

Esophageal Balloon-Dilation Feeding Tube (BE-Tube) Instructions For Use

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BACKGROUND: Dysphagia due to benign esophageal strictures is an important cause of morbidity and mortality in veterinary medicine. While intrinsic benign esophageal strictures most commonly occur as a result of esophagitis following gastroesophageal reflux, any significant chemical or mechanical injury to the esophageal mucosa can potentially result in formation of a stricture. The impact of esophageal strictures on pets and their owners is significant; they can be costly to treat and often associated with a poor prognosis.

The goal of treating benign esophageal strictures (BES) is to reduce the frequency of regurgitation to the extent that oral feeding can be used to maintain nutrition and hydration. The current mainstays of mechanical dilation therapy include endoscopic-guided balloon dilation and/or bougienage. A “good” outcome has been reported following balloon dilation (74-88%) and bougienage (74-78%) for benign esophageal strictures in dogs. Authors of these studies report that a “successful outcome” often requires two or greater dilation therapies; these treatments are performed under general anesthesia, which can encourage further esophageal reflux, and can be costly. In addition, a “good” outcome is often defined as requiring a soft food or gruel, as the stricture often remains to some degree. Few (likely under 20%) of these animals ever regain normal feeding regimens.

Esophageal stenting has been attempted as a possible one-stage solution for BES. Unfortunately, the authors’ experience with esophageal stenting has been disappointing, however these procedures were performed in patients with intractable recurrent benign esophageal strictures (RBES) defined as >3 dilation procedures with stricture recurrence. The major advantage of the presence of a stent is the consistent dilation performed, not permitting the stricture to reform, or the edges of the torn mucosa to meet. Unfortunately the stents are often not well tolerated by the patients, with subsequent high rates of dysphagia, gagging and discomfort.

From review of the data available in previous reports, it seems the ideal treatment for benign esophageal strictures would be to provide consistent (or nearly consistent) dilation of the stricture to prevent reformation, but also permit easy removal of the device if it is not well tolerated, or when the stricture has been effectively treated. The one-stage esophageal balloon dilation feeding tube, otherwise known as the ‘Balloon-Tube’ (or B-Tube) can be an effective, single-procedure alternative to repeated balloon dilation procedures for the treatment of benign esophageal strictures in dogs.

INDICATIONS: The B-Tube is indicated for dogs or cats with either naïve (not previously dilated) or recurrent benign esophageal strictures (BES). Relative contraindication could include strictures within 3-5cm of the upper esophageal sphincter, however the B-Tube has been placed through a pharyngostomy incision for more cranially located strictures with success.

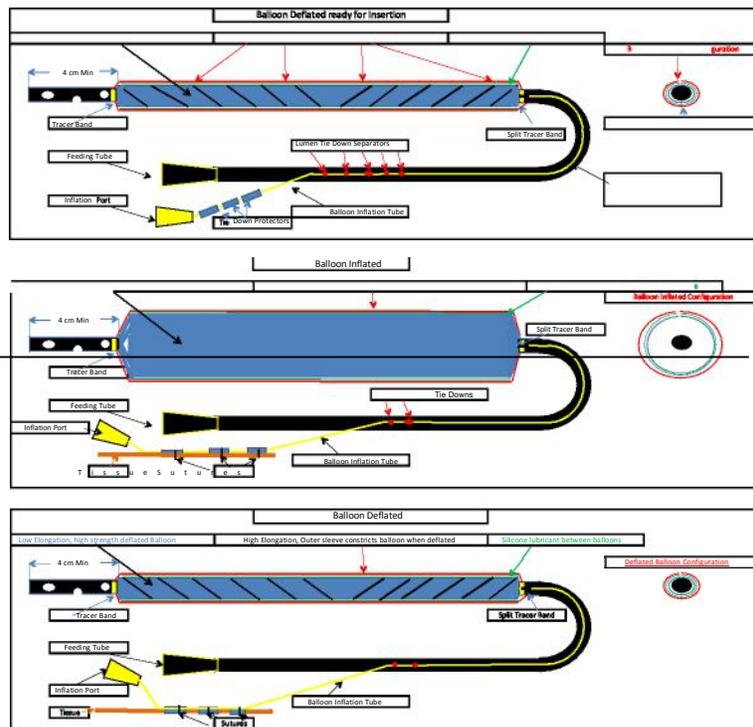


FIGURE 1: B-Tube double balloon design

DESIGN AND USE: The B-Tube is a non-compliant esophageal balloon dilation device mounted on a commercially available and commonly used esophageal feeding tube (FIGURE 1,2). The noncompliant balloon is covered with a compliant polyurethane balloon to help capture and constrict the noncompliant balloon contained inside to provide a low-profile device when it is not inflated. Once a BES has been diagnosed and traditionally balloon-dilated, the B-Tube is placed similarly to a standard esophageal feeding tube (E-Tube), with some technical differences. The owner performs twice daily

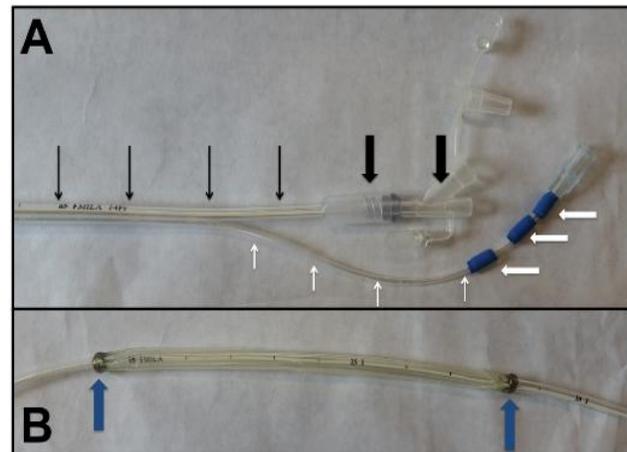


FIGURE 2: A. Two parts of the B-Tube – An esophageal feeding tube (black arrows) with a detachable hub for feeding (Black block arrows). Balloon inflation tubing (white arrows) mounted alongside the E-Tube with blue tube compression guards (white block arrows) to prevent inflation tubing occlusion when securing in place with finger-trap sutures. B. Blue arrows mark the radio-opaque bands placed at the cranial and caudal balloon extent.

balloon dilations at home, in their unsedated pet, using predetermined air volumes reported on the B-tube package. This tube can also provide supplementation of food, water and medications through the tube, if necessary. While stricture dilation can be uncomfortable in humans, the initial stricture effacement would occur under the initial anesthetic episode, so subsequent dilations would not be expected to be associated with discomfort. In between the daily dilation procedures, the balloon would be self-constrained permitting passage of normal food and liquid boluses during normal per os eating and drinking. The B-Tube is typically removed approximately 4 - 6 weeks later, often under general anesthesia for repeat esophagoscopy to confirm stricture resolution (alternatively, the B-Tube can be removed in the awake patient).

EXPECTATIONS: Initial results suggest that the B-TUBE can be an effective, single-procedure alternative to repeated balloon dilation procedures for the treatment of benign esophageal strictures in dogs. Preliminary results indicate minor complications including: insertion site irritation/infection, inflation discomfort, and early tube failure (repaired). All of these complications were relatively minor, self-limiting, and easily resolved. Performing the inflations does require dedicated owners. The first patients treated have been reported (Tan et al., JVIM) and have demonstrated that the B-Tube has the potential for improved (and less expensive) outcomes in the treatment of BES as well as some RBES with ~70% of patients eating a normal diet following B-tube removal.

THE B-TUBE: A GUIDE FOR PLACEMENT AND USE

RECOMMENDED EQUIPMENT

- 1) Fluoroscopy and Endoscopy
- 2) Bite block/Mouth guard
- 3) Variety of standard esophageal balloon dilation catheters for initial dilation
- 4) Manual digiflator (60 mL)
- 5) Iodinated contrast agent and saline
- 6) 5Fr Marker catheter (InfiniteMedical.com/products/marker) with 80cm .035 angled hydrophilic guidewire (MILA #BE-GW3580N)
- 7) Sterile drape and small surgical pack with surgical blade
- 8) Long right angled or Carmalt forceps
- 9) .035 x 150cm angled hydrophilic guidewire (Infinite Medical)
- 10) Compatible peel-away sheath (10Fr & 14Fr B-Tube use MILA #BE14PAI/18Fr B-Tube use #BE18PAI).
- 11) Centesis Valve - MILA #175450 and Stopcock MILA #2405
- 12) Variety of B-Tube sizes
- 13) 2-0 or 3-0 Nylon suture for securing B-Tube
- 14) Bandage material

PREPARATION

The patient is placed under general anesthesia and the left ventrolateral cervical region is clipped. The patient is placed in right lateral recumbency on the fluoroscopy table.

ESOPHAGOSCOPY AND BALLOON DILATION

A mouth gag is placed and esophagoscopy is performed to identify the stricture. A 0.035" x 80cm angled, hydrophilic guide wire is placed through a 5Fr marker catheter and both are advanced down the esophagus under fluoroscopic and endoscopic guidance. Once across the stricture, the guide wire is removed and a 50:50 iodinated contrast: saline mixture is injected through the marker catheter to outline the esophageal stricture and esophageal walls. Dilation of the esophagus is facilitated by air insufflation through the flexible endoscope; dilation permits accurate measurement of the esophageal diameter. The marker catheter is used to calculate radiographic magnification. **Once the normal esophageal diameter has been determined, the marker catheter is removed and the appropriate esophageal balloon dilation catheter is placed over the guidewire and alongside the flexible endoscope.** If over-the-wire dilation balloons are not available, any passage of a balloon down the esophagus and across the stricture must be monitored with the endoscope.



FIGURE 3: Serial esophageal stricture balloon dilation performed using endoscopic and fluoroscopic guidance. **A.** Marker catheter in place with contrast and air esophagram demonstrating stricture and maximal esophageal diameters. **B.** Balloon dilation demonstrating stricture dilation but not complete effacement. The lack of complete stricture effacement is often not completely appreciated endoscopically. **C.** Complete stricture effacement confirmed fluoroscopically.

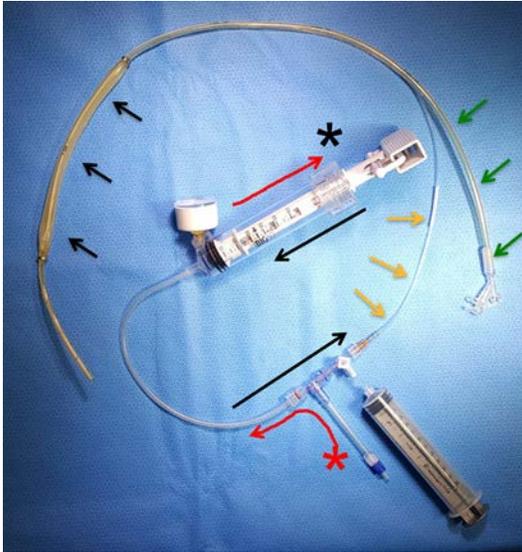


FIGURE 4A: Photo shows B-Tube device with balloon (short black arrows), proximal feeding tube (green arrows), and inflation tubing (yellow arrows) prepared for inflation. The Big 60 inflation syringe (*) is attached to the centesis valve, then three-way stopcock, then inflation tubing. Withdrawal of inflation syringe (red arrows) draws air in through centesis valve, followed by injection of inflation syringe (long black arrows) resulting in balloon inflation. After full inflation, turning three-way stopcock towards centesis valve permits air to evacuate through the stopcock.

A 60ml hand digiflator is filled with 50:50 iodinated contrast/saline and the balloon is inflated during endoscopic and fluoroscopic guidance. The use of fluoroscopy is **HIGHLY** recommended to confirm complete stricture effacement that may be difficult to fully discern with endoscopy alone (**FIGURE 3**). Standard esophageal balloon dilation catheters are necessary for initial stricture dilation as the B- Tube itself is **not designed for high pressure stricture effacement** and it has a rather large profile, limiting access across some of the smaller lumen strictures. Additionally, the B-Tube tends to have less radial force than many commercially available balloon dilation catheters that are smaller diameter. Once stricture effacement has been confirmed, the balloon is deflated and removed. Endoscopic evaluation is performed to identify any complications such as full thickness esophageal tears. The distal esophagus is also fully evaluated if the endoscope was initially unable to pass through the stricture.

B-TUBE PLACEMENT

The patient remains in right lateral recumbency and the clipped cervical region is scrubbed and prepared. A small fenestrated drape is placed over the proposed B-Tube exit site. This is chosen similarly to esophagostomy tube placements, or approximately mid-way between the angle of the mandible and thoracic inlet. For very proximal cervical esophageal strictures, the entry site may need to be more cranially located. Fluoroscopy can be helpful in identifying the cricoid cartilage and upper esophageal sphincter, and the B-Tube can enter the esophagus just caudal to the cricoid and crico pharyngeal muscle. B-Tubes have been placed as **pharyngostomy tubes** in extreme circumstances for strictures just caudal to the upper esophageal sphincter. Another important landmark is the jugular vein that should be identified and avoided. The appropriate B-Tube is chosen based upon previous esophageal diameter measurements and balloon dilations.



FIGURE 4: B-Tube placement using long right-angled forceps, 150cm angled hydrophilic guide wire, and peel-away sheath.

Placement of the B-Tube is a two-person procedure and demonstrated in **Figure 4**. The chosen B-Tube is opened in sterile fashion, a sterile field on an OR table is recommended. The B-tube should be inflated (not exceeding the recommended fill volume) prior to placement within the patient. A 150cm - 0.035" angled hydrophilic guide wire and appropriately sized peel-away sheath (see packaging for recommended sizes) are also opened in sterile fashion. The guide wire is flushed with sterile saline to provide lubrication. The B-Tube has two separate hubs on the proximal end (the feeding tube hub and the inflation tube hub, see above). The feeding tube hub is unscrewed and disconnected from the tubing in preparation for placement. At this time, you may consider trimming the distal end of the B- tube (distal to the balloon and metal marker) to minimize chances of it extending excessively into the stomach in patients with more distal strictures. Additional side holes can be made as well but this is not generally necessary. There has not been a problem identified with B-tubes (balloons or tips) extending across the lower esophageal sphincter.

One person passes a pair of long, right-angled or Carmalt forceps trans-orally into the esophagus and positions the tip to exit at the desired B-Tube entry site. Care is taken to avoid the jugular vein and prior to an incision, the tip is palpated for any pulsations suggestive of the carotid sheath (if a pulse is palpated, the forceps are repositioned).

While the skin is gently stretched, an incision is made directly over the raised instrument tips until they exit the incision. The tips are opened and the guide wire is advanced through the incision and out the mouth. The peel-away sheath is then passed over the guide wire and advanced through the incision until it is identified in the mouth. The guide wire and dilator are removed leaving the sheath across the incision site and into the mouth. The inflation tubing hub with the three blue bands is passed retrograde through the sheath from the mouth outwards towards the incision

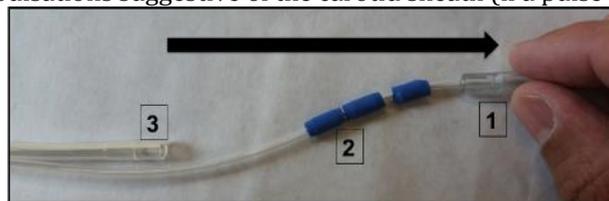


FIGURE 5: Hub (1) is passed retrograde through the peel away sheath first, followed by the blue compression guards (2) and then the end of the esophageal tube (3).

(**FIGURE 5**). This is followed by the feeding tubing (with the hub already removed). This is generally a snug fit. Once the inflation tubing exits the sheath, it can be gently pulled until the B-Tube is across the incision, half exiting the incision and half exiting the mouth. The peel-away sheath is then removed over the tubing. The 150cm hydrophilic angled guide wire is advanced down the feeding tube portion of the B-Tube from the hub end towards the distal tip. This wire is then redirected down the esophagus and monitored under fluoroscopic guidance as it enters the stomach. The distal portion of the B-Tube containing

the balloon is then advanced over this guide wire down the esophagus similar to a traditional esophagostomy tube placement procedure. The use of the guide wire ensures the B-tube passes through the effaced stricture without damaging the area further.

Fluoroscopy is used to ensure the balloon is positioned appropriately across the stricture location. The radiopaque bands mark the most proximal and distal extent of the balloon. It is imperative the balloon does not extend across the entry site for proximal strictures. Ideally the balloon is centered across the stricture, however this is only possible in centrally located lesions. For proximal and distal strictures, it is important to have as much balloon across the stricture as possible to prevent the tube from sliding off the stricture during inflation, rather than filling above and below the lesion and expanding it during full inflation. The balloon has been placed across the lower esophageal sphincter for distal strictures; this did not appear to cause major discomfort or harm in the few patients in whom it was performed. A Sharpie can be used to mark the B-Tube at the exit site to identify the ideal location prior to suturing in place.

A dry 60cc hand digiflator is used to inflate the B-Tube balloon with **AIR ONLY** (LIQUID SHOULD NEVER BE INTRODUCED INTO THE B-TUBE). This is performed using a 3-way stopcock and centesis valve, and inflation is monitored under fluoroscopy. The B-tube is inflated until the balloon is uniformly expanded across the lesion and additional syringes of air do not substantially add to the balloon diameter as evaluated with fluoroscopic visualization. **THE FILL VOLUME OF THE B-TUBE MUST NOT BE EXCEEDED.** The B-Tube is **ONLY USED** to maintain the lumen of a previously effaced stricture; high pressures are **NOT NECESSARY**. The total number of 60cc syringes of air is recorded to instruct the owner for future inflations. It is often not necessary to use the **ENTIRE** reported fill volume **BUT** the balloon should inflate completely across the stricture (there should not be a stricture evident after full inflation).



Once the positioning has been confirmed, the inflation tubing can be “peeled” down off the feeding tubing, and the feeding tube can be trimmed to an appropriate length. The inflation tubing can be trimmed as well. The two individual tubes are separated down to the entry site and each are sutured individually to the skin. The feeding tubing is sutured with a 3-0 or 2-0 nylon purse-string (loose to avoid pressure necrosis) and finger-trap suture pattern. The inflation tubing can also be sutured if necessary, however **the blue compression guards must be used**; otherwise the finger-trap sutures would compress the inflation tubing and prevent inflation of the balloon (**FIGURE 6**). After secured in place, the feeding tubing is trimmed and the hub is replaced. The B-tube is wrapped as is typical for esophagostomy tubes, using a small amount of triple antibiotic ointment, non-adherent gauze, cast padding and outer wrap.

FIGURE 6: Finger-trap securing the tubing. Note the sutures on the inflation tubing are tied around the blue compression guards to prevent compression of the relatively narrow tubing. **ALTERNATIVELY**, sutures may only be placed on the feeding tube portion of the device.

The patient is recovered, hospitalized overnight for monitoring, and there are no oral feedings or water overnight. Per os feeding is not initiated for 12 to 24 hours, rather the feeding tubing is used for medications and liquid feeding. A post-placement radiograph the following morning is typically performed to confirm placement prior to the first inflation if there are any concerns.

The veterinarian should perform an awake dilation prior to patient discharge. This is typically done in front of the owners and recorded on a cell phone or other device. The veterinarian should also watch

the clients perform a mock inflation procedure to confirm they are doing it appropriately (see below). Standard discharge medications include proton-pump inhibitors (such as omeprazole) and gastric mucosal barrier protectant (such as sucralfate) until 2 weeks after tube removal.

DILATION PROCEDURES

Performing balloon dilation in the awake patient is typically a two person job; One to work the three-way stopcock and the other to handle the manual digiflator (**FIGURE 7**). When possible, a third person to hold the patient is ideal. An extra B-Tube should be available to train the clients on the inflation procedure before attempting in the patient. The veterinarian should watch the clients perform a mock inflation procedure multiple times before they attempt the procedure themselves. In order to perform the inflation, follow the order below.

- 1) Remove the injection caps on the stopcock that remain in place when the B-Tube is not in use.
- 2) Attach the manual digiflator and centesis valve as demonstrated in **Figure 4A**.
- 3) Turn the stopcock "Off to atmosphere" as in **Figure 4A**, and completely fill the digiflator with air.
- 4) Inject the entire volume of air into the B-tube.
- 5) Repeatedly fill the digiflator again with air and inject again until the desired air volume as determined at placement (and NOT exceeding manufacturer recommendations) is reached.
- 6) When performing the final syringe inflation, immediately after the syringe of air has been administered, turn the stopcock "Off to digiflator". A release of air will be heard escaping from the B-tube and exiting the stopcock.
- 7) Turn the stopcock back "Off to atmosphere" and using an empty 60cc syringe, evacuate the B-Tube of any remaining air to maintain a low-profile tube within the esophagus **Figure 4A**.
- 8) Turn the stopcock "Off to patient", disconnect the digiflator and centesis valve, and reattach the injection caps. The inflation procedure is finished.

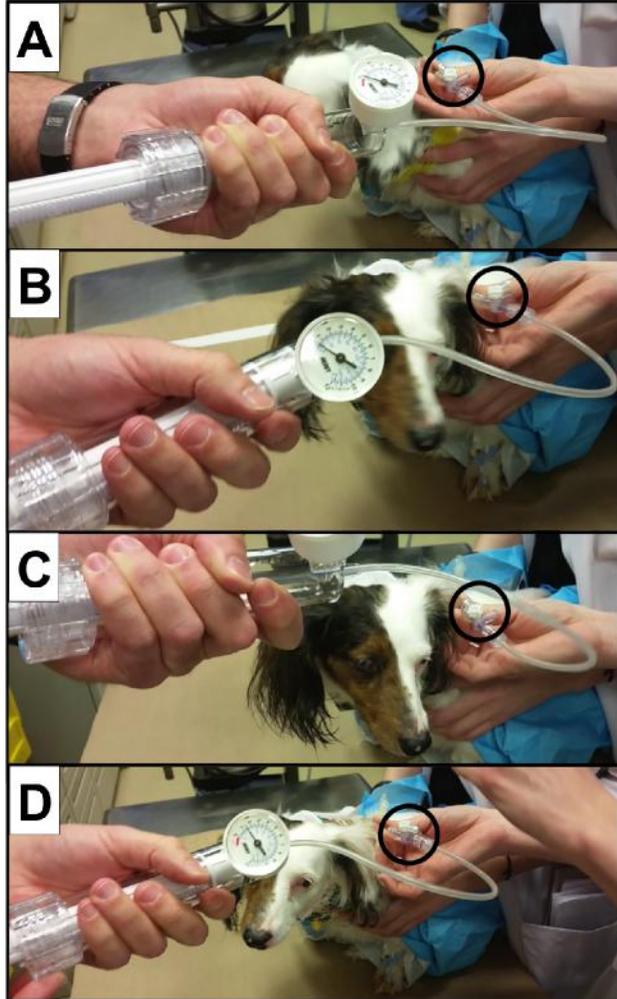


FIGURE 7: The B-Tube inflation procedure. The black circles indicate the position of the stopcock during the different steps of balloon inflation.

The clients should be warned that the inflations could cause some gagging. This resolves as soon as the balloon is deflated. There is no need to maintain balloon dilation for any period of time; simply fill the balloon and immediately deflate it. Balloon inflations continue twice daily for ~4-6 weeks until removal. While the feeding tube portion of the B-Tube can be used for nutritional supplementation, the clients are encouraged to feed to patient the day after placement and progressively thickened gruels, canned food, and dry kibble gradually over the next week if tolerated to encourage esophageal healing and function.

B-TUBE REMOVAL

In general, B-Tube removal is performed under general anesthesia to facilitate removal as well as to repeat endoscopy to characterize the status of the stricture. During endoscopy, it is not uncommon to see some esophageal irritation along the length of the B-Tube due to chronicity. In many cases performed to date, the B-Tube could have been removed in the awake patient simply by cutting the purse-string sutures and gently pulling the tube out. In some patients, the B-Tube balloon may be too large to easily pass through the exit site if the stoma is small and narrow. If so, this necessitates anesthesia, cutting of the tube, pushing it into the esophagus, and retrieving the tube in the esophagus with an endoscope and snare or graspers. After removal, a light neck wrap is placed over the exit site and removed in one or two days. Proton-pump inhibitors and gastric mucosal barrier medications are continued for 2-4 additional weeks as needed.

TROUBLE-SHOOTING

Problems during tube placement are uncommon but can theoretically include nausea, regurgitation, vomiting, hub loosening, exit site irritation/infection, and anorexia. Repeat radiographs can confirm proper B-Tube placement when compared those taken post-tube placement originally. If there is any increased discomfort experienced by the patient during inflation, the clients should be instructed to abort the inflation procedure and have the patient evaluated by the veterinarian immediately. If the client finds that the B-tube inflations become very easy (no resistance encountered during inflation likely due to a ruptured balloon), the patient should be evaluated immediately. No major complications have been encountered with the use of the B-Tube at this time.

PRELIMINARY DATA

Initial results have been presented¹⁹ and are encouraging. See attached journal manuscript. All patients had endoscopic and fluoroscopic guided balloon dilation of the strictures as well as esophagoscopy before and after EBDFT placement. Five dogs had EBDFT placement via esophagostomy and one dog received pharyngostomy placement due to the proximal stricture location. There were no major intra-operative complications. All patients were discharged the same or the following day.

Initial results suggest that the B-Tube can be an effective, single-procedure alternative to repeated balloon dilation procedures for the treatment of benign esophageal strictures in dogs. Preliminary results indicate complications including insertion site irritation/infection, inflation discomfort, and early tube failure (repaired) are relatively minor, self-limiting, and easily resolved. Performing the inflations does require dedicated owners. While there are certain size limitations currently, early prototypes have been updated.

These first patients have demonstrated that the B-Tube has the potential for improved (and less expensive) outcomes in the treatment of BES as well as some RBES.

VIDEO OF B-TUBE PLACEMENT
[youtube.com/watch?v=aXiGIZMxd7k](https://www.youtube.com/watch?v=aXiGIZMxd7k)

Dysphagia Score Sheet

A previously described and commonly used human "dysphagia score" of 0-4 was modified and used to determine outcome.

- Score 0: Patients able to eat a normal diet with no dysphagia.
- Score 1: Patients able to swallow some solid foods (kibble or canned food).
- Score 2: Patients able to swallow only semi-solid foods (gruel).
- Score 3: Patients able to swallow liquids only.
- Score 4: Patients unable to swallow anything including saliva; total dysphagia.

A **DECREASE** in dysphagia score is considered a clinical improvement.

| Case | Signalment | Cause | Previous Dilations | PRE-Dysphagia Score (0-4) | POST-Dysphagia Score (0-4) |
|------|-------------------|---------|--------------------|---------------------------|----------------------------|
| 1 | 8mon GSHP | OHE | 2 | 3 | 1 |
| 2 | 11mon Gldn-Doodle | OHE | 4 | 3 | 0 |
| 3 | 2yo LABR | Meds* | 1 | 3 | N/A |
| 4 | 7yo LABR | Dental | 10 | 3.5 | 2.5 |
| 5 | 2yo Chi | Parvo | 1 | 2.5 | 0 |
| 6 | 5yo Dach | IVDD Sx | 1 | 3 | 0 |

TABLE 1: Table demonstrating patient signalment, stricture etiology, number of previous balloon dilations performed prior to EBDFT placement, pre-EBDFT dysphagia score, and final dysphagia score at last follow-up. *Patient 3 was euthanized for other comorbidities prior to the EBDFT removal so a final dysphagia outcome could not be determined.

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