1). Nitinol is a nickel-titanium alloy that has the unique properties of shape memory and superelasticity. These qualities allow it to be much more flexible than other metals at lower temperatures and return to an original and more rigid shape at higher ones. Thus, as nitinol stents are put in place within the esophagus and warmed to body temperature, they expand to a predetermined caliber, providing radial dilation force. The nitinol is made into a metal mesh, covered in polyurethane to prevent tissue ingrowth, and a silicone internal lining provides smooth transit of food. Metal struts acting as antimigratory devices are positioned throughout the external surface of the stent. The AERO stent (Merit Endotek, South Jordan, UT, USA) is a covered nitinol stent designed for tracheobronchial use that has also been used in pediatric patients with esophageal pathology [8]. It differs from the Allimaxx stent primarily in its double-flange design. Otherwise, these stents are similar in structural features and materials. Stent costs, commercial, are $2000 (USA) for the AERO and $1900 (USA) for the Allimax stent. A special endoscopic delivery device for the AERO stent that allows for insertion through the endoscope biopsy channel is available, but a therapeutic advantage of this device has not been demonstrated. For the purposes of this paper, we have limited the discussion to over-the-wire devices. Also, a stent sizing device for tracheobronchial stents is available, but because we strongly recommend the use of fluoroscopy for stricture

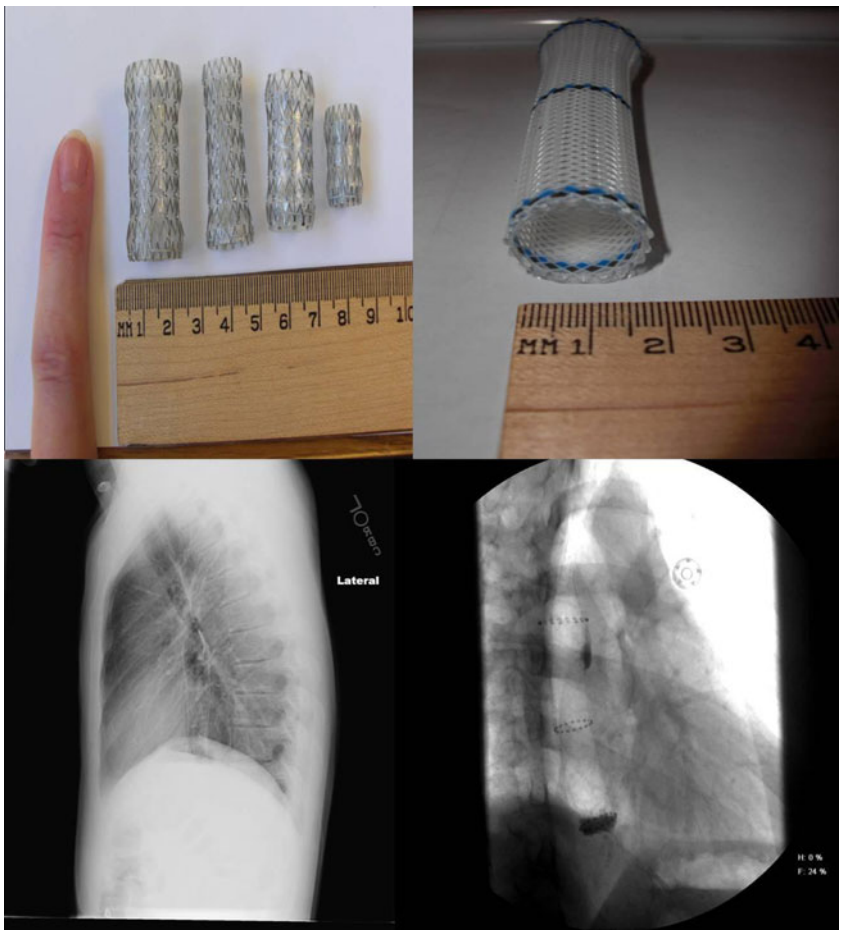

Fig. 1 Clockwise from upper left. **a** AERO tracheobronchial and Allimax-ES esophageal stents set side-by-side for comparison (from left to right): adult human finger for scale, Aero 20×80 mm, Allimax 18×70 mm, Aero 20×60 mm and Aero 18×40 mm. **b** Polyflex 18×90 mm stent. **c** Polyflex stent in 15-year-old male with trisomy 22, severe reflux esophagitis, and peptic stricture in lower esophagus. **d** Allimax-ES stent in 17-year-old male with stricturing esophageal Crohn's disease

evaluation and stent deployment, the utility of this device is also questionable.

Indications

No defined set of indications for esophageal stent placement in children have been established and the published literature on this topic is not helpful in drawing firm conclusions on optimal timing for stenting procedures. Generally speaking, stenting should be considered in children with fixed esophageal strictures that have failed medical and endoscopic treatment. Typically these will be children with caustic, postsurgical, or congenital strictures, who present with recurrent dysphagia, food impactions, or feeding problems despite repeated attempts at endoscopic dilation. These dilation attempts may have been by bougie, by balloon, or by a combination of both techniques. Corticosteroid injection and use of mitomicin C application at the stricture site may have been attempted in order to decrease or eliminate the need for repeated dilations. The decision to proceed with stenting as a therapeutic option depends on a variety of factors, including location of the stricture, frequency of required dilations, number of strictures present, age/size of the child, and maturity of the stricture. Another indication, although less frequent, is esophageal trauma. We have had good experiences using esophageal stents following injury to the lower cervical esophagus, thus sparing the patient a large thoracic surgery. Also, there have been reports of stents used after iatrogenic rupture and in fistula management, reducing the need for surgical repairs [9, 10]. We focus on stent use for the management of esophageal strictures because it seems the most common indication in pediatrics.

The ideal candidate for stent placement would be a single, isolated stricture in the mid-esophagus. High, cervical strictures may be complicated by interference with the upper esophageal sphincter (UES), inducing subsequent dysphagia, vomiting, and retching, and thus necessitating premature stent removal. There should be at least 2 cm between the upper margin of the stent and the UES. Lower esophageal strictures may require the bottom portion of the stent to pass beyond the lower esophageal sphincter (LES) into the gastric lumen. Some patients may tolerate this without difficulty, but those with a strong history of reflux or aspiration may develop complications from unencumbered passage of gastric contents into the upper esophagus, coupled with impaired esophageal ability to clear the refluxate. Because of these constraints, careful endoscopic mapping of the exact dimensions of the stricture in relation to the UES and LES must be performed prior to consideration of stent placement.

Required frequency of dilation procedures plays an important part in deciding the appropriate timing of a stenting procedure. This decision of when frequency of dilations becomes excessive can be influenced greatly by the opinions of the family, the ease of access for repeated dilation procedures, the effect of the stricture on the patient's nutrition, and the financial impact of repeated procedures on the family. Therefore, each case represents a truly individual assessment of all these factors. In our practice, stenting becomes a consideration if the frequency of dilations consistently exceeds every 2 to 3 months and the other stricture characteristics favor stent placement.

The number of strictures present and their proximity to each other must also be considered. In caustic ingestions, there may well be two or more areas of narrowing. If these are in close proximity, this may not be a contraindication for stenting. If, however, they are more than 6 to 8 cm from each other, it is unlikely that both can be covered by a single stent. Overlapping stents can be used in this case, but that obviously complicates placement [11]. The age, and thus size, of the child is another consideration, because available stent sizes are limited at this time. For smaller children, bronchial stents, with smaller diameters and shorter length, can be used, but patient tolerance is a significant issue. Dysphagia can be a common problem with stents in the proximal esophagus and can be difficult to manage in a young child. As a wider variety of stent sizes are produced, placement in smaller children will become more commonplace. Again, careful endoscopic and fluoroscopic assessment of the stricture to determine the diameter following dilation and the length of the entire esophagus will help determine if appropriately sized esophageal stents are available. Timing of stent placement in relation to the age and maturity of the stricture is also important. Earlier reports on the use of stents in children often were very early in the course of therapy, either as initial therapy or within the first few months following a caustic ingestion [2, 3, 12]. In these trials, however, the aim of stenting was to prevent rather than treat strictures. Prospective studies are needed to determine the role of expandable, removable stents for this indication. For treatment purposes, stenting should generally be considered for a stable, mature stricture of at least several months.

Procedural Considerations

Before making the decision to place an esophageal stent, several additional factors need to be considered. Complex strictures that do not offer a straight viable lumen are not good candidates for expandable stents. This is obviously not the case for malignant strictures, but this indication falls outside the scope of this review. Having an accurate determination of stricture length is important. The stent should be at least 3 to 4 cm longer than the stricture, allowing for enough stent overlap to minimize risk of

migration. This is true for both the plastic and covered nitinol stents.

The stricture should be carefully examined endoscopically prior to dilation. Evaluation of luminal patency beyond the apparent stricture is very important. In the absence of visual confirmation, fluoroscopic evaluation by injecting contrast using a catheter (ERCP cannula or the like) is a viable option. Clear demarcation of the proximal and distal stricture margins is important to ensure proper stent deployment. Placing radioopaque markers on the skin to mark the stent margins is an option, but care must be taken to place these directly on the skin and not on outside clothing or bedsheets, because the margin of error is too large. Even with skin marking, breathing motion will cause markers to change position by several millimeters. We have found radiopaque CT scan tape (S-Spots, Beekley Corporation, Bristol, CT, USA) to be helpful for this purpose. Stent deployment ideally should be done under fluoroscopic control.

In spite of manufacturer claims, all stents are subject to some foreshortening during deployment. One way to mitigate this and ensure adequate deployment to the stricture track is to initiate deployment slightly distal to the stricture. As the stent deploys, the stent is pulled up to the desired location while deployment continues until the stent is completely disengaged from the delivery device. If the lower end of the stent is expected to abut the gastroesophageal junction, our recommendation is to use a longer stent and allow the bottom of the stent to protrude into the stomach. In our experience, this will minimize the risk of proximal stent migration and, with appropriate feeding recommendations, should pose no problems to the patient. As noted above, for patients with aspiration risk, breaching the gastroesophageal junction may be an issue and must be considered on a case-by-case basis. For distal esophageal strictures, another option is to use metal clips, endoscopically deployed in the gastric cardia as markers.

The polyester-blend stents will deploy fully upon release, so that final configuration of placement is apparent immediately after deployment. The biggest technical issue is mis-deployment due to improper stent loading, causing the stent to fold inward on one side, requiring stent removal and reloading. The same stent may be used again after cleansing, if it is undamaged. However, tears in stent lining require the use of a new stent, because tissue ingrowth will occur and increase risk of trauma and bleeding at removal several weeks later. Use of a guidewire is necessary to lead the delivery device into position. A stiff guidewire is preferable, and most endoscopy supply companies manufacture a reusable Silastic device for this indication. Metal guidewires may be used, but are not necessary, and the risk of perforation with these is high in inexperienced hands.

Nitinol stents come preloaded, so care must be taken to select the correct stent size prior to opening the package. Nitinol belongs to the category of "memory metals." Once deployed, they will continue to expand for 24 to 48 h as the metal gets warmed by contact with human tissue. When indicated, allowing the patient to drink warm liquids after stent deployment can safely speed this process and minimize the risk of migration.

Distal migration of any of these stents can be remedied by pulling the stent back into position endoscopically. Proximal stent migration requires the removal of the whole stent and replacement. This is the more cumbersome of the two complications and reviewing these scenarios in the consent process is important. Softening of the stricture over time also increases the risk of stent migration. Usually examination of the stricture track endoscopically will suggest that this has occurred, thereby alleviating the need for repositioning in favor of simple removal of the malpositioned stent. Gastric stents should be removed endoscopically, because there are no data on safe passage of these stents through the gastrointestinal tract.

Management and Potential Complications

Complications of stent placement generally fall into the categories of dysphagia, chest pain, migration, reflux, respiratory problems, and perforation. In the immediate postprocedural period, dysphagia is the most common complication, with virtually all patients having at least transient complaints [13]. For those with more proximal strictures, the upper edge of the stent may irritate the UES and initiate more severe symptoms of gagging and retching. In these patients, severe dysphagia may necessitate premature removal of the stent. Although stenting in adults is often performed as an outpatient procedure, assessment of feeding tolerance in children should be confirmed during at least an overnight admission following placement. Similarly, transient chest pain due to persistent dilation from the stent may complicate the early postprocedure period and require intravenous analgesic therapy. Stent migration is perhaps the most common significant complication, occurring in 5% to 29% of patients in the reported pediatric series [2–6, 8]. Presentation of migration may vary from asymptomatic discovery on a routine chest film to signs of obstruction. Any abrupt change in a patient's status while a stent is in place should prompt an immediate evaluation to determine if migration has occurred. Surveillance endoscopy or chest radiograph studies to check stent position in asymptomatic patients should not be necessary. Choosing a stent with a larger diameter, relative to the degree of dilation performed, may help prevent migration. As noted above, if a distally migrated stent is still in place within the

esophagus, it may be possible to endoscopically reposition the stent across the stricture site. If the stent has migrated into the stomach, complete removal with a polyp snare is usually successful.

As noted, exacerbation of reflux can be a significant complication in patients with lower esophageal strictures requiring the bottom margin of the stent pass beyond the LES. In these cases, it is likely preferable to pass the stent well into the stomach rather than leaving the distal end of the stent right at the level of the LES, as this seems to potentiate even greater amounts of reflux. Regardless, for patients having a history of severe reflux, especially complicated by aspiration, close observation for any respiratory compromise is crucial and may prompt premature stent removal. Respiratory compromise may also occur as a result of tracheal compression from the stent. Perforation has not been observed in any of the small pediatric series, but remains a consideration when continual radial force is applied to a fibrotic stricture that has just been dilated. Small perforations, however, may end up healing spontaneously without sequelae if they are essentially being "sealed" by a covered esophageal stent. Removal of the stent, however, presents another opportunity for perforation to occur, as the mucosa typically adheres strongly to the outer surface of the stent, at times requiring use of substantial force to remove the stent.

Duration of stent placement is another area of controversy, with the limited reported pediatric series of covered expandable stents ranging from 7 to 133 days [2–6, 8, 12, 14]. Manufacturer guidelines generally recommend removal in 4 to 6 weeks, and this has been our practice as well. Longer stent placement risks greater adhesion of the mucosa, whereas shorter placement may not adequately "recast" the diameter of the stricture. For removal of the Polyflex stents, the upper margin of the stent is grasped with a rat-tooth or similar forceps through the scope, tension is applied, and the scope is withdrawn with a twisting motion, narrowing the caliber of the stent and folding the upper edge of it off the mucosal surface. For the covered nitinol stents, the purse-string suture at the proximal end is pulled with forceps under endoscopic guidance, which causes the stent to collapse and facilitates removal.

Future Considerations

Greater awareness of the dangers of caustic ingestion and institution of appropriate measures to prevent them has been successful in limiting the number of severe accidental caustic ingestions in children in the United States and other industrialized nations, compared to developing nations, where the prevalence is much higher. Nevertheless, these esophageal injuries still cause significant morbidity and are responsible for the majority of severe esophageal strictures in the pediatric population [15]. Covered esophageal stents in children offer endoscopists an additional tool in our arsenal for treatment of these challenging patients. A recent multicenter study examining the use of mitomycin C for refractory esophageal strictures suggests that this may be another important tool in this population [16]. Additional prospective studies are needed to define patients better suited to one or another of these treatment modalities, or to develop a treatment algorithm encompassing both. Furthermore, clinical trials comparing safety and efficacy of plastic versus nitinol stents in the pediatric population would be helpful in determining if there is a preferred option in children. As smaller lengths and diameters of these stents become more widely available, their potential use in pediatric patients will expand. Biodegradable stents have been developed and are especially attractive for use in children, alleviating the need for endoscopic removal, with success reported in one pediatric patient to date [7].

Conclusions

Although the reported literature on their use in children is sparse, the new generation of removable esophageal stents represents a significant advance in the management of benign esophageal strictures in the pediatric population. Likelihood of success seems most dependent on the ability of the patient to tolerate initial placement of the stent without complication and maintaining proper positioning for an adequate period of time before removal. Pediatric interventional endoscopists should become familiar with the various types, placement, indications, and risks of these devices. They offer an important therapeutic option bridging medical and surgical treatment.

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