

Simultaneous double balloon dilatation using double channel therapeutic endoscope in patients with cricopharyngeal muscle dysfunction

An observative study

Yong Seob Jo, MD^a, Jung Hyun Cha, MD^a, Yong Kyun Kim, MD, PhD^a, Sun Young Kim, PhD^b, Hong Sub Lee, MD, PhD^{c,*}

Abstract

The role of endoscopic balloon dilatation (EBD) using double-balloon catheters in patients with cricopharyngeal muscle dysfunction (CPD) is still unclear. Thus, the aim of this study was to compare the functional outcomes between patients receiving EBD and rehabilitative balloon swallowing (RBS).

A total of 36 patients with CPD, who visited a teaching hospital from February 2014 to June 2017, were included in the study. Among them, 12 patients with severe dysphagia underwent EBD. After propensity score matching, 24 patients who underwent RBS were selected for comparison. We compared the effects of EBD and RBS using 4 functional swallowing parameters: functional dysphagia scale score, penetration-aspiration scale score, pharyngeal transit time, and percentage of pharyngeal remnant (PR) at baseline and after the first and second treatments. Using simple and multiple regression, we examined the associations between EBD/RBS and changes of 4 parameters after the treatments since the baseline.

All functional parameters significantly decreased after RBS and EBD ($P < .05$). After the first therapy session, significant differences in the pharyngeal transit time ($P = .034$), percentage of PR ($P = .008$), and penetration-aspiration scale score ($P = .014$) were observed in the EBD group, compared with those in the RBS group. The regression analysis showed significant improvements in the PR after EBD compared with that after RBS ($\beta = 0.95$, $SE = 0.31$, $P = .005$).

EBD may be an alternative treatment for patients with severe CPD. A significant improvement would be expected in such patients with PR.

Abbreviations: CPD = cricopharyngeal muscle dysfunction, EBD = endoscopic balloon dilatation, FDS = functional dysphagia scale, OD = oropharyngeal dysphagia, PAS = penetration-aspiration scale, PR = pharyngeal remnant, PTT = pharyngeal transit time, RBS = rehabilitative balloon swallowing, UES = upper esophageal sphincter, VFSS = video-fluoroscopic swallowing study.

Keywords: cricopharyngeal muscle, endoscopic balloon dilatation, oropharyngeal dysphagia, upper esophageal sphincter

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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1. Introduction

Dysphagia is a common serious problem in the aging population, and its treatment has been actively improving.^[1,2] Oropharyngeal dysphagia (OD) is frequently present after stroke, community-acquired pneumonia especially in the elderly, Parkinson disease, and brain injuries.^[3] The prevalence of OD in independently living older individuals was estimated to be 11.4% to 33.7%.^[4] OD is a major cause of mortality and morbidity in old individuals; it also causes serious complications, including malnutrition and aspiration pneumonia.^[5,6] Despite its high prevalence and associated morbidities, the diagnosis and treatment of OD are usually overlooked.

Failed upper esophageal sphincter (UES) relaxation is a major cause of dysphagia in up to 80% of patients with a brainstem injury.^[7] In a study that used high-resolution manometry, failed UES relaxation was reported to be a risk factor for aspiration in patients with stroke and OD.^[8]

The UES is physiologically a high-pressure band between the hypopharynx and the upper esophagus and anatomically consists of the lower pharyngeal sinus muscle, including the cricopharyngeal muscle and a part of the cervical esophagus. The cricopharyngeal muscle plays a major role as a sphincter through

contraction and reflex relaxation. Therefore, the dysfunction of this muscle can be an important mechanism of OD. Cricopharyngeal muscle dysfunction (CPD) may occur as multiple muscle movements during swallowing, although the cause is unknown.^[9]

There is no standardized guideline for CPD; however, in the decision-making for the treatment method, the general condition of the patient, duration of treatment effect, possibility of complications, patient's choice, and proficiency of the medical staff should be considered.^[10] The current treatments for CPD include diet modification, swallowing maneuvers, and other interventions, including botulinum toxin injection, dilatation, peroral endoscopic myotomy, and surgery.^[11]

A recent systematic review showed insufficient evidence for swallowing outcomes after cricopharyngeal myotomy.^[12] The incidence of complications following surgery under general anesthesia is relatively high compared with those following other treatment modalities. In a retrospective study of 253 patients, infection, hematoma, fistula, and aspiration pneumonia occurred in 40 patients (16%).^[13] It has also been reported that endoscopic and percutaneous laser ablations can reduce these complications.^[14]

Botulinum toxin injection has also been studied as another option for patients with morbidities and has been shown to be effective.^[15] However, symptomatic remission for many years was rare. Most of them were reported to have a duration of effect of 5 to 6 months; however, repeated injections were needed to maintain them. In addition, peripheral diffusion of the toxin affects the larynx and may cause respiratory failure, resulting in paralysis of the pharyngeal muscles and consequently in dysphagia.^[16]

Among the dilatation methods, bougie and balloon dilatations with or without endoscopy were commonly used for patients with CPD. Further, rehabilitative balloon swallowing (RBS) can also be an effective technique in treating such patients.^[17,18]

However, the effects of endoscopic balloon dilatation (EBD) for CPD, except for stenosis, are not yet fully evaluated. We hypothesized that EBD using double-balloon catheters for patients with CPD would be more effective than RBS. Therefore, this study aimed to validate the effects of EBD on improvement of swallowing functions in patients with CPD compared with those of RBS.

2. Materials and methods

2.1. Study subjects and design

All patients' medical data diagnosed with CPD, who visited a teaching hospital from February 2014 to June 2017, were included for analysis. The inclusion criteria were as follows:

- (1) CPD confirmed via video-fluoroscopic evaluation in the presence of pharyngeal remnant (PR) equaling to or more than 40% after swallowing of a semisolid paste, as previously described^[17,18];
- (2) CPD onset period of between 6 months to 3 years; and
- (3) nonoral feeding (nasogastric or gastrostomy tube) at the time of study entry.

In addition, blood tests, esophagoduodenoscopy, and transnasal endoscopic evaluation using a fiberoptic rhinolaryngoscope (ENF-GP portable fiberoptic rhinolaryngoscope provided by Olympus Medical Systems Corp., Tokyo, Japan) were performed

in all participants to evaluate exclusion criteria below. Manometry was also performed to evaluate UES tone and other esophageal motility disorder. However, because of the risk of aspiration, conventional manometry was performed to possible participants only, who were able to obey command and show no sign of aspiration in video fluoroscopic swallowing study (VFSS).

The exclusion criteria were as follows:

- (1) hyperacute stroke with an onset period of 1 month;
- (2) active respiratory, cardiac, and other severe medical conditions;
- (3) prior or current anatomical abnormalities of the pharynx or larynx, causing OD;
- (4) facial deformity, fracture, or cervical hyperflexion/hyperextension.

The study protocol was approved by the institutional review board of the teaching hospital (IRB No. MJH 2018-03-001), and informed consent was obtained from the participants; the study was conducted in accordance with the guidelines of the Declaration of Helsinki.

2.2. EBD

UES dilatation was performed by 1 endoscopist via double-channel endoscopy (GIF-2T160; Olympus Optical, Tokyo, Japan) under intravenous sedation. A multidiameter hydrostatic wire-guided controlled radial expansion balloon (Boston Scientific Corporation, Natick, MA) was advanced through 1 channel and another dilator balloon through the other working channel. The first dilator balloon was situated through the left pyriform sinus and the second dilator balloon through the right pyriform sinus. We then simultaneously inflated the balloon, holding it in position for 60 to 120 second, with each distention reaching up to a maximum diameter of 8 to 12 mm (Fig. 1). After double-balloon inflation, the area was inspected. When no complication was visualized on the deflated balloon, the procedure was terminated.

2.3. RBS

The technique employed for RBS in the study was the same as that used by Kim et al^[17,18] (Fig. 2). Before performing Non-fluoroscopy-guided pyriform sinus ballooning, we evaluated the VFSS as reference data. During VFSS, physician applied a lubricant gel to the tip of 12-Fr Foley balloon catheter and inserted it to the nasal cavity until it reaches pyriform sinus. In case of patients who cannot endure this, it was performed orally. Then contrast media was injected to Foley balloon catheter in increasing order, starting with tip of catheter to 5cc until patient could tolerate to swallow enlarged balloon in pyriform sinus (Fig. 2). Thus, we checked depth of pyriform sinus by marking on the Foley balloon catheter at the end of nostril or mouth to reach pyriform sinus accurately.

Being supervised by physician who conducted this study, occupational therapist performed Non-fluoroscopy-guided pyriform sinus ballooning. As the catheter reached the pyriform sinus, we performed inflation of Foley balloon by air until it reached submaximal tolerable balloon size which was obtained by VFSS and triggered the swallowing reflex. Therapist did not force Foley catheter balloon to get through the UES, but to trigger swallowing reflex or voluntary swallowing. Therapist determined successful swallowing of Foley balloon catheter by feeling downward force through esophagus, and matching of the sites of

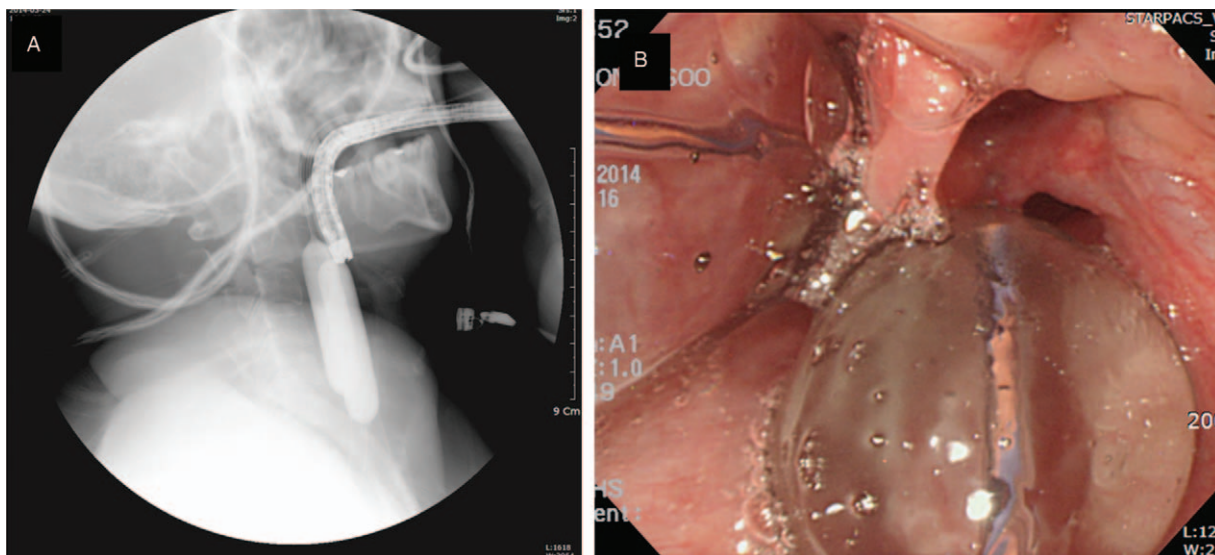


Figure 1. Endoscopic balloon dilatation by 2 controlled radial expansion balloon. (A) Fluoroscopic view. (B) Endoscopic view.

marking before and after swallowing in the VFSS without coughing reflex. During the procedure, physician closely monitored the patients for the gag reflex and complications, such as epistaxis, desaturation, bradycardia, and tachycardia. This technique was done for a maximum of 15 minutes.

2.4. Video-fluoroscopic evaluation

This study was performed with the patients seated in a chair and the chin-tucked position. First, the patients swallowed 4-cc bolus of a semisolid paste, which was prepared as a 2:1 volumetric mixture of dysphagia formula level 1 and contrast barium solution (375 g of barium sulfate powder [Solotop-HD provided by Taejoon Pharm Company, Ltd., Yongin, Korea] mixed with 90-mL water). Second, the patients capable of swallowing 4-cc bolus of the semisolid paste were tested whether they can swallow 8-cc bolus of the semisolid paste. Finally, we tested whether they

can swallow liquid, which was a mixture of 375-g barium sulfate powder and 90-mL water. All the procedures were recorded in 24 frames per second to a digital video file and analyzed. A blinded rehabilitation physician analyzed the VFSS findings.

2.5. Outcome measures

The primary outcome measures were the pharyngeal transit time (PTT) and PR on the VFSS. The PTT was defined as the period of time at which the food bolus passes from the pharyngeal fornix into the UES during the pharyngeal phase of swallowing. PR was measured by the initial remnant of the first swallowing and corresponded to the area of food retained in the pharyngeal space in 2-dimensional projection.^[17,18] The area was measured with a 2D screen AutoCAD (Autodesk, San Francisco, CA) using a 100-won coin as the reference size, which was attached to the patients' neck.

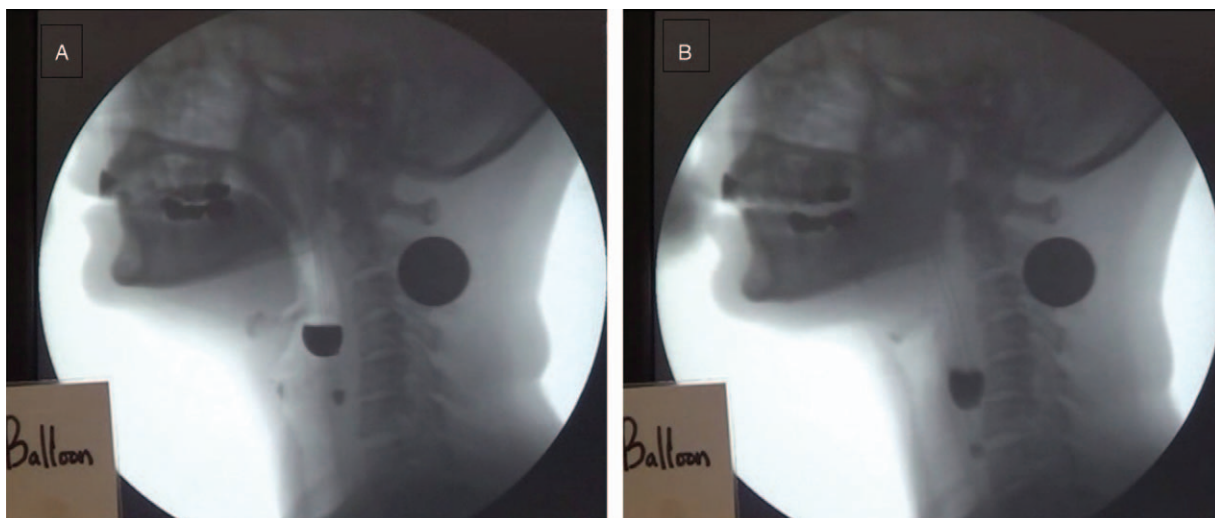


Figure 2. Fluoroscopic image of rehabilitative balloon swallowing. (A) Image just before swallowing. (B) Image just after swallowing.

The secondary outcome measures were the functional dysphagia scale (FDS) score and penetration-aspiration scale (PAS) score. The FDS, which was based on a VFSS in patients with stroke, is a sensitive and specific method for quantifying the severity of dysphagia.^[19] Conversely, the PAS consists of an 8-point, equal-appearing interval scale that describes penetration and aspiration events.^[20]

The baseline VFSS was performed before any treatment for RBS and EBD. In the RBS group, follow-up evaluation was performed 1 week after the first and second treatment. In the EBD group, the VFSS was performed 1 week after the first and second balloon dilatations. The interval between the first and second EBD was about 2 weeks to avoid immediate treatment effects.

2.6. Statistical methods

The statistical analysis between subjects with the EBS and RBS groups was performed using the Pearson Chi-square test and an independent sample *t*-test. We compared PTT, PR, FDS, and PAS scores between the EBS and RBS groups using the changes after the first and second treatments from baseline. The changes for PTT and PR were log-transformed after adding 3 to approximate the normality. The changes in the FDS and PAS scores were converted to binary variables because they do not have sufficiently unique values to be treated as continuous variables. Values of 0 and 1 were assigned when the differences were equal to 0 and greater than 0, respectively. *T*-test and Fisher exact test were used for testing statistical significance in the comparison of 4 outcomes between the 2 methods.

To examine the associations of EBD or RBS with the changes in the PPT and PR, a linear regression analysis was performed. In the model, we included EBD or RBS only to the unadjusted model and added feeding, tracheostomy, and balloon size to the adjusted model. The associations with the changes in the FDS and PAS scores were investigated using exact logistic regression analysis. Because of the small sample size, an unadjusted model was used only for the FDS and PAS scores.

A *P*-value of <.05 was considered significant. All analyses were performed using R version 3.2.5 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Subject characteristics

Among the 288 patients who visited a teaching hospital and underwent VFSS from February 2014 to June 2017, 12 patients with severe dysphagia provided their consent to undergo EBD. After propensity score matching, 24 patients who underwent RBS were selected for comparison.

The enrolled patients had 22 cases of supratentorial lesions, 12 cases of infratentorial lesions, and 2 cases of other diseases. The demographic features, including age, sex, and body mass index, and all 4 functional parameters were comparable in both groups (Table 1).

3.2. Changes after treatment

After the first treatment, all functional parameters measured by the VFSS significantly improved in both EBD and RBS groups (Table 2). After the first therapy session, differences in the PTT, PR, and PAS score from the baseline were greater in the EBD group compared with those in the RBS group (Tables 3 and 4). Of

Table 1

Summary statistics of demographic features, individual characteristics, and functional parameters of the study subjects at baseline.

Characteristics	EBD (n=12)	RBS (n=24)	<i>P</i> -value*
Age (yr)	56.67 ± 14.21	59.62 ± 15.57	.584
Duration of disease (mo)	21.17 ± 20.30	17.42 ± 16.72	.559
Body mass index (kg/m ²)	19.74 ± 1.96	20.92 ± 2.61	.178
Initial type of feeding (PEG/NG)	6/6	8/16	.334
Presence of cord palsy	4	4	.257
MMSE	18.83 ± 13.32	12.12 ± 11.41	.125
FDS score	72.33 ± 8.93	72.62 ± 8.62	.925
PAS score	6.25 ± 0.75	6.17 ± 1.20	.828
Pharyngeal transit time (s)	8.42 ± 5.69	8.15 ± 3.39	.860
Pharyngeal remnant (%)	83.85 ± 17.49	74.14 ± 18.36	.138

EBD=endoscopic balloon dilatation, FDS=functional dysphagia scale, MMSE=mini mental state examination, NG=nasogastric, PAS=penetration-aspiration scale, PEG=percutaneous endoscopic gastrostomy, RBS=rehabilitative balloon swallowing.

Values are presented as number or means ± SD, unless otherwise stated.

* *T*-test for continuous variables and Chi-square test for categorical variables.

the 12 patients who received EBD, 4 received only 1 session of treatment. One patient had solved the problem of dysphagia treated by first EBD, and able started oral feeding. Other 2 patients did not had any treatment effect by first EBD, so refused to do second EBD. Last patient lost to follow-up. Therefore, only 8 patients received a second balloon dilatation. After the second dilatation, the changes in the PTT, PR, and PAS score tended to be greater in the EBD group than in the RBS group.

3.3. Association between EBD/RBS and changes of 4 functional outcomes

The associations of EBD compared to RBS on the changes in the PTT and PR after first and second treatments since baseline are shown in Table 5. EBD was associated with changes in PR after the first and second treatments ($\beta=0.95$, SE=0.31, $P=.005$), after adjusting for feeding, tracheostomy, and balloon size. However, there was no evidence of the association of EBD and the changes in the PTT after treatments ($P>.05$).

The associations of EBD compared to RBS on the changes in the FDS and PAS scores after the first and second treatments from the baseline are shown in Table 6. EBD tended to be associated

Table 2

Comparison of the 4 functional parameters before and after first treatment by endoscopic balloon dilatation (EBD) and rehabilitative balloon swallowing (RBS).

Functional parameters	Baseline	After treatment	<i>P</i> -value*
Balloon dilatation			
Pharyngeal transit time (s)	8.42 ± 5.69	4.72 ± 3.63	.008
Pharyngeal remnant (%)	83.85 ± 17.49	58.37 ± 25.64	.001
FDS score	72.33 ± 8.93	62.00 ± 12.29	<.001
PAS score	6.25 ± 0.75	4.83 ± 1.40	.001
Balloon swallowing			
Pharyngeal transit time (s)	8.15 ± 3.39	6.85 ± 3.52	<.001
Pharyngeal remnant (%)	74.14 ± 18.36	66.71 ± 19.99	<.001
FDS score	72.62 ± 8.62	68.45 ± 10.54	<.001
PAS score	6.17 ± 1.20	5.58 ± 1.58	.001

FDS=functional dysphagia scale, PAS=penetration-aspiration scale.

Values are presented as means ± SD, unless otherwise stated.

* *T*-test for functional parameters.

Table 3

Summary statistics of changes in pharyngeal transit time (PTT) and pharyngeal remnant (PR) after the first and second treatments from baseline by endoscopic balloon dilatation (EBD) and rehabilitative balloon swallowing (RBS).

Outcome	Treatment session	All (N=36)			EBD (n=12)			RBS (n=24)			P-value*
		n	Mean	SD	n	Mean	SD	n	Mean	SD	
Log (PTT)	1	36	1.34	0.53	12	1.60	0.48	24	1.20	0.52	.034
	2	32	1.53	0.42	8	1.88	0.55	24	1.41	0.29	.051
Log (PR)	1	36	2.08	0.79	12	2.66	0.89	24	1.79	0.56	.008 [†]
	2	32	2.37	0.76	8	2.94	0.91	24	2.18	0.61	.054

EBD = endoscopic balloon dilatation, PR = pharyngeal remnant, PTT = pharyngeal transit time, RBS = rehabilitative balloon swallowing.

* T-test for the log (PTT) and log (PR).

[†] Statistically significant.

Table 4

Summary statistics of changes in binary status of functional dysphagia scale (FDS) and penetration-aspiration scale (PAS) scores after the first and second treatments from baseline by endoscopic balloon dilatation (EBD) and rehabilitative balloon swallowing (RBS).

Outcome	Treatment session	Value	All (N=36)		EBD (n=12)		RBS (n=24)		P-value*
			n	%	n	%	n	%	
FDS score	1	0	13	0.4	2	0.2	11	0.5	.143
		>0	23	0.6	10	0.8	13	0.5	
	2	0	6	0.2	0	0.0	6	0.3	.296
		>0	26	0.7	8	0.7	18	0.8	
PAS score	1	Missing	4	0.1	4	0.3	0	0.0	.014
		0	20	0.6	3	0.3	17	0.7	
	2	>0	16	0.4	9	0.8	7	0.3	.053
		0	14	0.4	1	0.1	13	0.5	
		>0	18	0.5	7	0.6	11	0.5	
		Missing	4	0.1	4	0.3	0	0.0	

EBD = endoscopic balloon dilatation, FDS = functional dysphagia scale, PAS = penetration-aspiration scale, RBS = rehabilitative balloon swallowing.

* Fisher exact test exact test for the binary status of FDS and PAS scores.

with the changes in the FDS score (odds ratio, 7.83; 95% confidence interval, 0.79–418.09; $P = .096$) and PAS score (odds ratio, 9.26; 95% confidence interval, 0.82–551.51; $P = .085$) after the second treatment. However, there was no evidence of the association of EBD and the changes in the FDS and PAS scores after the first treatment ($P > .05$).

4. Discussion

In this study, there were significant functional improvements observed in the patients who underwent EBD and RBS. When elderly and co-morbid patients require formal myotomy, cricopharyngeal dilatation and the swallowing approach appear

to be good choices when compared with endoscopic cricopharyngeal myotomy that is minimal invasive method with less complication, open cricopharyngeal myotomy.^[10] However, there are no standardized cricopharyngeal dilatation and swallowing techniques.

One of the widely used dilatation techniques is the use of bougies. Bougienage has some advantages, yielding symptomatic improvements by reducing UES pressure and increasing relaxation.^[21–23] In other ways, there are some reports of cricopharyngeal balloon dilatation using urethral catheters under fluoroscopic guidance, showing pharyngoesophageal function improvements.^[24–26] In a study that used high-resolution manometry, balloon dilatation using urethral catheters for

Table 5

Effect estimates of endoscopic balloon dilatation on the changes in the pharyngeal transit time (PPT) and pharyngeal remnant (PR) after the first and second treatments from the baseline compared to rehabilitative balloon swallowing.

Treatment session	Outcome	Model	Regression coefficient	Standard Error	T-value	P-value
1	log (PTT)	Unadjusted	0.39	0.18	2.20	.035
		Adjusted*	0.27	0.20	1.37	.181
	log (PR)	Unadjusted	0.87	0.24	3.57	.001
		Adjusted	0.99	0.26	3.78	.001
2	log (PTT)	Unadjusted	0.47	0.15	3.09	.004
		Adjusted	0.31	0.18	1.78	.086
	log (PR)	Unadjusted	0.76	0.28	2.68	.012
		Adjusted	0.95	0.31	3.09	.005

PTT = pharyngeal transit time, PR = pharyngeal remnant.

* Adjusted for feeding, tracheostomy, and balloon size.

Table 6
Effect estimates of endoscopic balloon dilatation on the changes in the functional dysphagia scale (FDS) and penetration-aspiration scale (PAS) scores after the first and second treatments from the baseline compared to rehabilitative balloon swallowing.

Treatment session	Outcome	Odd ratio	95% Confidence interval	P-value
1	FDS score	4.06	0.68–42.08	.141
	PAS score	4.27	0.66–48.50	.141
2	FDS score	7.83	0.79–418.09	.096
	PAS score	9.26	0.82–551.51	.085

FDS = functional dysphagia scale, PAS = penetration-aspiration scale.

CPD improved UES relaxation, restored UES resting pressure, strengthened pharyngeal propulsion, and improved functional oral intake, compared with regular therapy alone.^[27] Alternatively, RBS is a safer approach than mechanical balloon dilatation of the UES. It can be an effective technique in improving coordination of the pharynx and UES relaxation.^[17,18,28] In a study that compared dilatation modes, the effect of active balloon dilatation, in which patients were instructed to swallow saliva during balloon dilatation, was better than that of passive balloon dilatation in patients with neurological disorders.^[26] Paring sensory input with voluntary swallowing attempts in contrast to mechanical dilatation may be the strength of RBS.

There are few reports on CPD dilatation via controlled radial balloon dilatation under endoscopic guidance.^[29,30] Recently, it was reported that EBD using the retrograde method was also safe and effective for CPD, compared with the classic static technique.^[31] However, dilatation using 1 balloon or bougie would not be effective in patients with UES relaxation dysfunction because the UES is not round.^[32] Pilot data suggest that EBD using 2 simultaneous controlled radial expansion balloon dilators is feasible, safe, and effective.^[33] A follow-up study showed that 3 series of EBD for CPD improved dysphagia and fluoroscopic swallowing parameters.^[34]

There were significant differences between change of the PTT, PR, and PAS score in EBD and RBS, after treatment. It seems natural that expansion therapy is better than swallowing treatment. Therefore, this study shows a tendency that EBD is effective as RBS in severe CPD.

However, as to which between EBD and RBS is more appropriate was not determined. In this study, the significant improvement in PR would be suggestive of the indication of EBD in CPD. EBD induces stretching or tearing of the cricopharyngeal muscle. Therefore, EBD can be an effective treatment for patients with pharyngeal residues. However, it requires patient sedation and use of expensive balloons. In addition, artificial mechanical dilatation of the UES may cause mucosal injury, perforation, and pain. Conversely, RBS usually induces a state of relaxation with coordination between the pharynx and UES. However, this approach may not be appropriate for patients with severe CPD. It can be a more efficient approach for treating disorders with decreased pharyngeal and UES motilities and impaired rhythmic coordination. Since balloon swallowing under fluoroscopic guidance is a kind of active assistive dilatation and minimally invasive, it provides important diagnostic information and serves as an effective therapy. RBS should be the considered first for patients with CPD which is not well treated with conventional rehabilitation; EBD should be the second choice for patients with severe CPD and pharyngeal residues, refractory to RBS.

One of the main limitations of EBD is that it has a shorter duration of response than surgeries. It was reported that CPD treatment with EBD improved UES opening as with laser

myotomy for at least 6 months.^[35] Generally, the effect of EBD was inevitably shorter than that of surgeries, which cuts muscle. Thus, repeated balloon dilatation would be needed.^[36] Further follow-up studies are needed to clarify the repeated standardized schedule.

There was no complication observed in this study. The reported complication rates for dilatation therapy were between 0% and 20%; those for myotomy were between 0% and 39%; and those for botulinum toxin injection were between 0% and 25%.^[37] In a recent retrospective study including 46 cases, there were no major complications in 59 procedures.^[21] Thus, EBD using double-balloon catheters is a safe therapy for patients with CPD.

There are several limitations in this study. First, this study had a pilot study design which only a small number of patients had enrolled. Second, the long-term effects of balloon dilatation were not determined. Therefore, further studies including follow-up data of patients receiving balloon dilatation are needed. Third, functional tests that can assess the organic movement of the swallowing processes, including UES opening, pharyngeal constriction ratio, and esophageal pressure tests, were not performed in all patients. EBD and RBS are related to UES opening and pharyngeal passage, so further studies are needed to evaluate these parameters. Forth, pure CPD and relative CPD could not be distinguished, because inclusion criteria was not only about UES sphincter problem, but also included constrictor muscle, laryngeal protection, and velopharyngeal insufficiency problems which is relative CPD.

5. Conclusion

In conclusion, EBD is a safe procedure for patients with CPD. It can significantly improve functional parameters, including PR, compared with RBS. Therefore, only in selective cases who are refractory to conventional treatment could benefit from receiving EBD.

Author contributions

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