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Editorial Board Member of *World Journal of Gastrointestinal Endoscopy*, Andreas Sieg, MD, PhD, Assistant Professor, Department of Gastroenterology, Practice of Gastroenterology, 69115 Heidelberg, Germany

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 Xiu-Xia Song, Director  
*World Journal of Gastrointestinal Endoscopy*  
 Baishideng Publishing Group Inc  
 8226 Regency Drive, Pleasanton, CA 94588, USA  
 Telephone: +1-925-2238242  
 Fax: +1-925-2238243  
 E-mail: [editorialoffice@wjgnet.com](mailto:editorialoffice@wjgnet.com)  
 Help Desk: <http://www.f6publishing.com/helpdesk>  
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 E-mail: [bpgoffice@wjgnet.com](mailto:bpgoffice@wjgnet.com)  
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## Retrospective Study

**Endoscopic balloon catheter dilatation *via* retrograde or static technique is safe and effective for cricopharyngeal dysfunction**

Vinay Chandrasekhara, Joyce Koh, Lakshmi Lattimer, Kerry B Dunbar, William J Ravich, John O Clarke

Vinay Chandrasekhara, Joyce Koh, Lakshmi Lattimer, Kerry B Dunbar, William J Ravich, John O Clarke, Division of Gastroenterology and Hepatology, Department of Internal Medicine, the Johns Hopkins Medical Institutions, Baltimore, MD 21287, United States

Vinay Chandrasekhara, Gastroenterology Division, Department of Internal Medicine, University of Pennsylvania Health System, Philadelphia, PA 19104, United States

Vinay Chandrasekhara, Perelman Center for Advanced Medicine South Pavilion, Philadelphia, PA 19104, United States

Lakshmi Lattimer, Gastroenterology and Liver Diseases, Department of Internal Medicine, the George Washington University, Washington, DC 20037, United States

Kerry B Dunbar, Division of Gastroenterology and Hepatology, Department of Medicine, University of Texas Southwestern Medical School, Dallas VA Medical Center, Texas, TX 75216, United States

**Author contributions:** Chandrasekhara V and Clarke JO contributed to the study design, data analysis, manuscript preparation and revision; Koh J, Lattimer L and Dunbar KB contributed to data analysis, manuscript preparation and revision; Ravich WJ contributed to manuscript preparation and revision.

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**Correspondence to:** Vinay Chandrasekhara, MD, Perelman Center for Advanced Medicine South Pavilion, 3400 Civic Center Blvd, 4 South, Gastroenterology, Philadelphia, PA 19104, United States. [chandrav@uphs.upenn.edu](mailto:chandrav@uphs.upenn.edu)  
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**Fax:** +1-215-3495915

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**Abstract****AIM**

To evaluate the safety and efficacy of upper esophageal sphincter (UES) dilatation for cricopharyngeal (CP) dysfunction. To determine if: (1) indication for dilatation; or (2) technique of dilatation correlated with symptom improvement.

**METHODS**

All balloon dilatations performed at our institution from over a 3-year period were retrospectively analyzed for demographics, indication and dilatation site. All dilatations involving the UES underwent further review to determine efficacy, complications, and factors that predict success. Dilatation technique was separated

into static (stationary balloon distention) and retrograde (brusque pull-back of a fully distended balloon across the UES).

### RESULTS

Four hundred and eighty-eight dilatations were reviewed. Thirty-one patients were identified who underwent UES dilatation. Median age was 63 years (range 27-81) and 55% of patients were male. Indications included dysphagia (28 patients), globus sensation with evidence of UES dysfunction (2 patients) and obstruction to echocardiography probe with cricopharyngeal (CP) bar (1 patient). There was evidence of concurrent oropharyngeal dysfunction in 16 patients (52%) and a small Zenker's diverticula ( $\leq 2$  cm) in 7 patients (23%). Dilator size ranged from 15 mm to 20 mm. Of the 31 patients, 11 had dilatation of other esophageal segments concurrently with UES dilatation and 20 had UES dilatation alone. Follow-up was available for 24 patients for a median of 2.5 mo (interquartile range 1-10 mo), of whom 19 reported symptomatic improvement (79%). For patients undergoing UES dilatation alone, follow-up was available for 15 patients, 12 of whom reported improvement (80%). Nineteen patients underwent retrograde dilatation (84% response) while 5 patients had static dilatation (60% response); however, there was no significant difference in symptom improvement between the techniques ( $P = 0.5$ ). Successful symptom resolution was also not significantly affected by dilator size, oropharyngeal dysfunction, Zenker's diverticulum, age or gender ( $P > 0.05$ ). The only complication noted was uvular edema and a shallow ulcer after static dilatation in one patient, which resolved spontaneously and did not require hospital admission.

### CONCLUSION

UES dilatation with a through-the-scope balloon by either static or retrograde technique is safe and effective for the treatment of dysphagia due to CP dysfunction. To our knowledge, this is the first study evaluating retrograde balloon dilatation of the UES.

**Key words:** Cricopharyngeal dysfunction; Cricopharyngeal bar; Dysphagia; Esophageal dilatation; Endoscopic balloon dilation

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**Core tip:** Cricopharyngeal dysphagia can be treated with endoscopic balloon dilatation. In this series, a novel dilatation technique of pulling a fully inflated 15-20 mm balloon dilator in a retrograde manner across the upper esophageal sphincter was safe and effective for the treatment of cricopharyngeal dysphagia.

Chandrasekhara V, Koh J, Lattimer L, Dunbar KB, Ravich WJ, Clarke JO. Endoscopic balloon catheter dilatation *via* retrograde or static technique is safe and effective for cricopharyngeal dysfunction. *World J Gastrointest Endosc* 2017; 9(4): 183-188 Available from: URL: <http://www.wjgnet.com/1948-5190/full/v9/i4/183.htm> DOI: <http://dx.doi.org/10.4253/wjge.v9.i4.183>

## INTRODUCTION

The upper esophageal sphincter, comprised of the cricopharyngeus, or the cricopharyngeal (CP) muscle, inferior pharyngeal constrictor, and proximal cervical esophagus serves a pivotal role in the act of deglutition. The CP muscle normally remains in a contracted state and relaxes during swallowing prior to penetration of a food bolus into the cricopharyngeal region. Cricopharyngeal dysfunction (CPD) refers to incoordination of the cricopharyngeal muscle either due to a primary functional disorder or as a result of an underlying neurological or medical condition<sup>[1]</sup>. Symptoms of CPD can range from a globus sensation to oropharyngeal dysphagia manifested by regurgitation, coughing, choking and recurrent aspiration.

The diagnosis of CPD can be difficult to make and often requires a meticulous history and physical examination. Videofluoroscopy is often helpful for the diagnosis of CPD with the typical appearance of a shelf in the posterior column of barium at the level of the cricoid cartilage, more commonly described as a cricopharyngeal bar<sup>[2]</sup>. The incidence of CP bars is variable in the reported literature, ranging from 5% to 22% in patients who undergo videofluoroscopic swallow studies for dysphagia<sup>[2-4]</sup>. CP bars are frequently detected in asymptomatic individuals and therefore other modalities such as esophageal manometry and upper endoscopy must be performed to exclude other etiologies of dysphagia.

Endoscopic treatment for CPD has not been well studied and remains controversial. Historically, management has relied upon surgical CP myotomy<sup>[5-7]</sup>. Endoscopic dilatation poses an attractive option, given the risks associated with myotomy; however, published case series to date have included very small numbers of patients with varying dilatation techniques<sup>[8-13]</sup>. The aim of our study was to determine the efficacy and safety of through-the-scope (TTS) balloon dilatation of the upper esophageal sphincter (UES) in patients with CPD and to compare the traditional static technique of sequential distention of the balloon with a brusque "pull-back" retrograde approach across the UES.

## MATERIALS AND METHODS

The study was approved by the Johns Hopkins Medicine institutional review board. The medical records of all patients that underwent esophageal dilatation with a through-the-scope balloon dilator at the Johns Hopkins Hospital over a consecutive 3-year period were reviewed. Patients were included in the study cohort if they had CPD that was treated with TTS balloon dilatation of the UES, including those with a Zenker's diverticulum. Patients were excluded if they were under the age of 18 years old and if balloon dilatation of the UES was not performed. Patient demographics, prior radiographic data, procedural indications, test results, complications and follow-up clinical outcomes were recorded.

Data was analyzed using Stata version 9 (StataCorp,

**Table 1 Patient demographics *n* (%)**

Patients undergoing UES dilatation	<i>n</i> = 31
Age, yr, median (range)	63 (27-81)
Sex	
Male	17 (55)
Female	14 (45)
Indications	
Radiographic CP hypertrophy with dysphagia	22 (71)
Endoscopic UES tightness with dysphagia	3 (10)
Inclusion body myositis with dysphagia and prominent cricopharyngeus	3 (10)
Globus sensation with evidence of UES dysfunction	2 (6)
Obstruction to echocardiography probe with CP bar, but otherwise asymptomatic	1 (3)
Presence of oropharyngeal dysfunction	16 (52)
Presence of Zenker's diverticulum	7 (23)

UES: Upper esophageal sphincter; CP: Cricopharyngeal.

College Station, TX) on a per-patient basis. Descriptive statistics were calculated for all covariates and outcomes including *t* test,  $\chi^2$  test, and Fisher's exact test, where appropriate.

### Procedural technique

Balloon dilatation of the upper esophageal sphincter was performed using two different techniques: Static and retrograde. With the traditional "static" technique, a through-the scope balloon dilation catheter (Boston Scientific Corporation, Natick, MA) is positioned across the upper esophageal sphincter under visual guidance without the use of a guidewire or fluoroscopy. The balloon is then sequentially inflated, holding the balloon in position for 30 to 60 s with each distention to a maximum diameter of 15 mm to 20 mm at the discretion of the endoscopist.

The retrograde approach across the UES is a newly described technique for the management of CPD. The actual technique has been used for mucosal disruption and treatment of esophageal rings, but has not been described in the management of CPD<sup>[14]</sup>. In this approach, the TTS balloon is inflated to the maximal desired diameter under visual guidance in the proximal esophagus, distal to the UES. The fully distended balloon is then brought back to the tip of the endoscope. Both the endoscope and distended balloon are then withdrawn across the UES into the oropharynx as one unit, usually with moderate resistance.

In all cases, individuals were sedated for the procedure. After dilatation was performed, the UES and the surrounding structures were closely inspected for evidence of mucosal damage.

## RESULTS

Over a consecutive three-year period 488 esophageal TTS balloon dilatations were performed at our institution, of which 31 patients had dilatation of the UES for CPD. The median age at time of UES dilatation was 63 years and 55% of the patients were male (Table 1). Indications

**Table 2 Balloon dilatation procedural details *n* (%)**

	Enrolled ( <i>n</i> = 31)
Number of procedures per patient, median (range)	1 (1-3)
Type of initial dilatation	
Retrograde (brusque pull-back)	24 (77)
Static (sequential distention)	7 (23)
UES dilatation alone	20 (65)
Concurrent dilatation of the UES and other portions of the esophagus	11 (35)
Maximal diameter size, median (range)	20 mm (15-20 mm)
Total Number of complications	1 (3)
Serious complications requiring hospitalization	0

UES: Upper esophageal sphincter.

for UES dilatation are summarized in Table 1. Twenty-eight patients (90%) were experiencing dysphagia symptoms. In addition to CPD, 16 patients (52%) had evidence of concurrent oropharyngeal dysfunction and 7 patients (23%) were also found to have a Zenker's diverticulum.

Each individual underwent a median of 1 dilatation (range, 1-3), with 24 individuals (77%) receiving a retrograde approach (Table 2). The majority of individuals (26) underwent only 1 dilatation session. Four individuals underwent two dilatation sessions and one patient had three dilatation sessions. Eleven individuals had dilatation of other esophageal segments concurrently with UES dilatation and 20 patients had UES dilatation alone. Of those with multiple sites of esophageal dilatation, nine were for a Schatzki ring, one was for a peptic stricture and one was for subjective stenosis at the esophagogastric junction. The median maximal diameter for UES balloon dilatation was 20 mm, ranging from 15 to 20 mm. Three individuals were dilated with a 15 mm balloon, nine individuals were dilated with an 18 mm balloon, and nineteen individuals were dilated with a 20 mm balloon.

Follow-up was available for 24 of the 31 patients, 19 of whom underwent retrograde brusque technique. The median duration of follow-up was 2.5 mo (interquartile range: 1-10 mo), of whom 19 (79%) reported symptomatic improvement. Sixteen patients (84%) patients with the retrograde approach responded to dilatation, whereas 3 patients (60%) with the static dilatation approach responded to treatment. However, there was no statistically significant difference in symptom improvement between the two techniques ( $P = 0.5$ ). Successful symptom resolution was also not significantly affected by dilator size, presence of oropharyngeal dysfunction, presence of a Zenker's diverticulum, age or gender (Table 3). Of those patients undergoing UES dilatation alone, follow-up was available for 15 patients, 12 of whom (80%) reported symptom improvement.

One patient developed uvular edema and a shallow ulcer after static dilatation of the UES that spontaneously resolved in the recovery room and did not require hospitalization. A second patient initially underwent dilatation of the GE junction that resulted in a

**Table 3 Predictors of clinical response *n* (%)**

Characteristic	Clinical response		<i>P</i> value
	Y (19)	N (5)	
Age, mean ± SD	61.9 ± 11.9	66.4 ± 22.4	0.48
Sex, Male	10 (53)	2 (40)	0.68
Technique			
Retrograde	16	3	0.49
Static	3	2	
Maximal dilator size (mean ± SD, mm)	19.2 ± 1.4	19.6 ± 0.9	0.25
Oropharyngeal dysfunction	11 (58)	2 (40)	0.68
Zenker's diverticulum	4 (21)	2 (40)	0.45

small mucosal tear that was adequately treated with placement of a single endoclip. During the same endoscopy, subsequent to endoclip placement, the patient underwent retrograde dilatation of the UES without complication. There were no adverse events associated with the retrograde brusque technique of the UES.

## DISCUSSION

Oropharyngeal dysphagia can be associated with significant morbidity and treatments to date are imperfect and limited. Since first used for treatment of post-poliomyelitis dysphagia in 1951<sup>[15]</sup>, surgical myotomy has been the traditional approach for dysphagia related to cricopharyngeal prominence or dysfunction<sup>[16-18]</sup>. However, efficacy remains controversial and this procedure is not without risk - particularly in elderly patients in whom cricopharyngeal bars are more common<sup>[18-20]</sup>. Botulinum toxin injection has also been studied as a potential therapy and has been shown to be of benefit in several series<sup>[21-23]</sup>. Reported complications have stemmed from diffusion of Botox to adjacent muscles leading to aspiration, worsened dysphagia, vocal cord paralysis and at least one recorded death<sup>[24-26]</sup>. Moreover, the average duration of effect appears to be approximately 4 mo and waning efficacy may be observed with repeated therapy<sup>[25]</sup>.

Endoscopic dilatation of the upper esophageal sphincter poses an attractive therapeutic alternative for dysphagia related to CPD. Data, however, is limited to small case series - most of which contained less than 10 patients. The published data suggest that endoscopic dilatation may be a safe and effective option for carefully selected patients. A small series reported clinical improvement in 7 of 12 patients (58%) after dilatation with a Savary dilator (17 mm)<sup>[8]</sup>. Another limited series reported higher rates of symptomatic improvement in 9 of 10 patients (90%) with similar dilatation techniques (18-20 mm)<sup>[9]</sup>. Patel *et al*<sup>[13]</sup> recently reported a larger experience with 31 patients undergoing Savary dilatation with 45 French to 60 French size dilators. In this study, 65% of patients had significant improvement for at least 6 mo using a functional outcome swallow score.

One study of 5 patients undergoing static balloon dilatation of the UES to a maximal diameter of 20 mm achieved 100% success rate<sup>[10]</sup>. Another study reported

complete success in 6 patients undergoing dilatation of CP bars, but this study only included one patient with balloon dilatation to 20 mm and the five others underwent Savary dilatation<sup>[12]</sup>. In these series and reports, there have been no recorded major complications. There has been one report of superficial mucosal injury after dilatation that was self-limited and did not require treatment or hospitalization<sup>[10]</sup>. The recent systematic review on management of CPD reported comparable success rates of endoscopic dilatation and myotomy; however, the authors comment that there were significantly fewer studies investigating endoscopic dilatation (6 studies involving 113 patients) and therefore the data were insufficient to make a strong recommendation on the role of endoscopic dilatation for CPD<sup>[1]</sup>.

Our series represents the largest published series to date looking at endoscopic balloon dilatation of the upper esophageal sphincter for dysphagia related to CPD. When compared to reported success rates for cricopharyngeal myotomy<sup>[18,20]</sup>, the results for endoscopic dilatation appear equivalent. Moreover, the safety profile of this approach appears to be excellent. In our series, the only reported complication was uvular edema and a shallow ulcer after balloon dilatation using a static technique in 1 patient that did not require admission and spontaneously improved over time. To our knowledge, there have been no perforations reported in the literature with this approach and certainly no fatalities.

At our institution, the preference has been to utilize endoscopic balloon dilatation via either a static or retrograde technique for CPD. The idea behind the static approach is to maximize radial forces while avoiding any sheering movements, whereas the concept for the retrograde approach is to combine radial and sheering forces with directed attention to the upper esophageal sphincter. As opposed to a Savary dilatation, the retrograde balloon technique may allow a more rapid increase in diameter and, with experience, a better subjective gauge of sphincter resistance. To our knowledge, this technique has not been previously reported in the literature for the management of CPD but has been used frequently at our institution for disruption of Schatzki rings, mucosal webs and upper esophageal sphincter dysfunction. While the safety of this approach has not been directly compared to conventional static dilatation, it has been our subjective opinion that the safety of these two approaches is equivalent. The one patient who developed a shallow ulcer in our series did so in the context of a static dilatation.

Traditionally, the presence of a Zenker's diverticulum has often been felt to represent a relative contraindication to endoscopic dilatation; however, mechanistically, these diverticula often arise in the context of elevated intrabolus pressure and/or upper esophageal sphincter dysfunction and for this reason may actually portend a better prognosis<sup>[27]</sup>. Certainly in our series, response rates seemed equivalent between patients with and without a diverticulum and there did not appear to be any safety concerns. Likewise, oropharyngeal

dysfunction has been hypothesized to be a potential issue that may limit efficacy. However, this group may actually be more sensitive to minor mechanical alterations in outflow resistance and the presence of oropharyngeal dysfunction in our series did not affect or predict response.

Our study does have several limitations worth noting. To begin with, it is a retrospective evaluation and clinical response was determined subjectively through review of medical records. A prospective study with validated dysphagia questionnaires would have been ideal and this certainly is worth future consideration. Second, 11 of our patients had dilatation of other esophageal segments other than the upper esophageal sphincter and it is unclear if the symptom response was due to dilatation of the cricopharyngeus or the other segment of the esophagus. However, even without including these patients, this remains the largest published experience with endoscopic balloon dilatation for CPD. Third, the indications for dilatation in our series were heterogeneous and it is possible (and indeed likely) that certain subsets have significantly varied responses. For example, it is our subjective opinion that patients with inclusion body myositis likely have a greater response to dilatation; however, given the total number of patients in our study there is no way to statistically address that question. Finally, our median follow-up was 2.5 mo and given the underlying mechanisms of upper esophageal sphincter dysfunction a longer evaluation period would have been ideal.

In summary, UES dilatation with a TTS balloon by either static or retrograde technique is safe and effective for the treatment of dysphagia in the context of CPD dysfunction. As suggested in prior smaller series, this appears to be a safe and effective approach. Our series, however, is the first to describe retrograde balloon dilatation of the UES. Given this data is tandem with the reported complications of surgical myotomy and Botulinum toxin injection, we suggest that endoscopic dilatation of the upper esophageal sphincter should be the first therapy offered for patients with oropharyngeal dysphagia in the context of upper esophageal sphincter dysfunction. In addition, our experience would suggest that balloon dilatation *via* a retrograde technique is at least as safe and effective as conventional methods with either Savary or static balloon dilatation.

## COMMENTS

### Background

Cricopharyngeal dysfunction (CPD) is associated with a variety of symptoms including globus sensation, oropharyngeal dysphagia, regurgitation, coughing, choking and recurrent aspiration. While a variety of treatment options have been proposed, endoscopic dilatation by pulling a fully inflated 15-20 mm balloon dilator in a retrograde manner across the upper esophageal sphincter appears to be safe and effective for the treatment of cricopharyngeal dysphagia.

### Research frontiers

Optimal management of cricopharyngeal dysphagia is not clear. Endoscopic dilatation appears to be safe with immediate relief of symptoms. Several small

series have demonstrated benefit with endoscopic dilatation using a variety of techniques. Additional research into the durability of the procedure and objective parameters of relief are needed.

### Innovations and breakthroughs

This represents the largest endoscopic experience for managing CPD. In this series, a novel dilatation technique of pulling a fully inflated 15-20 mm balloon dilator in a retrograde manner across the upper esophageal sphincter was safe and effective for the treatment of cricopharyngeal dysphagia.

### Applications

The retrograde dilatation technique provides another method for effective dilatation and disruption of the upper esophageal sphincter complex to relieve symptoms associated with cricopharyngeal dysphagia. Many endoscopists are more comfortable with balloon dilatation and this technique may allow them to better treat CPD using this technique.

### Terminology

CPD - refers to incoordination of the cricopharyngeal muscle either due to a primary functional disorder or as a result of an underlying neurological or medical condition.

### Peer-review

This is a study assessing the efficacy of endoscopic balloon catheter dilatation for treatment of cricopharyngeal dysfunction. The authors retrospectively reviewed all UES dilatations performed during a three year period. Thirty-one patients were included although follow-up was only available for 24. A symptomatic improvement was confirmed for 80% of patients. The manuscript is well written and describes a large series of cases.

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