A New Type of Balloon Catheter-Based Dilatation Intervention for Patients With Cricopharyngeus Achalasia After Stroke: A Randomized Study

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Abstract

Purpose

To investigate the efficacy and safety of a new type of balloon catheter in dilatation intervention for patients with cricopharyngeus achalasia after stroke.

Methods

Fifty-two patients with cricopharyngeus achalasia after stroke received routinely swallowing rehabilitation trainings and were randomly assigned to: an experimental group (n = 26) that received dilatation therapy using this new balloon catheter one time per day for 5 days per week and a control group (n = 26) that received dilatation therapy with NO.14 ordinary urinary catheter one time per day for 5 days per week. Duration of intervention, EAT-10 and FOIS scores were recorded at baseline and every day during intervention. The time for FOIS score ≥ 3 , the time for recovery of oral intake of water, liquid food, mushy food and solid food were recorded and estimated. Complications were recorded during intervention.

Results

The Exp group had shorter duration of intervention compared to the Con group ($p < 0.001$). Exp group improved faster than Con group with shorter recovery time for oral intake of liquid food ($p < 0.001$), mushy food ($p = 0.001$) and solid food ($p < 0.001$). At the termination of intervention, EAT-10 score was lower in Exp group than in Con group ($p = 0.002$). Compared to the Con group, Exp group had similar incidence of complications but better tolerability ($p = 0.006$).

Conclusion

Using this new balloon catheter for dilatation improves more and faster than using ordinary urinary catheter in patients with cricopharyngeus achalasia after stroke.

Introduction

Cricopharyngeus achalasia is one of the common cause of dysphagia due to the failure of relaxation of the cricopharyngeus muscle during the pharyngeal phase of swallowing¹⁻³. Clinical symptoms and complications include dysphagia, coughing, choking, nasopharyngeal regurgitation, aspiration pneumonia, weight loss, and malnutrition^{4,5}. Cricopharyngeus achalasia is responsible for a spectrum of neurological diseases, including stroke, multiple sclerosis, amyotrophic lateral sclerosis, primary muscle disorders, skull base neoplasia, and Parkinson's disease³, especially the stroke. It was reported that, half

of the stroke patients experienced dysphagia with the life-threatening complications of pulmonary aspiration and malnutrition⁶. When the stroke occurred in brainstem, the number can up to 70%⁷.

A range of managements exist to improve the function of cricopharyngeus muscle and swallowing, including: compensatory strategies, rehabilitation exercise, physical dilation, pharmacological interventions and surgery. The most commonly used is dilatation, including: bougies, a wire-guided polyvinyl dilator, air-filled pneumatic dilatation, and water-filled balloon dilatation with or without endoscopy guidance⁸⁻¹⁰. Among these, balloon catheter dilation is the most effective way investigated by studies¹¹. However, balloon catheter dilatation protocols are not yet standardized. Urethral catheters (No.14 to No.16) are commonly used in China, but these balloons are oval and small with several disadvantages: heterogeneous pressure distribution, short ice stimulation time and small expansion range.

In this study, we improved the tube material, internal circulation structure, balloon shape and length of the ordinary urinary catheter to developed a new type of balloon dilatation catheter. The aim of this study was to display this new balloon catheter and to investigate the effectiveness of dilatation intervention using this new balloon catheter for patients with cricopharyngeus achalasia after stroke.

Methods

This study protocol was approved by the ethics committee of the Hunan Provincial People's Hospital (NO. 2019705). Informed consent of each participant was obtained for study inclusion. All methods were carried out in accordance with relevant guidelines and regulations.

Registration: Chinese Clinical Trial Registry, 08/03/2021, ChiCTR2100044034. **[A new type of balloon catheter-based dilatation intervention for patients with dysphagia after stroke: a randomized controlled trial]**

Design

This is a randomized controlled trial with concealed allocation, intention-to-treat analysis and blinded assessment. The study was performed in the Department of Rehabilitation at Hunan Provincial People's Hospital, Changsha, Hunan, China. Patients in hospital with cricopharyngeus achalasia after stroke who need the dilatation therapy were invited to participate the study. Eligible and willing participants received routine swallowing training and nursing care, and were randomly divided into the experimental group (treated with the new type balloon catheter) and control group (treated with No.14 ordinary urinary catheter) in a 1:1 ratio. All participants had the following data collected: age, gender, cause of dysphagia, comorbidities and the course of disease.

Concealed allocation of the randomization was performed using a computer-generated random sequence and opaque envelopes by a researcher who did not involve in this study. This research informed only the

physiotherapist who administered the intervention for each patient. Another rehabilitation physician who was blinded to the information measured the outcomes.

Dilatation were commenced after baseline measurements and were continued one time per day, 5 days per week. EAT-10 score, FOIS score, ability of oral intake and complications were assessed every day during intervention by a rehabilitation physician blinded to the study. This physician decided whether the dilatation therapy should be terminated or not. If the swallowing function recovered basically before completing the intervention protocol period, outcomes were measured after the last dilatation intervention to homogenize the analyses.

Participants

Patients with cricopharyngeus achalasia after stroke who need dilatation therapy in hospital were recruited, screened for eligible and willing to participated in this study from July 2019 to July 2021. The inclusion criteria included: 1) having a diagnosis of cricopharyngeus achalasia confirmed by the video fluoroscopy swallowing study or clinical swallowing evaluation; 2) Radiologists confirmed stroke by head Magnetic Resonance Imaging; 3) being aged 20 -80 years. The excluded criteria included: 1) organic obstruction of nasal or pharyngeal; 2) sever heart, lung and kidney diseases; 3) mental illness; 4) severe cognitive disorder and aphasia.

Intervention

Routine swallowing rehabilitation trainings were performed on all of the participants including the basic swallowing training (oral and facial function training and Shaker training, one time per day with 30 mins/time), oral intake training and the Vitalstim electrical stimulation (one time per day with 30min/time). Nutritional and mental care were provided to all participants.

Experimental Group

Patients in this group undertook dilatation therapy using this new type balloon catheter with following steps.

New type balloon catheter

This new balloon catheter consists of a Y-shaped connector with inlet and outlet valve, a catheter body and a balloon (Fig 1C). The catheter body is divided into two cavities (inlet cavity and outlet cavity) which are connected to the inlet and outlet valve respectively. Both of the cavities are connected to the balloon. Water can be injected from the inlet valve, flows through the inlet cavity to the balloon, passes through the balloon to the outlet cavity, then flows out from the outlet valve (Fig 1A). There are several advantages of this new balloon catheter☐

1. Contrast to the No.14 ordinary urinary balloon catheter (Fig 1B) which only have single cavity, this new balloon catheter with double-cavities separates the inlet and outlet water to ensure that the water can

continuously and evenly flow in and out of the catheter.

2. The shape of the new balloon is ellipsoid instead of sphericity after being completely filled (Fig 1D), which is conducive to more adequate expansion of the cricopharyngeal muscle.

3. The catheter is marked with a scale so that the operator could clearly read the depth of catheter insertion.

Dilatation steps:

Step 1: Patients were asked to fast 2 hours before dilatation. The catheter was gently inserted into the patient's nasal cavity (or oral cavity when patient's deglutition reflex disappeared) after confirming its integrity. At the same time, patients were instructed to swallow. When the catheter was completely inserted into the esophagus (about 30 cm in length from nasal cavity), patients were asked to make sounds. If they sounded normal without cough, can proceeded to the next step.

Step 2: After the catheter was fully inserted into the esophagus, opened the inlet and outlet of the Y-connector, injected ice water into the inlet cavity continuously using a syringe. Kept the ice water flowing in and flowing out for 3-5 minutes.

Step3: Closed the outlet valve and injected 5-7ml of ice water to fill the balloon, then closed the inlet valve.

Step 4: After that, operator could pull out the catheter gently. When the balloon passed through the cricopharyngeal muscle (the position where the catheter was hard to pull out), the balloon size can be adjusted by adjusting the water volume of the balloon to ensure that the operator can only feel slight resistance. At the same time, operator pulled the balloon slowly and repeatedly while instructing the patient to swallow until the balloon leaved the esophagus.

Step 5: After the balloon leaved the esophagus, opened the outlet valve to drained the water, then pulled out the catheter completely.

Step 6: Repeated the above steps 5-6 times, and the whole treatment lasted about 30 minutes.

Note: The balloon volume increased by 1-2ml daily with total amount <20ml.

Control group

Patients in this group undertook dilatation therapy using No.14 ordinary urinary catheter with following steps.

Step 1: The same as the exp group

Step 2: After the catheter was completely inserted into the esophagus, 1-2ml of ice water was injected into the balloon and then closed the inlet valve.

Step 3: Operator pulled out the catheter gently until the balloon leaved the esophagus, while instructed the patient to swallow. The specific process was the same as the experimental group.

Step 4: After the balloon leaved the esophagus, withdrawn the ice water from the balloon with a syringe, and then pulled the catheter completely out of the patient. Subsequently, drained the remaining water and repeated the above steps for 5-6 times. The entire process lasted about 30 minutes.

Note: The same with Exp group.

Outcome measures

All participants were assessed before and every day during intervention period by the rehabilitation physician blinded to this study using the following measurements. The primary outcome was the duration of dilatation which was quantified in days until the recovery of the swallowing function assessed by the physician using the criteria as FOIS score of 6 or more. Swallowing function was performed using the FOIS score¹² and EAT-10 score system¹³. EAT-10 score is composed of 10-item question including various symptoms of dysphagia, clinical characteristics, psychological feelings and social influence. Each question is divided into 5 levels: none (0), mild (1), moderate (2) severe (3) and extreme (4). A final total EAT-10 score of 3 or more is considered abnormal. FOIS score categorizes oral intake into 7 grades from I to VII, corresponding to 1 to 7 points respectively. When FOIS score up to 3 or more, the clinical outcome is considered to be significantly improved. Oral intake training was administered every day during intervention period by the physician using one-bite size of water, liquid food, mushy food or solid food. According to the water swallow test, recovery of oral intake of water was defined as swallow at once without coughing. During the intervention period, complications, like laryngeal edema and mucosal hemorrhage were evaluated for all patients by the rehabilitation physician and the senior nurse who were blinded to the study. Pain status were assessed using a five-point oral grading scale (VRS-5)¹⁴ (0 points for painlessness, 1-5 points for mild pain, moderate pain, severe pain, extreme pain, and intolerable pain, respectively) by the nurse.

Data analysis

Sample size was calculated based on the primary outcome of duration of intervention. Mean duration of 8 days for Exp group and 16 days for Con group with a standard deviation of 10 and 2 respectively were anticipated, and a significance level of 5% and study power of 86% were used. Finally, it was calculated that a sample of 50 participants (25 per group) was required. Totally, sample size of 52 participants were used to allow the possible loss.

All data analyses were performed by a researcher who was not involved in this study assessments and interventions. Baseline characteristics of the participants were summarized with descriptive statistics. Statistical analysis was performed following the intent-to-treat principle. The Kruskal-Wallis ANOVA was used for the continuous variables, like: EAT-10 score, the recovery time for oral intake of water, liquid food, mushy food. Due to non-normal distribution of the data, the between-group difference in the duration of

dilatation and the recovery time for oral intake of solid food were investigated using Mann-Whitney U test. Chi-square tests were used for the categorical variables (complications). Kaplan-Meier survival analysis was used to test the duration time. A significance level of 5% ($p < 0.05$) was adopted for all statistical analyses. All of the statistical analyses were performed using SPSS (IBM).

Results

Flow of participants through the study

Sixty consecutive patients with cricopharyngeus achalasia after stroke were evaluated for eligible from July 2019 to July 2021. Among these, eight patients were excluded for the reason in Figure 2. Remaining fifty-two participants were eligible and willing for the study and were randomized into Exp group ($n=26$) and Con group ($n=26$). All participants received correct designated intervention. One participant in Exp group and three participants in Con group had interrupted treatment and discharged during intervention due to the personal reason unrelated to the study. None of the physician and nurses were unblinded to the information during the study. Finally, measurements of twenty-five participant in Exp group and twenty-three participants in Con group were calculated and analyzed.

Characteristics of the participants

According to the baseline characteristics that summarized in Table 1, there were no statistically significant differences in gender, age, course of disease, and combinations between two groups.

Effects of the intervention

Duration of dilatation

The total intervention time was ranged from 5 to 28 days with 5 to 15 days in Exp group and 6 to 28 days in Con group. Duration of dilatation was shorter in Exp group than in Con group with significantly statistics (7 vs 15, $p < 0.001$) (Table 2). According to the Kaplan-Meier curve (Figure 3), the probability of remaining therapy was lower in Exp group than in Con group. For 10 days, 16% in experimental group and 75% in control group still need dilation.

EAT-10 score

Both groups showed significantly improves in EAT-10 score at the end of the intervention. At the time of intervention termination, Exp group had lower EAT-10 score than Con group with significantly statistically difference (3 vs 5, $p = 0.002$) (Table 2).

Recovery time for oral intake

All participants completely recovered oral intake of water and 3 different foods (liquid food, mushy food and solid food). In Exp group, the recovery time for oral intake of liquid food ($P < 0.001$), mushy food ($P = 0.001$) and solid food ($P < 0.001$) were significantly shorter than in Con group (Table 2). However, the

recovery time for oral intake of water were similar in both Exp group and in Con group (5 vs 5 days, $p=0.085$).

Complications

During the intervention, the incidence of mucosal bleeding (4.0% vs 21.7%, $P = 0.077$) in the experimental group were similar with those in the control group. Regarding the tolerability. Compared the exp group, laryngeal edema happened more common in con group (4.0% vs 26.1%, $P = 0.038$). Four patients (16.0%) in the Exp group felt pain with the median score of 0, while eight patients (34.8%) in the Con group felt pain with the median score of 1. Patients in Exp group had better tolerability than Con group with significantly statistically difference ($p=0.006$), as shown in Table 2.

Discussion

This study estimated that using this new type balloon catheter for dilation was more beneficial than ordinary urinary catheter with several outcomes, including shorter duration for dilatation, shorter recovery time for swallowing function and shorter recovery time for oral intake. Compared to the ordinary urinary catheter, this new balloon catheter did not produce higher complication incidence but had better tolerability.

This is the first study of this new balloon catheter used for patients with cricopharyngeus achalasia. We believe that the reasons for it can help patients recover more quicker than ordinary urinary catheter including 2 points.

First and the most important is ice stimulation. Ice stimulation is an effective method to improve the motor and sensory activities of tongue and soft palate through repeatedly mechanical, temperature and pressure stimulation¹⁵. It increases the sensitivity of the swallowing reflex areas by stimulates the sensory input nerve fibers and eventually induces the swallowing reflex to improve the swallowing function^{16,17}. Michiyuki et al. firstly reported the excitability of the human cortical swallowing motor pathway after oral ice stimulation. They found that oral ice stimulation increased the excitability of the corticobulbar projection to the mylohyoid muscles for 10 mins but neck superficial skin ice stimulation did not have any effects¹⁸. No.14 ordinary urinary catheter which was commonly used in clinical practice have a balloon with only one water inlet valve. Filling the balloon with ice water and inserting it into the esophagus can achieve a relatively short time of ice stimulation, because the temperature rises quickly. To extend the ice stimulation time, we created this new catheter with two relatively independent cavities both connected to the balloon which could achieve the continuous circulation of ice water in and out. Thus, the cricopharyngeus muscle could continuously receive constant low temperature ice stimulation. The combination with physical dilatation and relatively long time of ice stimulation improves better.

In addition, the shape and size of the balloon might be the second reason. As we know that the cricopharyngeus muscle is the main muscle of the upper esophageal sphincter. The upper esophageal sphincter is a high-pressure zone lying in between the pharynx and the cervical esophagus. Lang IM et

al.¹⁹ and Gerhardt D et al.²⁰ demonstrated that UES consists of the proximal esophageal circular muscle, cricopharyngeus muscle and the thyropharyngeal muscle, and the pressure is gradually increasing in order. Goyal et al. compared the manometric data from three different source of upper esophageal sphincter and concluded that the peak high-pressure zone lies above the anatomical extent of the cricopharyngeus muscle²¹. Although the cricopharyngeus muscle only 1 to 2 cm wide, the high pressure-zone may be 2.5–4.5 cm in length²². Thus, patients with cricopharyngeus achalasia needed to be dilatated not only the cricopharyngeus muscle, but also the entire high-pressure upper esophageal sphincter zone. The ordinary urinary catheter with only 2 cm in length will make the expansion insufficient. When the balloon slowly passed through the upper esophageal sphincter, muscles that exceed the balloon will quickly return to close status after transient dilatation. So, we increased the length of balloon to 4cm, in order to approached the length of upper esophageal sphincter high-pressure zone and to fully dilatated all sours of the it.

Despite the recovery time for oral intake of different foods, including liquid food, mushy food and solid food were shorter in Experimental group with significant statistic differences, the recovery time for oral intake of water was not markedly differ between two groups. Mostly likely, the definition of recovery oral intake of water is to drink without choke. There are many other reasons for choke during drinking, besides the dysfunction of the cricopharyngeus muscle, especially in patients with stroke. Therefore, even when the function of cricopharyngeus muscle recovered, patients might still choke during drinking water for a while.

Despite the total time required for each intervention looks similar between two groups, approximately 30 min per each intervention in both two groups, but the new balloon catheter was used easier than ordinary urinary catheter. We believe it benefits from the characteristics of the new catheter which was made by medical silicone material instead of latex for urinary catheter. A stiffer catheter makes it easier to pass through the high-pressure zone of upper esophageal sphincter. At the same time, due to the single inlet valve of the ordinary urinary balloon catheter, the syringe needs to be used multiple times during operation which increased the time and difficulty of the operation.

Regarding adverse events, at the present study, the rate of mucosal bleeding and laryngeal edema and the pain score were similar in both groups. In P. I. Wu et al²³. study, minor, self-limiting mucosal bleeding was commonly observed during dilatation but none of them neither endoscopic hemostasis nor blood transfusion was required. These results show that, this kind of intervention is a relatively safe and tolerable method for patients with cricopharyngeus achalasia, the new balloon catheter is also as safe as ordinary urinary catheter.

In this study, the physician who was blinded to the study decided whether the dilatation therapy should be terminated or not using the FOIS score system. The FOIS score system is a 7-point ordinal scale which reflects the functional oral intake²⁴. Michael A. Crary, et al have demonstrated that FOIS score system was an independent measure of functional oral intake in prospective study²⁵. In our study, intervention was estimated when FOIS score of participants up to 6 or more which indicates totally oral intake without

special requirements, with or without special diet restrictions. This also be used in ordinary clinical practice as one of the discharge criteria for patients with dysphagia. According to the article from Huai, et al, the clinical outcome of dysphagia patients was considered to be significantly improved when FOIS score up to 3 or more⁵. In this study, the recovery time for FOIS score ≥ 3 in experimental group was shorter than control group indicated that the clinical outcome improved quicker when patients received new type balloon catheter dilatation. Another scale used in this study, EAT-10, is a 10-item self-administered questionnaire about the severity of symptoms of dysphagia and its clinical and social impact²⁶. Previous study has demonstrated that

a final EAT-10 score ≥ 3 was considered as abnormal²⁷. In this study, the mean score of EAT-10 at the termination in experimental group (mean of 3) was lower than control group (mean of 5) with statistically difference. From the result, we can see that not all of participants had a EAT-10 score ≥ 2 when the intervention was terminated. We believed the reason why FOIS score system recovered to normal but EAT-10 system did not may be the psychological feelings and social influences. Although some patients could completely oral intake of water and foods, they still maintained some psychological barriers.

There were still some limitations of our study: Firstly, this study used the EAT-10 and FOIS scores to clinical evaluated the swallowing function, and in future studies we will add gold standards like video-fluoroscopic swallowing study (VFSS) or video-endoscopy swallowing study (VSS) examinations. Secondly, this study was focused on the patients with dysphagia after stroke. But the degree of dysphagia and the recovery ability are variant according to the location and distribution of stroke. In future studies, we will conduct a subgroup analysis of patients with brain stroke in different locations.

In conclusion, dilation intervention using this new balloon catheter improves more and faster than using ordinary urinary catheter in patients with cricopharyngeus achalasia after stroke. This new type balloon catheter can be recommended for clinical practices.

Declarations

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Author's contributions

Substantial contributions to the conception or design of the work: Fanghua Gong, Yeyu Cai

Acquisition, analysis, or interpretation of data: Tingting Hui, Zhaohui Shen, Ailian Chen, Tao Song, Jia Liu, Yacen Wu

Drafted or revised the work: Yeyu Cai, Tingting Hu, Chujuan Liu

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Tables

Table 1 Participants demographic and baseline characteristics.

Participants demographic and baseline characteristics.

Characteristics	Exp (n=26)	Con (n=26)
Age(y), median (IQR)	63 (49 to 79)	53 (21 to 77)
Gender, n male (%)	23 (88)	18 (69)
Cause of dysphagia, n (%)		
Infarction	23 (88)	23 (88)
Hemorrhage	3 (12)	3 (12)
Comorbidities, n (%)		
Hypertension	19 (74)	20 (76)
Diabetes	8 (31)	6 (23)
Coronary heart diseases	5 (19)	3 (12)
Course of dysphagia(d), median (IQR)	26 (7 to 90)	28 (9 to 90)
FOIS, median (IQR) (0 to 7)	2 (1 to 4)	1 (1 to 2)
EAT-10, median (IQR) (0 to 40)	29 (15 to 36)	29 (17 to 36)

Exp=experimental group (using new balloon catheter dilatation), Con=control group (using ordinary urinary catheter dilatation).

Table 2
Effects and complication measurements between group.

Outcomes	Group		<i>p</i> value
	Exp (n = 25)	Con (n = 23)	
Duration for dilatation (d), median (IQR)	7 (5 to 15)	15 (6 to 28)	< 0.001
EAT-10 score, median (IQR)			
Baseline	29 (15 to 36)	29 (17 to 36)	0.850
Termination	3 (2 to 6)	5 (2 to 11)	0.002
Recovery time for FOIS up to 3 or more (d), median (IQR)	3 (1 to 6)	5 (3 to 15)	0.006
Recovery time for oral intake(d), median (IQR):			
Water	5 (1 to 10)	5 (3 to 20)	0.085
Liquid food	4 (1 to 8)	9 (4 to 20)	< 0.001
Mushy food	5 (3 to 10)	10 (5 to 25)	0.001
Solid food	6 (4 to 15)	12.5 (6 to 28)	< 0.001
Complications (n.%)			
mucosal bleeding	1 (4.0%)	5 (21.7%)	0.077
laryngeal edema	1 (4.0%)	6 (26.1%)	0.038
Pain score, median (IQR)	0 (0 to 1)	1 (0 to 2)	0.006
Exp = experimental group (using new balloon catheter dilatation), Con = control group (using ordinary urinary catheter dilatation).			

Figures

Figure 1

Figure and rendering of the new type of balloon catheter (A and C) and No.14 ordinary urinary catheter (B).

Figure 2

Design and flow of participants in study.

Figure 3

Kaplan-Meier curve for the duration of dilation therapy between two groups. * $P < 0.001$