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Safety of a Novel Upper Esophageal Sphincter Balloon Dilator

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Objective: The shape of esophageal dilators has not changed in over 350 years. Clinical and animal research suggests that the upper esophageal sphincter (UES) is not round but approximates a kidney shape and that cylindrical dilators may be suboptimal. The Infinity UES Dilation System has been developed specifically for the anatomic configuration of the UES. This study evaluates the safety of the UES-specific Infinity Dilation System.

Methods: All patients undergoing dilation of the UES between January 1, 2022 and September 1, 2023 were included. Demographics, procedure indication, dilator type, minor adverse events, and major complications were abstracted. Minor adverse events, complications, and maximum dilation dimension (mm) were compared between groups.

Results: A total of 477 patients were included. Eight hundred and seventy-three total UES dilations were performed. The primary indications for UES dilation were cricopharyngeus muscle dysfunction (43%) and stenosis from radiation toxicity (40%). Twenty-three percent (202/873) of dilations were performed with an Infinity balloon, 31% (270/873) were performed using two conventional balloons placed side by side, and 46% (401/873) were performed with one singleton conventional balloon. The average maximum dilation dimension was 33 (±4.7) mm for Infinity balloons, 32 (±3.8) mm for two side-by-side balloons, and 18 (±3.4) mm for singleton balloons. There were three major complications with conventional balloons and none with Infinity balloons. There were no significant differences in minor adverse events between groups.

Conclusions: A UES-specific esophageal dilator provides a greater maximum dilation dimension and appears to be at least as safe as dilation with a single cylindrical balloon designed to dilate the esophagus.

Key Words: dilation, pharyngoesophageal dysphagia, pharyngoesophageal segment, upper esophageal sphincter.

Level of Evidence: 3

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INTRODUCTION

Swallowing impairment may be debilitating, resulting in chronic discomfort, weight loss, malnutrition, dehydration, social isolation, aspiration pneumonia, and death.[1,2] In a national cohort of inpatients, a dysphagia diagnosis resulted in a 13-fold increase in mortality.[3] The prevalence of dysphagia in the elderly population may be as high as 20% and up to 40% of patients who are treated for head and neck cancer develop silent aspiration and upper esophageal sphincter (UES) stenosis.[4,5]

Dilation of the esophagus and UES is one of the most commonly performed procedures to treat dysphagia. Indications for esophageal dilation include esophageal webs, rings, and stricture.[5,6] In 1674, Sir Thomas Willis described the first esophageal dilator developed from a carved whalebone to treat a patient with achalasia.[7,8] Napoleon's surgeon, Dr. Alexis Boyer, performed the first esophageal bouginage in the 1880s.[9] Despite the storied history and pervasiveness of esophageal dilation, the cylindrical shape of esophageal dilators has not changed since the use of a whalebone over 350 years ago.

Dilators were initially developed to distend the round lumen of the esophageal body. The UES, however, is dissimilar to the shape of the esophagus.[10] The pyriform sinuses are bound medially by the aryepiglottic folds, laterally by the thyroid cartilage, and posteriorly by the posterior hypopharyngeal wall. The inferior pharyngeal constrictor makes up the muscular component of the fossae and is divided into thyropharyngeus and cricopharyngeus components. The thyropharyngeus arises from the oblique line of the thyroid ala and the tendinous arch of the cricothyroid muscle. The muscular fibers course posteriorly, insert into the midline raphe, and then transition inferiorly to the cricopharyngeus component. The cricopharyngeus muscle spans the posterior arch of the cricoid cartilage and does not have a midline

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raphe. Its muscle fibers make up only the distal third of the UES and are contiguous with the circular muscle of the esophagus caudally. The elastic recoil of the thyroid and cricoid cartilages against the cervical spine at rest precludes direct visualization of UES opening. The UES opens as little as necessary to accommodate a passing bolus. Visualization of the open UES requires anterior distraction of the laryngeal cartilages off the spine, such as with a rigid laryngoscope or balloon dilator (Fig. 1).

We have been dilating the UES with radial expansion balloon dilators passed through the nose for over 15 years.[11] UES dilation using this technique affords a view that is not attainable with traditional peroral endoscopic dilation (Fig. 1). In our experience with the transnasal view, it became readily apparent that the shape of the UES is not cylindrical and that cylindrical esophageal dilators were insufficient to maximally expand this anatomic region (Fig. 1).

Subsequent casting of the UES in an ovine model and in human cadavers later confirmed that the narrowest dimension through the UES approximates a kidney shape and is geometrically dissimilar to the round esophageal body.[12,13] We sought to develop a device shaped specifically for the anatomical configuration of the UES. This device has the cross-sectional shape of the Infinity symbol and has since been named the Infinity Dilation System (Hope Medical, Cincinnati, OH). It is a three-stage UES dilation system that comes in small (23 mm maximum dimension, Infinity 1000 "Farwell" device), medium (32 mm, Infinity 3000 "Merati" device), and large (38 mm, Infinity 5000 "Postma" device) sizes. Our series of three approach has been described previously and is modeled after the technique recommended for esophageal achalasia that is utilized to minimize perforation risk.[14,15] The purpose of this investigation was to evaluate the safety of the Infinity Dilation System and compare it to UES dilation with cylindrical dilators that were designed to distend the esophageal body.

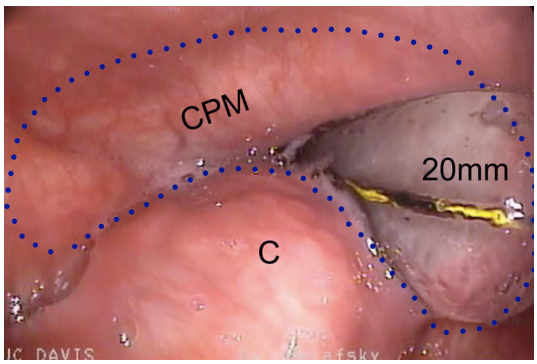

Fig. 1. Transnasal video-endoscopic image of the hypopharynx during UES dilation with a 20 mm Cook radial expansion balloon (20 mm). The posterior arch of the cricoid (C), cricopharyngeus muscle (CPM), and kidney-shaped configuration of the UES (blue dotted line) is easily visible. This dilator only partially distends the left pharyngoesophageal segment.

METHODS

This was a retrospective cohort approved by the UC Davis Institutional Review Board (Study number 2092222-1). Procedure dates with associated medical record numbers were assembled by searching the clinical repository using Current Procedural Terminology (CPT) codes for esophageal dilation between January 1, 2022 and September 1, 2023. All patients undergoing UES dilation at an outpatient endoscopy suite were included. Exclusion criteria included patients with a history of esophagectomy and laryngectomy, procedures performed transorally, terminated procedures, and esophageal dilations performed in locations outside the UES (esophageal body or gastroesophageal junction). Charts were abstracted for patient demographics, relevant diagnoses, procedural details, minor adverse events (MAEs), and major complications.

Our technique of transnasal balloon dilation of the UES is as follows. Procedures are performed in an outpatient endoscopy suite under moderate sedation.[11] Moderate sedation is achieved with a combination of fentanyl and midazolam. The patient is placed in a 30-degree reclined position on a stretcher. The nose is topically anesthetized and decongested. Comprehensive diagnostic esophagoscopy is performed through the more patent nare with a Pentax EE-1580 K 60 cm (5.1 mm OD) video esophagoscope (Pentax Medical, Montvale, NJ). Esophageal dilation is performed using Seldinger technique. A guidewire is placed through the endoscope into the stomach, and the endoscope is withdrawn. The endoscope is then replaced through the contralateral nare and positioned "side-car" with a view of the larynx and hypopharynx. The balloon is then passed over the guidewire and positioned to span the UES (Fig. 2). Slowly withdrawing the guidewire 5–6 cm during balloon advancement assists with the ease of device progression through the pharynx and keeps the guidewire from curling. UES dilation is performed under endoscopic visualization with slow 0.5 mm increments on the manometric saline insufflator. If the balloon migrates proximally, the device is completely deflated and repositioned back within the UES. Proximal migration indicates that maximum UES distension has been achieved. Patience during dilation gives the device time to safely expand adherent or fibrotic tissue. Maximum inflation pressure is achieved when the balloon consistently migrates proximally (requiring deflation and repositioning), or any blood is visualized on the balloon or in the hypopharynx. The balloon is kept at maximum inflation pressure for 60 s (Fig. 3). All procedures were performed under the direct supervision of attending physicians.

The Infinity Dilation System became commercially available in the Spring of 2023 (Hope Medical, Cincinnati, OH). Since this time, the majority of UES dilations at our institution were performed with the Infinity System. Conventional UES dilation with one balloon was performed with a Cook Hercules dilator (Cook Medical, Bloomington, IN). If a double balloon technique was used, two guidewires were passed simultaneously through the port on the endoscope and each Cook balloon was inflated independently under endoscopic visualization.[15] The two balloon side-by-side technique was performed against manufacturer recommendation. Patients with severe UES obstruction typically get scheduled for a "series of 3" dilations separated by 3–4 weeks between procedures. We begin with a 23 or 32 mm and then use larger devices over ensuing procedures. If patients have mild cricopharyngeal (CP) dysfunction, the initial dilation may be performed with the 32 mm balloon.

Charts were abstracted for minor adverse events (MAEs) and major complications. All patients were contacted by telephone on the first postoperative day by a registered nurse. Adverse events or complications that were attributed to other procedures performed at the time of dilation were not counted as an adverse event (e.g., a report of dysphonia that occurred

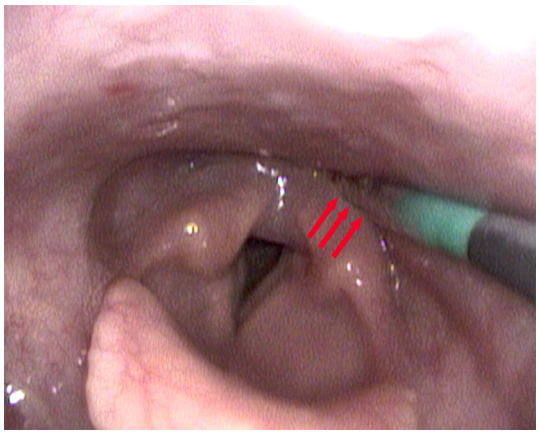

Fig. 2. Transnasal video-endoscopic image of the hypopharynx showing the Infinity 3000 (32 mm Merati) balloon correctly positioned in the UES (red arrows). The 5.1 mm Pentax EE-1580 K transnasal esophagoscope is positioned "side-car" to the balloon and indwelling guide wire.

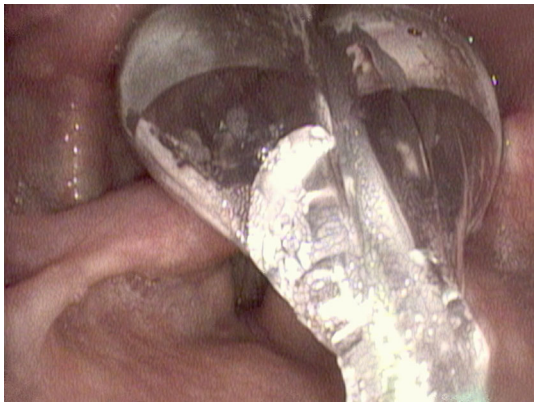

Fig. 3. Transnasal video-endoscopic image of the hypopharynx during UES dilation with an Infinity 5000 (38 mm Postma) balloon. The entirety of the pharyngoesophageal segment is distended.

following a dilation combined with vocal fold injection medialization). Major complications were considered as any sequelae requiring additional evaluation, hospital admission, intervention, or change in feeding status. Technical failures or concerns related to balloon use or malfunction were also noted. Data analysis was performed using descriptive statistics. ANOVA with pairwise comparisons was utilized to evaluate group differences between continuous data, and a Fisher's exact test was utilized to evaluate group differences between categorical data. A probability of Type I error of 0.05 was utilized to ascertain statistical significance.

RESULTS

A total of 1059 procedures were identified based on search criteria. One hundred and eighty-six procedures were excluded secondary to cases being miscoded (n = 103), esophagectomy (n = 25), esophageal body or lower esophageal sphincter (LES) dilation performed without UES dilation (n = 23), dilation performed transorally (n = 20), or UES dilation that was canceled (n = 11; e.g., a tumor was unexpectedly discovered). A total of 873 dilations in 477 patients were ultimately included in the final analysis. The mean age was 66.3 (± 12.2) years. Fifty-one percent of patients were female. The indications for UES dilation were CP muscle dysfunction (CPMD) (289/477, 61%), UES stenosis secondary to head and neck radiation toxicity (122/477, 26%), post-laryngectomy stricture (23/477, 5%), and Zenker's diverticulum (16/477, 3%). One percent (6/477) of dilations were performed empirically without clear UES pathology (Table I). CPMD included CP webs, idiopathic CP bars, and intrinsic CPMD secondary to vagal paralysis or neuromuscular disease (e.g., inclusion body myositis and oculopharyngeal muscular dystrophy). The post-laryngectomy neopharynx is cylindrical in approximate shape, and only singleton conventional dilators were used to distend laryngectomy anastomotic strictures. Infinity devices should not be used for post-laryngectomy strictures.

Thirty percent (262/873) of cases had concurrent procedures at the time of UES dilation. Examples included but were not limited to injection pharyngoplasty, vocal fold injection, impedance planimetry, wireless pH capsule placement, bronchoscopy, esophageal body or distal esophagogastric junction dilation, and/or botulinum toxin injection.

Of the 873 total dilations performed, 23% (202/873) were performed using the Infinity Dilation System, 46% with a singleton conventional balloon (401/873), and 31% (270/873) with double conventional balloons. The balloon type used by primary diagnosis is detailed in Table II. During the study period, patients underwent a median 1.0 (range 1–16) dilations. Two hundred and two Infinity dilations were performed among 141 unique patients. The Infinity 1000 (23 mm) was used as the first dilator in 29% (25/87) of cases, while the Infinity 3000 (32 mm) was used first in 66% (57/87) of cases. The Infinity 5000 (38 mm) balloon was not used as the initial device in any cases. The average maximum dimension dilated was 33 (±4.7) mm with the Infinity device, 32 (±3.8) mm with two conventional balloons, and 18 (±3.4) mm with one conventional balloon ($p < 0.0001$ Infinity vs. single, $p > 0.05$ Infinity vs. double; Fig. 4).

MAEs occurred in 6.8% of all dilations. The incidence of MAEs was similar between types of balloons, with rates of 8.9% with Infinity, 7.4% with two balloons, and 5.2% with a singleton balloon ($p > 0.05$; Table III). MAEs included new or worsening throat pain (2.86%, 25/873), dysphagia (1.83%, 16/873), reflux or regurgitation (0.92%, 8/873), abnormal throat sensations or globus (0.69%, 6/873), nausea or vomiting (0.57%, 5/873), nasal congestion (0.46%, 4/873), fever (0.34%, 3/873), epistaxis (0.23%, 2/873), dysphonia (0.23%, 2/873), cough, (0.23%, 2/873), dyspnea (0.11%, 1/873), and neck stiffness (0.11%, 1/873). MAEs were similar across balloon methods (Table S1). The prevalence of MAEs in head and neck cancer (HNC) survivors with intact larynges was similar to patients undergoing UES dilation for other indications (6.3% vs. 7.1%, $p > 0.05$).

No major complications occurred in patients dilated with Infinity balloons. The three major complications are detailed in Table IV. They included two esophageal perforations, one with a single 15 mm Cook device and one with two 18 mm Cook devices (36 mm), and a death after dilation with a 20 mm Cook device. The overall perforation rate was 0.22% (2/873). It was 0% (0/202) with Infinity balloons, 0.25% (1/401) with one Cook balloon, and 0.37% (1/270) with two Cook balloons. The overall major complication rate among procedures performed in HNC survivors with intact larynges was 0% (0/351) versus 0.57% (3/522) among other patients without a cancer history ($p > 0.05$).

Table I.
Demographics of the 477 patients who underwent pharyngoesophageal segment balloon dilation.

	Mean	(SD)
Age	66.3	±12.2
	N	(%)
Gender		
Female	244	(51%)
Male	233	(49%)
Race/ethnicity		
White	271	(57%)
Hispanic or Latino	80	(17%)
Other/Unknown	78	(16%)
African American or Black	26	(5%)
Asian	20	(4%)
American Indian or Alaska Native	1	(<1%)
Native Hawaiian or Pacific Islander	1	(<1%)
Primary upper esophageal pathology		
Cricopharyngeal muscle dysfunction	289	(61%)
Radiation toxicity following head and neck cancer	122	(26%)
Total laryngectomy	23	(5%)
Pharyngoesophageal stenosis	21	(4%)
Zenker's diverticulum	16	(3%)
Empiric/unknown	6	(1%)

There were two intraoperative equipment failures using singleton Cook balloons. Both involved balloon rupture when the UES was dilated to 20 mm to treat CPMD. Patients suffered no harm from these events.

All procedures were performed under the supervision of attending laryngologists at this institution. There was some variation in the balloon dilation method by attending preference, but no significant difference in complication or MAE rate (Table S2).

DISCUSSION

Dilation of the UES over a guidewire with a radial expansion balloon under moderate sedation and transnasal endoscopic visualization is safe. Traditional UES dilation uses dilators developed for the anatomy of the cylindrical esophagus with a maximum 20 mm diameter. The Infinity Dilation System is a novel device developed to dilate the unique anatomy of the UES. This study highlights the safety of UES dilation using the technique described herein and demonstrates an equivalent safety profile using Infinity balloons.

Endoscopic esophageal dilation is an extremely common procedure, which may be performed using a variety of devices and techniques. It may be performed via bouginage,[16] or using rigid or pneumatic dilators. It may be performed via transnasal or transoral routes, under direct visualization, fluoroscopic guidance, or blind. It may be performed awake, under sedation, or general anesthesia. Maloney dilators have a tapered, weighted end and are passed blindly through the mouth. Savary dilators are similar but are passed over a guidewire placed at the time of per oral endoscopy.[17] Catheter- or wire-based balloon dilation is rapidly becoming the most common form of dilation, yet no systematic review specifically focuses on safety.[18] Large-scale trials comparing the efficacy and safety of different dilation methods are lacking.[18,19] Further, most studies do not distinguish between UES and esophageal body or gastroesophageal junction dilation. This study highlights the safety of performing staged dilation of the UES to nearly twice the maximum dimension previously reported with singleton balloons. There is observational evidence supporting the use of large diameter dilation of the UES.[15,20] Further

Table II.
Number of dilations by method and primary diagnosis.

	Total	Infinity	One	Two	*p*
N, % of total	873	202 (23%)	401 (46%)	270 (31%)	
Diagnosis					<.01
CPMD	379 (43%)	92 (46%)	199 (50%)	88 (33%)	
Rad Tox	351 (40%)	99 (49%)	86 (21%)	166 (61%)	
TL	85 (10%)	0 (0%)	85 (21%)	0 (0%)	
ZD	27 (3%)	7 (3%)	9 (2%)	11 (4%)	
PES stenosis	25 (3%)	3 (1%)	17 (4%)	5 (2%)	
Empiric	6 (1%)	1 (0%)	5 (1%)	0 (0%)	

CPMD = cricopharyngeal muscle dysfunction; Rad Tox = radiation toxicity following head and neck cancer treatment; TL = total laryngectomy; ZD = Zenker's diverticulum.

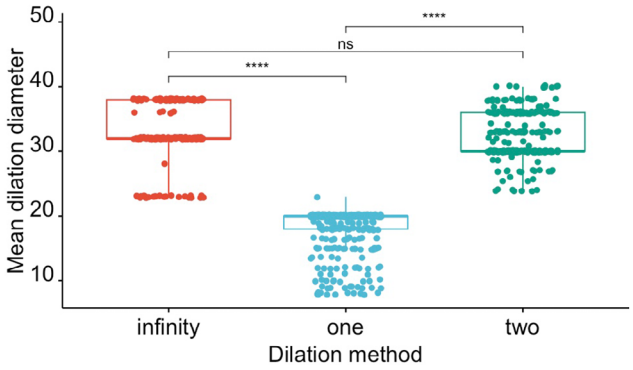

Fig. 4. Average maximum dilation diameter by balloon type. Comparisons represent ANOVA with pairwise comparisons. ****p value <0.001; ns, non-significant.

study is needed on the theorized superiority of greater dilation diameters and improved functional and fluoroscopic outcomes.

Major complications of esophageal dilation are rare and include perforation, hemorrhage, aspiration, and even death. No significant hemorrhages were reported in this study other than self-limited epistaxis. Our recommendation is to withhold blood thinners prior to dilation, although we have periodically performed UES dilation in persons who forgot or could not stop these medications. Our overall mortality for the entire cohort of 0.11% ($n = 1$, single Cook balloon) is similar to a 0.01% mortality observed in an insurance claims database study.[21] A systematic review of treatment for CPMD quotes a complication rate between 0% and 20% for different forms of UES dilation.[22]

TABLE III.
Rates of complications and adverse events by primary UES diagnosis and balloon dilation method

					p-Value	
	Total ($N = 873$)	Infinity ($N = 202$)	One ($N = 401$)	Two ($N = 270$)	Infinity versus One	Infinity versus Two
Complications, *n* (%)						
Total	3 (0.34%)	0%	2 (0.50%)	1 (0.37%)	0.55	1.00
By diagnosis					<.001	0.03
CPMD	2 (0.23%)	-	1 (0.25%)	1 (0.37%)		
Rad Tox	-	-	-	-		
TL	1 (0.11%)	-	1 (0.25%)	-		
ZD	1 (0.11%)	-	-	-		
UES stenosis	-	-	-	-		
Empiric	-	-	-	-		
Minor adverse events, *n* (%)						
Total	59 (6.76%)	17 (8.91%)	21 (5.24%)	20 (7.41%)	0.11	0.61
By diagnosis					<.001	0.05
CPMD	34 (3.89%)	13 (6.44%)	14 (3.49%)	7 (2.59%)		
Rad Tox	22 (2.52%)	5 (2.48%)	5 (1.25%)	12 (4.44%)		
TL	1 (0.11%)	-	1 (0.25%)	-		
ZD	1 (0.11%)	-	-	1 (0.37%)		
UES stenosis	1 (0.11%)	-	1 (0.25%)	-		
Empiric	-	-	-	-		

CPMD = cricopharyngeal muscle dysfunction; Rad Tox = radiation toxicity following head and neck cancer treatment; TL = total laryngectomy; ZD = Zenker's diverticulum.

Table IV.
Complications following transnasal upper esophageal balloon dilation.

Complication	Age	Diagnosis	Balloon Dilation Method	Management/Notes
Perforation (presumed)	69	TL	Single conventional (15 mm)	Presented to ED ~3 weeks post-up with neck fluid collection and no clear perforation on esophagram. Attempted needle aspiration ×2. Ultimately admitted for 3 days and treated with antibiotics.
Perforation	75	CPMD	Double (36 mm)	Admitted POD1 for approximately 2 weeks. Treated with IV antibiotics and NG feeds.
Death	84	CPMD	Single conventional (20 mm)	Found down within 24 h. Asystole on ED admission and cause of death unknown.

CPMD = cricopharyngeal muscle dysfunction; ED = emergency department; NG = nasogastric tube; TL = total laryngectomy; ZD = Zenker's diverticulum.

We report a low overall perforation rate of 0.22% among 873 cases (2 dilations with single and double Cook balloons). This number approximates several other studies. A national database of 169,618 inpatient procedures reported a 0.5% perforation rate.[23] A national insurance database of 202,965 procedures reported perforation rates among patients with and without comorbid malignancy of 0.92% and 0.08%, respectively.[21] Dilation using bougienage may be associated with a higher perforation rate as it is performed blind and distributes shear instead of radial forces.[24,25] A study comparing Maloney to Savary dilators among 348 procedures reported 4 perforations in the Maloney group and none in the Savary group.[24] Another study of 154 dilations reported a 3.3% perforation rate using bouginage.[16] A systematic review of five heterogenous studies including 461 patients, however, found no significant difference in perforation rates between bougie and balloon dilation.[19] The 0% perforation rate of UES dilation with Infinity balloons even up to dimensions of 38 mm appears to be significantly better than the perforation rate of 3.3% reported with bouginage. Prospective, randomized investigation is necessary to confirm these observations.

Dysphagia related to fibrosis, webs, and stenosis of the UES is extremely common among HNC survivors treated with radiation. A total of 13%–14% of HNC survivors treated with radiotherapy undergo esophageal dilation.[26] In one systematic review, the complication rate was 10.6% and the perforation rate was 7.4%.[27] The major complication and perforation rate (0%) in our cohort of cancer survivors ($n = 351$) dilated with the Infinity System appears to be significantly lower than that reported using other devices and techniques. This may be due to a variety of factors. Many of the previous studies on dilation safety in HNC survivors were performed blindly under general anesthesia and used bougies,[28–31] or a mixture of balloons and bougies,[1,5] which could be problematic for the shear forces previously discussed. Several studies included the management of complete stenosis with a combined antegrade–retrograde technique.[1,5,32] We only examined procedures performed in our outpatient suite utilizing moderate sedation. Management of complete stenoses is associated with higher perforation risk and typically treated under general anesthesia.[28,33] Further investigation with randomization and direct comparison is necessary to confirm that transnasal UES dilation with the Infinity System under moderate sedation is safer than dilation performed on HNC survivors using other dilators and techniques.

This study describes MAEs less typically highlighted in studies examining esophageal dilation. They are not life-threatening but are important to report for patient counseling, expectations, and satisfaction. MAEs were not significantly different among balloon dilation types, and the data suggest that UES dilation with the Infinity System is at least as safe as dilation with conventional esophageal dilators ($p > 0.05$; Tables III and S1). The overall incidence of MAEs of 6.8% in our investigation is similar to the 8.5% minor event rate reported by Clary et al. using bougienage under general anesthesia.[6] Further studies are needed to compare outcomes and patient experience using differing devices and techniques for UES dilation.

This study is limited by its retrospective design. Examining medical records is prone to imperfection and under-detection of MAEs and complications. It is our center's practice to perform postoperative follow-up phone calls on every patient undergoing dilation. Thus, we feel that the postoperative assessment of immediate MAEs and major complications is relatively accurate. This process, however, may have underreported delayed MAEs and complications. In addition, dilations were performed by fellowship trained laryngologists with at least 5 years of experience at a high-volume center. These results may be less generalizable to clinicians with less experience. Further investigation is required to establish the safety of the Infinity System in a variety of centers and contexts. This study did not assess improved efficacy and there is an ongoing prospective clinical trial currently underway addressing this.

CONCLUSIONS

The shape of esophageal dilators has not changed in over 350 years. This is the first investigation to report the safety of a dilator designed specifically for the anatomic configuration of the UES. The data suggest that dilation of the UES with the Infinity Dilation System provides greater maximum dilation dimension and appears to be at least as safe as UES dilation with a single cylindrical balloon originally designed to dilate the esophageal body.

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