APSA toolkit for Use of Magnets in Esophageal Atresia

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on behalf of the APSA New Technology Committee

Description:

The use of magnets is a nonsurgical alternative for esophageal anastomosis in selected patients. The US Food and Drug Administration has approved a catheter-based magnetic device, the Flourish^{TM} Pediatric Esophageal Atresia Device, for use in lengthening atretic esophageal ends and creating an anastomosis in patients up to one year of age (Cook Medical, Bloomington, IN). It has been federally authorized as a humanitarian use device. The device consists of an esophageal and gastric catheter each containing an inner catheter fitted with a bullet-shaped neodymium iron boron magnet. (**Figure 1**) The proximal portion has a central opening for insertion of a guide wire as well as a port for suctioning saliva and for injection of contrast to confirm anastomosis. The distal catheter has a channel for enteral feeds and a 5 ml balloon.

The magnets situated in the proximal and distal esophageal pouches have opposite polarity, and thus once aligned attract one another which results in lengthening of the ends. Once the magnets connect, or couple, the intervening tissue becomes ischemic and sloughs off while the outer rim heals establishing the anastomosis. The length of the gap must be within the magnetic field achievable by the two magnets to attain attraction and connection.

The magnetic anastomosis procedure may be performed under anesthesia or sedation and is done under fluoroscopic guidance. After completion, daily chest radiographs are done to verify proper alignment of the magnets. Successful anastomosis is confirmed by esophagram, saliva in the gastrostomy catheter, or feeds in the esophageal catheter. After confirmation, the magnets may be removed and replaced with an oro or nasogastric tube over a wire.

In addition, there is a magnetic device approved for compassionate use that has also been developed and is undergoing clinical testing. This device has disc-shaped magnets in a convex-concave orientation. Once anastomosis is achieved, it is spontaneously expelled.

Advantages:

The main advantage of using magnets for creation of esophageal continuity in esophageal atresia is to avoid an operation. The use of magnets for esophageal atresia may be particularly beneficial for patients with a pure esophageal atresia without a long gap or patients that have undergone multiple operations or who have other co-morbidities that increase the surgical risk.

Indications for use:

The distance between the upper and lower pouches must be less than 4 cm in length to use the Flourish Device and within the specified gap distance of other magnetic devices. Magnets can be used in pure esophageal atresia cases or with a repaired fistula. For the catheter-based magnet device, a gastrostomy

with a tract able to accommodate an 18 Fr catheter must be present. The magnets can be used as a primary procedure for anastomosis, as a staged procedure after surgical esophageal lengthening, or for a recalcitrant stricture after tracheoesophageal fistula repair.

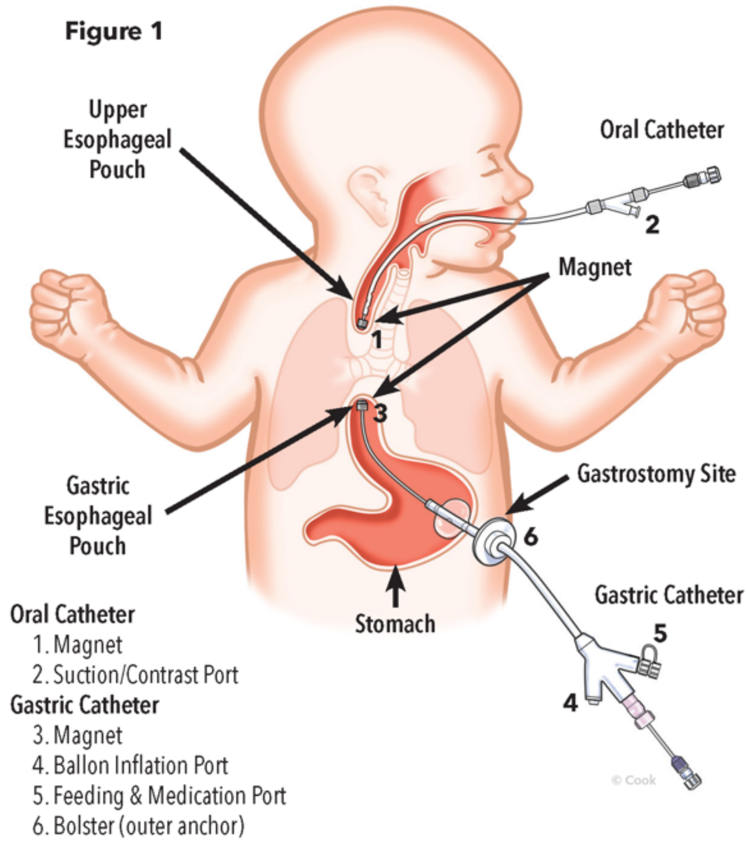
Review of Evidence

Hendren and Hale first reported the use of electromagnetic bougienage to lengthen the esophageal ends in a patient with EA facilitating later surgical repair.[1] Catheter-based magnetic anastomosis was initially described in five infants with EA in Argentina.[2] Anastomosis was achieved in all of the patients in an average of 4.8 days. A later series was published describing achievement of primary esophageal anastomosis in an additional four patients with EA using catheter based bullet-shaped magnet pairs.[3] A recent study described a two-staged approach whereby young infants had an initial esophageal approximation without luminal continuity followed by magnamosis.[4] In addition, a retrospective study was recently published describing the use of the catheter-based magnet device in 13 patients. All achieved anastomosis with a 100% stricture rate and two patients required surgery for a refractory stricture.[5] Woo et al. published a series of two patients that underwent magnetic compression stricturoplasty to treat refractory strictures are esophageal atresia repair.[6] (**Table 1**)

Table 1 – Summary of studies of magnets for Esophageal Atresia

Study	No of EA pts	Use of magnet	Avg no days to anastomosis	% stricture
Takamizawa 2007[7]	1	stricture	34	100
Zaritzky 2009[2]	5	anastomosis	4.8	80
Zaritzky 2014[3]	9	anastomosis	4.2	89
Lovvorn 2014[4]	2	staged anastomosis	7.5	100
Dorman 2016[8]	1	staged anastomosis	13	100
Woo 2017[6]	2	stricture	8.5	100
Greenstein 2018[9]	1	anastomosis	10	100
Slater 2019[5]	13	anastomosis	6.3	100

Figure 1 – Figure of Flourish device with proximal suction port and distal port for feeds



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