

*Original Article***Immediate effectiveness of balloon dilatation therapy for patients with dysphagia due to cricopharyngeal dysfunction**

Keiko Onogi, MD, PhD,¹ Eiichi Saitoh, MD, DMSc,¹ Izumi Kondo, MD, PhD,²
Megumi Ozeki, MD, PhD,³ Hitoshi Kagaya, MD, PhD¹

¹Department of Rehabilitation Medicine I, School of Medicine, Fujita Health University, Toyoake, Aichi, Japan

²Department of Rehabilitation Medicine, National Hospital for Geriatric Medicine, NCGG, Obu, Aichi, Japan

³Faculty of Rehabilitation, Fujita Health University, Toyoake, Aichi, Japan

ABSTRACT

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Purpose: To determine the immediate effectiveness of balloon dilatation therapy for patients with dysphagia due to cricopharyngeal dysfunction on videofluoroscopy (VFSS).

Methods: The subjects were 11 consecutively recruited patients with central nervous system disease who were suspected of having upper esophageal sphincter (UES) insufficiency based on the presence of a large amount of residue in the pharynx on VFSS. The amount of residue and the occipitofrontal diameter of the UES were measured before and after dilatation.

Results: The mean amount of pharyngeal residue was significantly smaller after than before dilatation. However, no significant difference was seen in the occipitofrontal diameter of the upper esophagus after dilatation. When the subjects' brain lesions were divided into brainstem and supratentorial lesions, the pharyngeal residue was significantly lower in patients with supratentorial lesions than in those with brainstem lesions.

Conclusion: Balloon dilatation therapy immediately decreases the amount of pharyngeal residue in patients with dysphagia due to cricopharyngeal dysfunction.

Keywords: balloon dilatation therapy, cricopharyngeal muscle, dysphagia

Introduction

Cricopharyngeal dysfunction is typical of the pharyngeal stage of dysphagia. The cricopharyngeal muscle is controlled by branches of the pharyngeal nerve plexus, and it usually contracts to prevent aerophagia. During swallowing, it relaxes and enables bolus transportation. Cricopharyngeal dysfunction occurs with disorders of the nucleus of the vagus nerve or the glossopharyngeal nerve due to central nervous system lesions, especially of the brainstem. In addition, similar dysfunction is seen in pseudobulbar palsy. If bolus transportation is affected by cricopharyngeal dysfunction, residue of the bolus remains in the pharynx and may cause aspiration pneumonia.

Treatments for cricopharyngeal dysfunction consist of conservative and surgical approaches. The bougie method and the balloon dilatation method have been used for patients with esophageal strictures as conservative approaches.

Treatment of symptomatic esophageal stricture often requires dilatation through intraluminal distension. Several different instruments can be used for intraluminal dilatation, such as Savary-Gillard graded polyvinyl chloride bougies [1] and a balloon dilator under endoscopic or videofluoroscopic guidance [2–5]. The advantage of dilatation with an inflatable balloon is that many patients tolerate the procedure well, with only topical anesthesia or very light sedation. Balloon dilatation is recognized to be safe and effective and has become an accepted treatment for esophageal strictures. Kelly discusses balloon dilatation and suggests that it should work optimally in patients with suspected fibrosis of the cricopharyngeal muscle [6].

On the other hand, dilatation has been widely used for cricopharyngeal dysfunction caused by central nervous system lesions since Sumiya et al. [7] and Hojo et al. [8] reported the dilatation method with an indwelling bladder catheter.

Correspondence: Keiko Onogi, MD, PhD
Department of Rehabilitation Medicine I, School of Medicine,
Fujita Health University, Toyoake, Aichi 470–1192, Japan.
E-mail: keionogi@fujita-hu.ac.jp

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In the balloon dilatation method, the catheter is inserted into the esophagus through the mouth under radiographic guidance by VFSS. The position of the balloon during inflation is monitored on fluoroscopy. The catheter is raised to the part with resistance, and it is pulled up simply or synchronized with swallowing. If this method is effective for the impaired UES passage, it is introduced to train patients with dysphagia.

There are many reports of a long-term training effect, and a case report about the effect of the first dilatation has appeared [9], but there are few reports in which that effectiveness has been examined quantitatively. Therefore, the immediate effectiveness of the first dilatation using the balloon method was evaluated.

Methods

In this study, a balloon catheter developed in our department exclusively for UES dilatation was evaluated.

The existing catheter for treatment of esophageal strictures is too expensive. Therefore, a urethral catheter (14–18 Fr) is generally used. Though this catheter is not as expensive, there are some problems: 1) It is difficult to confirm the position of the balloon under fluoroscopy; 2) the shape of the balloon is not suitable for the UES, and it is difficult to obtain sufficient dilatation; and 3) because the materials of

the catheter are flexible, it is difficult to insert into the oral cavity.

Given this background, we have developed a new balloon dilator specifically for use in patients with UES dysfunction. The design of this balloon dilator is shown in Fig. 1. This catheter's full length is 65 cm, the outer diameter is 16 Fr, and the tip is a 2-opening aperture type. There are two balloons 7 cm proximal to the tip of the catheter. The shape of the outer stratum balloon is an oval, with a longer axis of 5 cm. The inner layer balloon is located in the distal edge of the outer stratum balloon, the longer axis is 1/2 of the outer stratum balloon, and it expands spherically. A radiologically visible line is attached to the catheter, and a marker is attached to the center of the outer balloon. It is made with silicon to have moderate hardness so that excessive bending does not occur at insertion.

The catheter is inserted into the esophagus through the mouth under radiographic guidance. The position of the balloon during inflation is monitored on fluoroscopy. The inner balloon is initially inflated with 2–5 mL of air, and then it is pulled up until the balloon reaches the UES. The dilator is held against the resistance produced by elevated UES pressure. Dilatation of the UES is then achieved by inflating the outer balloon. The amount of air inflated into the outer balloon ranges from 10–20 mL.

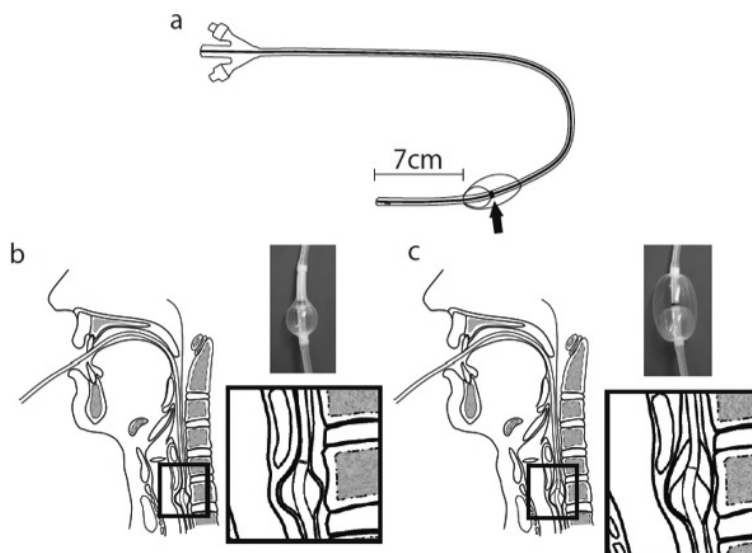


Figure 1. Balloon dilator.

- a) The total length of the dilator is 65 cm. The length from the tip to the distal end of the balloon is 7 cm. Radiologically visible markers are attached to the catheter and proximal ends of the inner balloon (arrow).
- b) The inner balloon is inflated first, then pulled up until it reaches the UES. When 5 mL of air are injected, the balloon becomes 18 mm in diameter and 22 mm in length.
- c) The inflated outer balloon dilates the UES. When 10 mL of air are injected, the balloon becomes 23 mm in diameter and 38 mm in length.

With this balloon catheter, pharyngeal residue and occipitofrontal diameter before and after dilatation were compared in patients with dysphagia due to suspected cricopharyngeal dysfunction on VFSS. Because it appeared that the presence of a brainstem lesion caused a difference in the dilatation effect in a preliminary experiment, the number of cases was selected to be 11 to achieve statistical power of 80%, α error of 5%, and β error of 20%.

The subjects were 11 patients (8 men, 3 women; mean (\pm standard deviation) age, 58.6 \pm 17.4 years; range, 22–82 years). Four patients had suffered a stroke, one patient had a subarachnoid hemorrhage, 2 patients had traumatic brain injuries, 2 patients had undergone surgery for brain tumors, and 2 patients had other CNS disorders (postoperative brain ischemia). As for the etiology of dysphagia, 5 patients had medullary lesions and 4 had brain lesions in other areas. The subjects were divided into two groups based on imaging findings: 4 patients showed only a supratentorial lesion (A group) and 7 patients had medullary lesions (B group) (Table 1).

Severity of dysphagia was evaluated according to the Dysphagia Severity Scale (DSS) (Table 2). Three patients were grade 2, 5 were grade 3, and 2 were grade 4. Five patients were receiving enteral feeding, and the remaining 6 maintained oral feeding with paste. The median time after onset was 311 days (24–3,150 days).

VFSS was performed before and after dilatation therapy to examine the amount of pharyngeal residue and the diameter at the opening of the esophagus during swallowing. A total of 4 mL of 50% barium liquid was used as the contrast agent for a single bolus swallow.

The amount of residue was measured by digital tracing on lateral view radiographs when the bolus had passed through the UES (Fig. 2). The maximum width during bolus passage was defined as the diameter of the upper esophagus based on the line parallel to the vocal cords running to the upper edge of the fourth cervical vertebral body. Data were standardized based on the image of a 1-cm marker attached to the chin during VFSS.

Table 1. Subjects.

Lesion	Age	Sex	Diagnosis	Time after onset (day)	DSS
A	52	M	traumatic brain injury	62	3
A	69	M	multiple cerebral infarction	175	2
A	75	M	multiple cerebral infarction	225	2
A	22	F	traumatic brain injury	311	3
B	62	M	cerebral ischemia post operation of thoracic aortic aneurysm	193	2
B	74	F	multiple cerebral infarction	311	4
B	82	M	cerebral ischemia post operation of mandible tumor	374	3
B	48	M	brain tumor	403	4
B	51	F	subarachnoid hemorrhage	931	3
B	38	M	brain tumor	24	3
B	72	M	multiple cerebral infarction	3,150	4

A: supratentorial.

B: including brain stem.

Table 2. Dysphagia Severity Scale ; DSS.

Grade 1	Saliva Aspiration	Severe aspiration. Medical condition will not be stable.
Grade 2	Food Aspiration	Severe aspiration. Medical condition will be stable using tube feeding.
Grade 3	Water Aspiration	Water Aspiration: Aspiration of liquid. Compensatory swallowing techniques are not enough to prevent the aspiration.
Grade 4	Occasional Aspiration	Possibly aspiration or aspiration under chewing swallow. The aspiration will be prevented by compensatory swallowing techniques.
Grade 5	Oral Problem	Significant symptoms of dysphagia about oral function and need of rehabilitation or exercise, but no aspiration.
Grade 6	Minimum Problem	Significant symptoms of dysphagia about oral function and need of rehabilitation or exercise, but no aspiration.
Grade 7	Within Normal	Within Normal

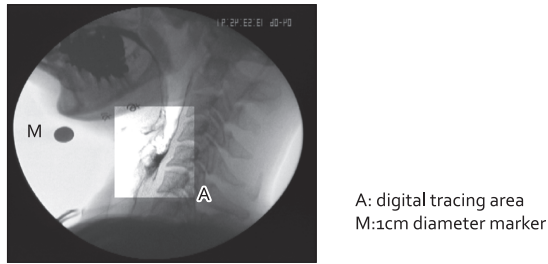


Figure 2. Method of measurement by digital tracing on the lateral view of the radiographic image. The amount of residue was measured by digital tracing on lateral view radiographs when the bolus had passed through the UES.

For statistical evaluation, the paired *t*-test was used for comparisons between before and after dilatation. A student's *t*-test was used for comparisons by lesion location. The numerical value is shown as the average ± standard deviation. JMP9.0.2 was used for statistical analysis, and *p* values of less than .05 were considered significant.

Ethics Committee approval was not obtained because the institution within which the work was undertaken did not have an Ethics Committee when this study was started. Nevertheless, this research was conducted according to the highest ethical standards and conformed to the provisions of the Declaration of Helsinki, and written, informed consent was obtained from all patients.

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Results

Adverse events, such as changes in the vital signs or pain, were not observed during balloon dilatation therapy.

Mean amounts of residue in the vallecula, pyriform sinus, and the total of both before dilatation therapy were 1.19±0.91, 1.89±1.20, and 3.08±2.02 cm², respectively; the respective values after dilatation were 0.70±0.90, 1.05±0.96, and 1.75±1.72 cm². The residual ratios before and after dilatation (the ratio were calculated by dividing the residue after dilatation by the residue before dilatation) were 46.0%, 49.2%, and 47.8%, respectively. There were significant reductions after dilatation therapy (*p*=0.01, 0.002, 0.001) (Fig. 3).

The total residue before and after dilatation and the residual ratio were as follows in groups A and B: A) 1.51±0.97 cm², 0.34±0.47 cm², and 17.0%; and B) 3.97±1.94 cm², 2.55±1.67 cm², and 65.4%. The residual ratio was significantly lower in group A than in group B (*p*=0.005) (Fig. 4).

According to the grade of DSS, the total residue before and after dilatation and the residual ratio were: 2.46 cm², 1.49 cm², and 39.3% in DSS2; 2.43 cm², 1.06 cm², and 44.1% in DSS3; and 4.76 cm², 3.18 cm², and 62.6% in DSS4. There were no significant differences, but the residual ratio showed a tendency to decrease with lower DSS grade.

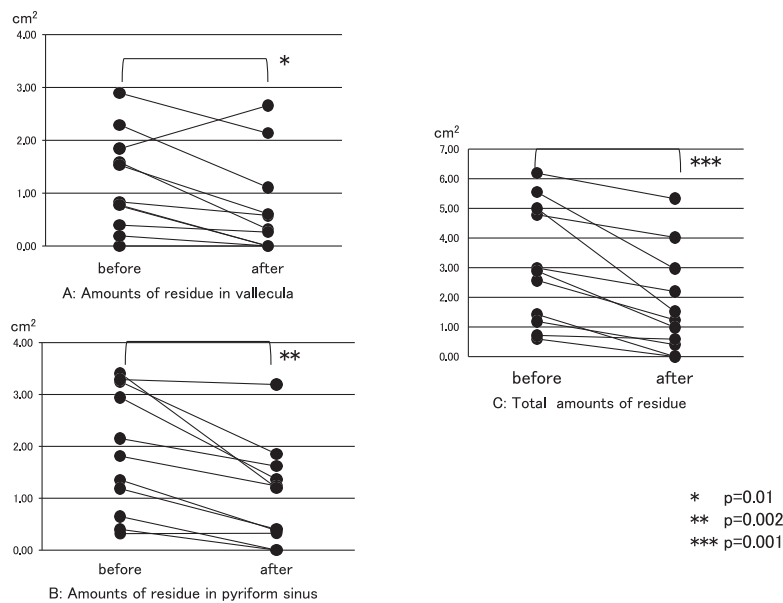


Figure 3. Change in the mean amounts of pharyngeal residue before and after dilatation therapy. Changes in the mean amounts of pharyngeal residue at the vallecula, pyriform sinus, and their total were shown; they were significantly reduced compared with after therapy.

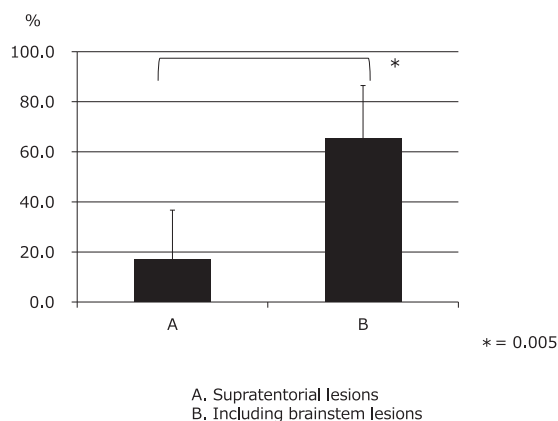


Figure 4. Change in the mean amounts of pharyngeal residue according to the site of the brain lesion. Pharyngeal residue was significantly less in patients with a supratentorial lesion than in those with a brainstem lesion ($p=0.005$).

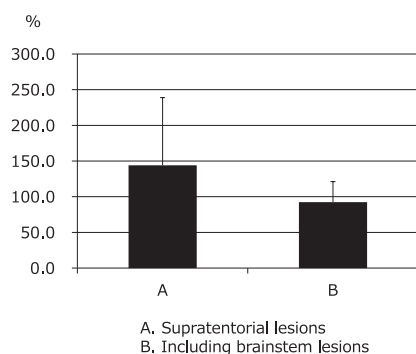


Figure 5. Change in the mean occipitofrontal diameter of the upper esophagus before and after dilatation therapy.

No significant difference was seen in the mean occipitofrontal diameter of the upper esophagus between before and after dilatation therapy.

With respect to the occipitofrontal diameter of the UES, the average diameter before dilatation was 9.8 ± 1.96 mm, while that after dilatation was 10.2 ± 0.36 mm, and the ratio before and after dilatation (the ratio was calculated by dividing the diameter after dilatation by the diameter before dilatation) was 111.2%, with no significant difference.

The diameters before and after dilatation and the ratio of before to after dilatation by group were: A) 0.84 ± 0.09 cm, 1.16 ± 0.62 cm, and 144%; and B) 1.06 ± 0.21 cm, 0.93 ± 0.14 cm, and 92%. The subjects with supratentorial lesions showed a tendency to have a greater dilatation effect than subjects with brainstem lesions, but the difference was not significant (Fig. 5).

According to the grade of DSS, the diameter before and after dilatation and the ratio of before and after dilatation were: 0.85 cm, 1.00 cm, and 118.9% in DSS 2; 0.97 cm, 1.11 cm, and 125.6% in DSS 3; and 1.14 cm, 0.88 cm, and 79.8% in DSS 4. There were no

significant differences.

Discussion

Balloon dilatation therapy is relatively widely used clinically for patients with dysphagia due to cricopharyngeal dysfunction. Use of this method depends on the following: 1. Whether a large bolus remains behind in the pharynx without UES opening on VFSS or videoendoscopic examination of swallowing; 2. Whether there is no organic disease of the pharynx or larynx; 3. Whether there is no pressure from outside, such as that due to tumor; 4. Whether the gag reflex at the insertion of the catheter is not very strong; and 5. Whether the patient is cooperative with this therapy.

Although there was no significant change in the diameter of the UES before and after dilatation in this study, pharyngeal residue decreased significantly, and it was suspected that there was an effect on pharyngeal residue. In addition, pharyngeal residue was lower in patients with supratentorial lesions than in patients with brainstem lesions. There have been many reports of the curative effect in patients with brainstem lesions, and the present results suggest that balloon dilatation therapy is effective for patients with dysphagia caused by supratentorial lesions. Moreover, it seems that oral-intake training just after dilatation is effective. The results by DSS were not significant, but it seemed that pharyngeal residue decreased with lower DSS grade. When oral intake was limited even after the acute period had passed, immobilization of the pharyngeal muscle would occur because the bolus did not pass the hypopharynx. The cricopharyngeal muscle was extended by this therapy and facilitated UES opening.

Hatlebakk et al. [10] reported that the UES pressure decreased significantly after dilatation therapy. In addition, Dou et al. [11] reported that sensory stimulation caused by balloon dilatation might affect the central pattern generator of swallowing. It is thought that many factors may be involved in decreasing the amount of pharyngeal residue after balloon dilatation therapy.

One limitation of this study was that the balloon pressure was not measured. It is necessary to know the course of pressure reduction during treatment in order to understand the precise mechanism of the effect of balloon dilatation. In addition, while the change in size of the balloon could be monitored fluoroscopically, measurement of the intraluminal pressure during treatment will be necessary to avoid the risk of mucosal injury.

With respect to the method used in the present study, bias in the measurements of residue and in the UES diameter could have occurred because the measurements were not performed blindly.

In the general dilatation method, an indwelling bladder catheter is used, and the results with the present catheter and an indwelling bladder catheter

will need to be compared in the future.

Recently, injections of botulinum toxin to the cricopharyngeal muscle have been used abroad when bolus passage in the UES is severely affected [12–14], and surgical management approaches such as myotomy [15] are chosen when conservative treatment fails. The multiplier effect with these treatments will be discussed in the future.

Conclusion

Balloon dilatation therapy immediately decreases the amount of pharyngeal residue in patients with dysphagia due to cricopharyngeal dysfunction caused by supratentorial and brainstem lesions.

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