The Upper Esophageal Sphincter Is Not Round: A Pilot Study Evaluating a Novel, Physiology-Based Approach to Upper Esophageal Sphincter Dilation

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Objectives: Recent basic science investigations have suggested that the upper esophageal sphincter (UES), in cross section, is not round, but that it more closely approximates a kidney shape. Dilation with simultaneous use of two cylindrical dilators provides a novel, physiology-based approach to UES distention. We evaluated the initial safety and efficacy of UES dilation with simultaneous use of two controlled radial expansion balloon dilators.

Methods: Using a computerized database, we reviewed the charts of all persons who underwent UES dilation with simultaneous use of two radial expansion balloon dilators between December 1, 2011, and March 15, 2012. Information regarding patient demographics, indications, technique, and complications was abstracted. Self-reported swallowing impairment was assessed with the validated 10-item Eating Assessment Tool (EAT-10).

Results: Ten individuals underwent simultaneous dilation with two dilators. Their mean age was 65 years (SD, 14 years), and 7 (70%) of them were male. The indications for dilation were radiation-induced UES stenosis (50%), cricopharyngeus muscle dysfunction (30%), upper esophageal web (10%), and anastomotic stricture (10%). After the double-balloon dilation, no complications were reported. The mean EAT-10 score improved significantly, from 34.3 (SD, 13.5) to 16.7 (SD, 8.4), after the simultaneous dilation (p = 0.003).

Conclusions: Pilot data suggest that simultaneous dilation of the UES with two controlled radial expansion balloon dilators is feasible, safe, and effective. Further investigation is necessary to confirm the safety of this technique in a larger cohort and to use objective measures of efficacy to compare the technique to conventional dilation with a single dilator.

Key Words: balloon, bougie, controlled radial expansion balloon, dilation, dysphagia, esophagus, stricture, UES, upper esophageal sphincter, web.

INTRODUCTION

Esophageal stricture represents a common cause of oropharyngeal dysphagia. Some of the most common causes of esophageal stricture seen in an outpatient swallowing center include radiation-induced stenosis from definitive management of head and neck cancer, anastomotic stricture after head and neck oncological surgery, and peptic stricture from gastroesophageal reflux. Radiation-induced stenosis of the upper esophageal sphincter (UES) is reported in up to 23% of patients who undergo definitive treatment for head and neck cancer. Other causes of oropharyngeal dysphagia include advancing age, cricopharyngeus muscle dysfunction, and the presence of an upper esophageal web. Cricopharyngeus muscle dysfunction is responsible for 11% of visits to an outpatient swallowing center, and upper esophageal webs are present in 14% of persons who present with dysphagia and in 7% of the general population. One of the most common treatments of oropharyngeal dysphagia caused by UES stenosis, cricopharyngeus muscle dysfunction, or a cervical esophageal web is esophageal dilation.

Mechanical dilation of the UES can be performed with either a balloon or a bougie. Despite the widespread use of UES dilation, the treatment outcomes are suboptimal. Treatment failure occurs in 16% of patients, and up to 58% of patients require multiple dilations. An important consideration in reviewing these outcomes is the fact that the currently used dilators were designed to stretch the esophageal lumen — not the UES, for which they are being used. Additionally, the surface area of the esophagus is round, but recent advances in clinical practice sug-
gest that the surface area of the distended UES is shaped like a kidney. Therefore, contemporary cylindrical dilators may not provide optimal UES expansion.

New techniques of transnasal esophageal dilation provide a novel view of UES anatomy not previously afforded. Distention of the UES by this technique suggests that unlike the anatomy of the esophagus, the circumference of the UES may not be round (Fig 1). Casting of the distended UES in an ovine cadaveric model in our laboratory has confirmed that the UES more closely resembles the cross-sectional dimension of a kidney (Fig 2) and would therefore be more appropriately dilated with two cylindrical dilators (Fig 3). On the basis of these findings, we have commenced dilating complex strictures of the UES with simultaneous use of two dilators. The purpose of this report was to review our initial clinical experience and evaluate the feasibility, safety, and efficacy of UES dilation with two simultaneously controlled radial expansion balloon dilators.

METHODS
The procedure of UES dilation was performed under intravenous sedation and monitored anesthesia care with a combination of midazolam maleate and fentanyl citrate in all cases. The precise steps of the procedure are as follows. First, the nasal cavity is anesthetized with a combination nasal anesthetic and decongestant (4% lidocaine hydrochloride and 0.05% oxymetazoline hydrochloride).

Second, a transnasal esophagoscope (EE-1580-K Color Video Esophagoscope; KayPENTAX, Montvale, New Jersey) is lubricated with 2% viscous lidocaine hydrochloride, passed through the most patent naris, and advanced through the UES into the cervical esophagus. Comprehensive esophagoscopy is performed to exclude comorbid disease. A flexible guidewire (Hydra Jagwire Guidewire; Boston Scientific, Natick, Massachusetts) is then passed through the working channel of the esophagoscope and advanced into the distal esophagus or stomach. If the UES stenosis is too tight to allow passage of the esophagoscope, the guidewire is placed without esophagoscopy. The endoscope is then removed, and the guidewire is left in place. The esophagoscope is placed through the same nasal cavity “sidecar” to the guidewire and advanced into the hypopharynx. A second guidewire is then placed through the UES into the esophagus, and the endoscope is then removed and replaced through the same naris “sidecar” to both guidewires.
Fig 2. Casting of upper aerodigestive tract in cadaveric sheep. Point a represents narrowest region through upper esophageal sphincter and resembles cross-sectional area of kidney. Point b represents cross-sectional area of cervical esophagus 2 cm below point a and resembles cross-sectional area of circle.

Third, a multidiameter hydrostatic wire-guided controlled radial expansion balloon (Boston Scientific) is advanced over one guidewire under endoscopic visualization, and another dilator is advanced over the second guidewire. The specific dilator size is based on individual patient size, UES configuration, preoperative fluoroscopic swallow results, airway patency, ease of passage of the esophagoscope through the UES, and severity of the stenosis.

Finally, both balloon dilators are sequentially inflated to a desired diameter based on manufacturer specifications for insufflation pressure, kept inflated for 90 seconds, and then deflated. One balloon is inflated initially, and the size of the second balloon is based on the amount of residual UES that remains for expansion. After double-balloon inflation, the area is inspected and a decision is made as to whether an additional dilation with larger dilators is indicated. If blood is visualized on a deflated balloon, the procedure is terminated.

Charts of all patients who underwent dilation of the UES with simultaneous use of two radial expansion balloon dilators between December 1, 2011, and March 15, 2012, were identified and retrospectively reviewed from a clinical electronic database. The database is approved for scientific use by the Institutional Review Board of the University of California, Davis. Information regarding patient demographics, clinical indications, safety, and efficacy was abstracted and coded into SPSS 17 for Macintosh (SPSS Inc, Chicago, Illinois). Swallowing improvement was determined by a change in findings on the validated 10-item Eating Assessment Tool (EAT-10). A repeated-measures analysis of variance was utilized to assess a significant change between the predilation and postdilation EAT-10 scores. A probability of type I error (α) of 0.05 was used to ascertain clinical significance.

RESULTS

Ten patients were identified as meeting the inclusion criteria for this retrospective review. The mean age of the cohort was 65 years (SD, 14 years), and 7 of the patients were male. The indication for dilation was radiation-induced UES stenosis (50%), cricopharyngeus muscle dysfunction (30%), upper esophageal web (10%), or anastomotic stricture (10%).

No complications from simultaneous dilation were reported in this cohort. The use of dilators ranged from simultaneous use of two 8-mm balloons to simultaneous use of two 18-mm balloons; the median was use of two 15-mm balloons. Four patients had dilation performed with more than 1 pair of dilators. The mean follow-up time was 3.7 months (range, 2 to 6 months). The Table displays the patient diagnoses, dilator sizes, and follow-up times for the entire cohort. The mean EAT-10 score improved from 34.3 (SD, 13.5) to 16.7 (SD, 8.4), indicating a significant improvement in self-reported swallowing impairment (p = 0.003).

DISCUSSION

Recent evidence suggests that the UES is not
round. Canonical variance analysis of a cast of the UES in an animal model of oropharyngeal dysphagia supported the notion that the UES and cervical esophagus can be statistically allocated into distinct groups based on shape variance. Area-under-the-curve analysis of the same cast demonstrated that an inscribed circular model is not an ideal estimation of the surface area of the maximally distended UES, and a generalized Procrustes superimposition suggested that the consensus shape of the narrowest UES region across 10 animals approximated a kidney shape. High-frequency ultrasound mini-probes and concurrent fluoroscopy and manometry were used to simultaneously record UES luminal pressure and muscle images. The investigators reported that the UES transformed from a flat region in the distal hypopharynx to a C-shaped configuration at the level of the cricopharyngeus muscle to an oval configuration in the proximal esophagus. This is consistent with the shape transformation of the UES we found in our casting studies (Fig 2).

Contemporary dilators used to treat UES dysfunction were designed for the cylindrical shape and circular diameter of the esophagus, and not for the specific shape of the UES. The casting data suggest that the kidney shape of the UES can accommodate simultaneous use of two cylindrical dilators (Fig 3). Dilation of the UES with one cylindrical device pushes the dilator to one side, effectively treating only half of the sphincter (Fig 1). Although no data are available comparing it to traditional single-balloon dilation, our initial clinical experience suggests that dilation with two balloons results in a more effective dilation than does dilation with one balloon and is safely tolerated in individuals with UES dysfunction. Improving the diameter of the esophageal inlet by even a couple of millimeters may make a substantial difference to a patient with a complicated swallowing disorder. The largest dilator currently available for stricture dilation is 20 mm (60F). The simultaneous double-balloon technique used in this study challenges the contemporary model of UES dilation and essentially doubles the effective surface area of the UES that is distended. It is possible to perform dilation of the UES through the mouth with two fixed-diameter cylindrical bougies. Performing the procedure through the nose with two controlled radial expansion balloons, however, allows the region of the UES to be observed as the dilation progresses in real time. This method affords a more precise evaluation of UES expansion and allows the clinician to choose an appropriate second dilator based on the amount of UES that remains undistended with use of a single balloon (Fig 1).

Whenever a novel surgical technique is introduced, evaluating the safety and feasibility of the procedure is of principal importance. There were no adverse outcomes in this case series. The limited sample size of this cohort, however, precludes the definitive confirmation of the safety of this technique. The most serious complication of aerodigestive tract dilation is perforation. The dilations in this cohort were performed by a clinician who was experienced in treating UES dysfunction. The size of the dilators chosen was based on the results of preoperative videofluoroscopy and endoscopy. Similar results may not be obtained by clinicians with limited experience, or by those who do not have access to sophisticated fluoroscopic assessment. The clinician must balance the need for enhanced luminal enlargement and clinical improvement with the dangers of luminal rupture. Although the patients in this investigation reported significant improvement in swallowing impairment as measured by the EAT-10, a direct comparison with single-dilator therapy utilizing objective fluoroscopic measurements of swallowing improvement was not performed, and no conclusions can be drawn regarding the additional benefits of simultaneous double-balloon dilation over conventional single-dilator therapy. Until the safety and benefits of double-balloon dilation are confirmed or refuted, the potential for theoretical

<table>
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<th>Pt No.</th>
<th>Diagnosis</th>
<th>Initial Set of Dilators Used</th>
<th>Second Set of Dilators Used</th>
<th>Follow-Up (mo)</th>
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<tr>
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<td>Anastomotic stricture</td>
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improvement with this technique must be weighed against the potential increase in perforation risk. To this end, future research is needed to confirm the long-term safety and efficacy of this technique over conventional dilation.

CONCLUSIONS
Recent evidence suggests that the cross-sectional area of the UES is not round, but kidney-shaped. This is the first study of UES dilation to utilize a novel, physiology-based approach with simultaneous use of two cylindrical dilators. The results of this investigation support the initial safety, efficacy, and feasibility of UES dilation with simultaneous use of two controlled radial expansion balloon dilators.

REFERENCES