

The Therapeutic Effect of Swallow Training with a Xanthan Gum-Based Thickener in Addition to Classical Dysphagia Therapy in Chinese Patients with Post-Stroke Oropharyngeal Dysphagia: A Randomized Controlled Study

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Abstract

Objective: In patients with post-stroke oropharyngeal dysphagia (PSOD), classical dysphagia therapy (CDT) continues to provide unsatisfactory outcomes and makes it challenging for them to remove the nasal feeding tube. Increasing bolus viscosity helps prevent aspiration in PSOD. However, conventional starch thickeners enhance post-digestion residue. This study aims to evaluate the efficacy of swallow training with xanthan gum-based thickener (XGT) (Softia G, NUTRI Co., Ltd., Yokkaichi, Japan) additional to CDT in Chinese PSOD patients with a nasogastric tube when compared to CDT alone. **Methods:** Patients with PSOD who had a nasogastric tube were randomly assigned to either the experimental group (E-group) or the control group (C-group) in this randomized controlled, single-blind, parallel-group study. Both groups received CDT for 4 weeks. The E-group cases received additional swallow training with a Softia G-prepared hydrogel training material. The Functional Oral Intake Scale (FOIS) and modified volume-viscosity swallow test (M-VVST) for swallowing safety and efficacy according to adjusted Chinese dietary habits were administered before and after treatment. Post-training, both groups' nasogastric tube removal rates were calculated. **Results:** One hundred sixty-seven participants (E-group: 82 and C-group: 85) completed the study. The E-group's median score of FOIS improved significantly than the C-group after training (median = 5 vs. 3, $P < 0.001$). The incidence of coughing, voice changes, oxygen desaturation of 3% or more, pharyngeal residue and piecemeal deglutition in the E-group was significantly lower than that in the C-group ($P < 0.05$). The E-group had 100% nasogastric tube removal, while the C-group had 28.24% ($P < 0.001$). **Conclusion:** Swallow training with XGT Softia G in addition to CDT can promote swallowing safety and efficacy in Chinese patients with PSOD more effectively than CDT alone.

Keywords: Oropharyngeal dysphagia, swallow training, stroke, volume-viscosity swallow test, xanthan gum-based thickener

INSTRUCTION

Post-stroke oropharyngeal dysphagia (PSOD) is a common complication affecting about 45% of patients.^[1] Part of these patients recover their swallowing ability within 2 weeks, but up to 15–18% of patients have long-term swallowing dysfunction.^[2,3] It may lead to chest infection and pneumonia, malnutrition, inability to rehabilitate, increased risk of infection, prolonged length of stay in the hospital, and an increased risk of death.^[4,5]

It was reported that only 65% of stroke patients could resume oral feeding after 1–4 weeks in the hospital, and even after 6 months of follow-up, not all of them could be completely weaned off the nasogastric tube.^[6] However, nasogastric tube feeding in dysphagia patients with stroke compared to avoiding artificial nutrition has no significant effect on death or disability and may lead to increased rates of complications, including nasopharyngeal discomfort, sore mouth or thirst, gastro-esophageal reflux, gastrointestinal symptoms,^[7] tube blockage,^[8] misplaced or dislodged,^[9] and increasing incidence of aspiration pneumonia.^[10] Therefore, removing the tube as soon as possible and resuming independent eating safely has become the goal for various rehabilitation treatments of PSOD.

Currently, classical dysphagia therapy (CDT) is suggested for dysphagia patients after a stroke, which recovers their ability to swallow by enhancing the physiological operation of their swallowing organs. There are a variety of specific techniques, such as oral sensory training,^[11] oral motor training,^[12] airway protection techniques,^[13] low-frequency electrical stimulation,^[14] etc., However, CDT still produce results that are unsatisfying. Some of the therapeutic effects of the techniques may be short-term^[11] and require lengthy treatment periods of up to 52 weeks for severe dysphagia.^[15]

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Additionally, the placement of the electrodes during electrical stimulation therapy is crucial; if done incorrectly, it will have an impact on the treatment's outcomes. Hence, it is essential to create more efficient therapies to enhance oropharyngeal swallowing function following a stroke.

Fluid adaptation (volume and viscosity with thickeners) and texture-modified food are another part of the treatment plan for PSOD.^[16] Thickening agents are employed to keep dysphagia patients' hydration levels stable.^[17] Patient benefits associated with thickening liquids in terms of reducing penetration and aspiration.^[16] Still, these benefits bring with them a risk of post-swallow residue in the pharynx with traditional thickener—modified starch (MS) granules—as viscosity increases.^[18] A new type of thickener, the xanthan gum-based thickener (XGT), can be dissolved in food or liquid to increase bolus viscosity and may thicken a variety of liquids at various temperatures while preserving the transparency of clear liquids, possessing amylase resistance to keep bolus viscosity stable during saliva contact.^[19] According to several research, XGT can increase swallow safety without raising residue.^[17,20-22]

Limited research, however, supports the therapeutic value of swallow training using XGT Softia G in PSOD patients using a nasogastric tube when combined with CDT as opposed to CDT alone. Therefore, the goal of this study aims at addressing the clinical knowledge gap.

MATERIALS AND METHODS

Study design

This was a randomized controlled, single-blind, parallel-group study with trial registration: Chinese Clinical Trial Registry ChiCTR2100043352. The enrolled patients were divided

into the experimental group (E-group) and the control group (C-group) according to the random number table.

Participants

This prospective analysis enrolled 214 patients with PSOD recruited consecutively between March 2018 and September 2020. Figure 1 displays the case recruiting procedure.

Inclusion criteria were as follows: 1) the occurrence of a cerebrovascular accident with hemorrhagic or ischemic infarction confirmed with computed tomography or magnetic resonance imaging for approximately 7 days to 3 months, with the course of the indwelling nasogastric tube being no more than 90 days; 2) 18–80 years old; and 3) Functional Oral Intake Scale (FOIS) [See Supplemental Table 1] evaluated as grade 1–3.

Exclusion criteria were as follows: 1) a previous neurological condition that could cause dysphagia; 2) an existing pulmonary infection at the time of admission; and 3) collaborators with severe mental or cognitive impairment.

Procedure

Modified Volume Viscosity Swallow Test (M-VVST)

The volume-viscosity swallow test (V-VST)^[23] is a bedside method to screen patients for dysphagia, to identify clinical signs of impaired safety and efficacy of swallowing, and to select the appropriate bolus volume and viscosity to achieve the highest safety and efficacy of deglutition.^[24] In a validation study of the V-VST, the sensitivity and specificity for clinical signs of impaired safety of swallowing (aspiration or penetration) were 88.2% and 64.7%, respectively, and a sensitivity of 100% in recognizing patients with aspiration was subsequently confirmed by videofluoroscopy study (VFSS).^[23] Nevertheless, the bolus volume seems large for Chinese people

Table 1: Patient characteristics at baseline

Characteristics	Experimental Group (n=82)	Control Group (n=85)	t/ χ^2 value	p
Age, years old	67.39±7.81	66.92±8.65	0.370	0.712
Gender, male	45 (54.9)	50 (58.8)	0.256	0.607
Disease duration, days	43.06±15.20	41.28±15.24	0.755	0.451
Duration of retention nasogastric tube, days	41.48±14.40	39.99±14.54	0.664	0.508
Risk factors				
Hypertension	64 (78.0)	60 (70.6)	1.215	0.270
Diabetic	56 (68.3)	49 (57.6)	2.026	0.155
Atrial fibrillation	12 (12.6)	15 (17.6)	0.280	0.597
Dyslipidemia	50 (61.0)	57 (67.1)	0.671	0.431
Smoking	34 (42.5)	33 (38.8)	0.121	0.728
Drinking	19 (23.2)	23 (27.1)	0.335	0.563
Type of stroke			0.113	0.736
Ischemic	51 (61.2)	55 (64.7)		
Hemorrhagic	31 (38.8)	30 (35.3)		
Stroke lesions			0.741	0.864
Cerebral lobe	23 (28.0)	24 (28.2)		
Basal ganglia	34 (41.5)	31 (36.5)		
Cerebellum	7 (8.5)	10 (11.8)		
Brain stem	18 (22.0)	20 (23.5)		

considering their small bite eating and careful tasting habits. For better cooperation by Chinese people, researchers modified the V-VST procedure with a smaller bite size, a uniform thickener concentration, and a new type of thickener, which is still high in sensitivity.^[25,26]

The modified V-VST was performed at the patient's bedside using liquid boluses of different viscosities (low, moderate, and high viscosity) at increasing volumes (3, 5, and 10 ml). The low viscosity was obtained by adding 1.0 g (74–78 mPa-s) of a new generation of thickener based on xanthan gum (Softia S, NUTRI Co., Ltd., Yokkaichi, Japan) to 100 ml of mineral water at room temperature; the moderate and high viscosities were obtained by adding 2.0 g (203–208 mPa-s) and 3.0 g (361–381 mPa-s), respectively, of thickener to 100 ml mineral water. The test started at moderate viscosity, and if any of the safety variables were altered, it continued with high viscosity. If no safety alterations were observed, the test continued at low viscosity and high viscosity [Figure 2].

Training materials and process

All the participants received the CDT for 30 minutes each time, twice a day, 5 days per week, for 4 weeks. The E-group received the additional swallow training twice a day, 20 minutes each time, for a total of 4 weeks. All participants were evaluated before and after the whole training. The nasogastric tube removal rate was calculated in both groups post-training. The assessments were performed by two trained nurses who had received professional training to use the methods in terms of the basic theory and standard methods of screening for dysphagia and were unaware of exact grouping. The training was supervised by a senior speech dysphagia therapist, who had learned specialized knowledge from school, practiced for years in a standard stroke unit, and passed the National Health Professional and Technical Qualification Examination for the attending level.

Classical dysphagia training

CDT includes oral sensation and motor training, airway protection techniques, and low-frequency electrical stimulation therapy. [Details see Supplemental file 1].

Swallow training with Xanthan gum thickener

The training material for the experimental group was obtained by adding 1.5 g of the new generation of food texture modification based on xanthan gum (Softia G, NUTRI Co., Ltd., Yokkaichi, Japan) to 200 ml boiled water, stirred and cooled to form a hydrogel, and set aside without adding any food. Notes for this additional training contain the following: sip volume, total food intake volume, eating speed, posture and “how to eat” [Details see Supplemental file 2].

Clinical measurements

Functional Oral Intake Scale (FOIS)

According to the patient's oral intake, the FOIS was used for swallowing function grade [Supplemental Table 1].

Incidence of safety and efficacy changes

During the M-VVST, impaired safety of swallow signs included coughing during or after eating, voice changes, or decreased oxygen saturation $\geq 3\%$. Oral and pharyngeal residue and piecemeal deglutition were signs of impaired efficacy. Complaining about inability to swallow completely or repeated swallowing or aspiration after the swallow (within 1–2 min after swallowing) were residual signs in the pharynx.^[27]

Rate of tube removal

The indication for removing the nasal feeding tube was as follows: If the patient could eat more than 200 ml of mushy or texture-modified food in 30–40 min each meal for three consecutive days without swallow safety or efficacy change, the nasal feeding tube could be removed.

Statistical analysis

Categorical variables were presented in number (percentage), continuous variables in mean \pm standard deviation, and median data. Statistical analysis was performed using SPSS 25.0 software. Comparisons of continuous variables were evaluated using an independent sample *t* test, and comparisons of rate were assessed using the χ^2 test or Fisher exact test. The Mann–Whitney U test or Wilcoxon signed-rank test was performed for the ranked data. A value of $P < 0.05$ was statistically significant.

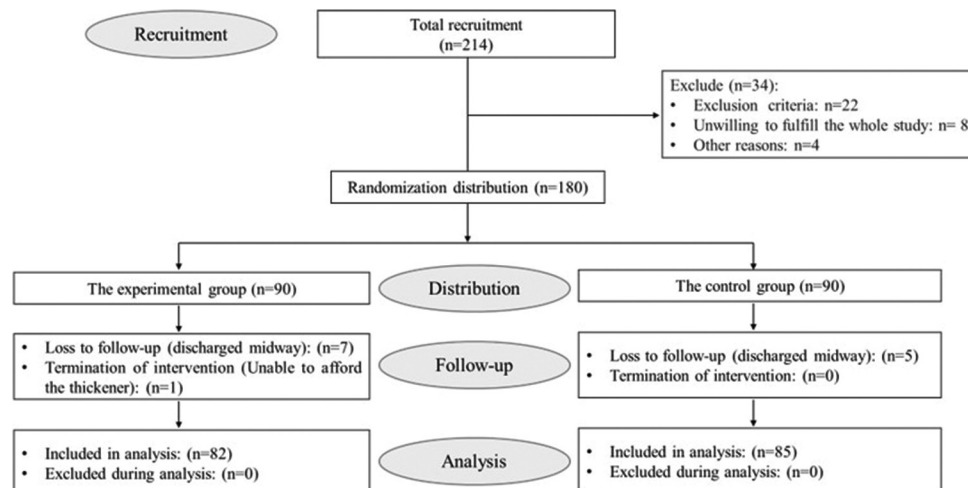


Figure 1: The number of participants at each step during the study, including recruitment, randomization distribution, follow-up, and analysis

RESULTS

Sample description

In total, 34 patients were excluded from the study; 22 did not meet the inclusion criteria, 8 were not willing to fulfill the whole trial, and 4 for other reasons [Figure 1]. According to the random number table, the remaining 180 patients were divided into the E-group and the C-group, 90 patients equally. Eight participants (7 discharged midway and 1 was unable to afford the thickener) in the E-group and five (discharged midway) in the C-group were lost to follow-up, and the follow-up rate was 92.78%. Recruitment, randomization distribution, follow-up, and analysis have been reported in a flow chart stating the number of participants at each step [Figure 1].

The average age, gender, average duration of disease, intermediate course of retention of the nasogastric tube, disease risk factors, stroke type, and stroke lesions of the

patients showed no significant differences between the two groups ($P > 0.05$) [Table 1].

FOIS scores

After treatment, the median FOIS level was significantly higher than before treatment in the C-group (2 vs. 3, $Z = -8.210$, $P < 0.001$) and E-group (2 vs. 5, $Z = -8.119$, $P < 0.001$). Compared with the C-group (median = 3), the median FOIS level of the E-group (median = 5) was significantly higher after treatment ($U = 736$, $P < 0.001$) [Figure 3].

Changes in safety

In the C-group, coughing was observed in 65 patients pre-training, voice changes in 34 patients, and oxygen desaturation of 3% or more in 23 patients. The numbers decreased to 32, 14, and 10 for the three security signs, respectively, post-training, and the differences were significant ($P < 0.001$, $P = 0.001$, $P = 0.012$, respectively) [Table 2].

Meanwhile, we found that coughing declined from 60 patients to 6 post-training, voice changes from 32 to 4, and oxygen desaturation by $\geq 3\%$ from 20 to 2 patients in the E-group (all $P < 0.001$). Compared with the C-group, the incidence of changes in safety in the E-group was lower after treatment ($P < 0.001$, $P = 0.023$, $P = 0.032$, respectively) [Table 2].

Changes in efficacy

After conventional training in the C-group, the number of oral residue cases decreased from 13 to 2, pharyngeal residue decreased from 42 to 24, and piecemeal deglutition decreased from 25 to 14 patients ($P = 0.005$, 0.005 , 0.045 , respectively) [Table 2]. After 4 weeks of additional ingestion training in the E-group, oral residue, pharyngeal residue, and piecemeal deglutition decreased from 12 to 0, 44 to 0, and 28 to 2, respectively (all $P < 0.001$). Meanwhile, after treatment, the occurrence of pharyngeal residue and piecemeal deglutition in the E-group was significantly lower than that of the C-group after training ($P < 0.001$, $P = 0.003$, respectively). However, we found no significant differences in the occurrence of oral residue between the two groups post-training ($P = 0.497$) [Table 2].

Removal of nasal feeding tube

After treatment, all 82 patients in the E-group removed their nasogastric tubes, a rate of 100%. In the C-group, the rate was 28.24%. The difference was statistically significant ($P < 0.001$) [Table 2].

DISCUSSION

CDT is usually given to conscious stroke survivors with dysphagia in the oropharyngeal phase, and most of the training programs have been recognized by researchers,^[11-14] but there is a lack of large-sample and high-quality with evidence-based medicine studies, and we still find that in the clinic, the contribution of these treatments alone to the removal rate of patients carrying nasogastric feeding tubes is unsatisfactory. As a result, there is an urgent need to continue exploring new treatments or combining them with established approaches,

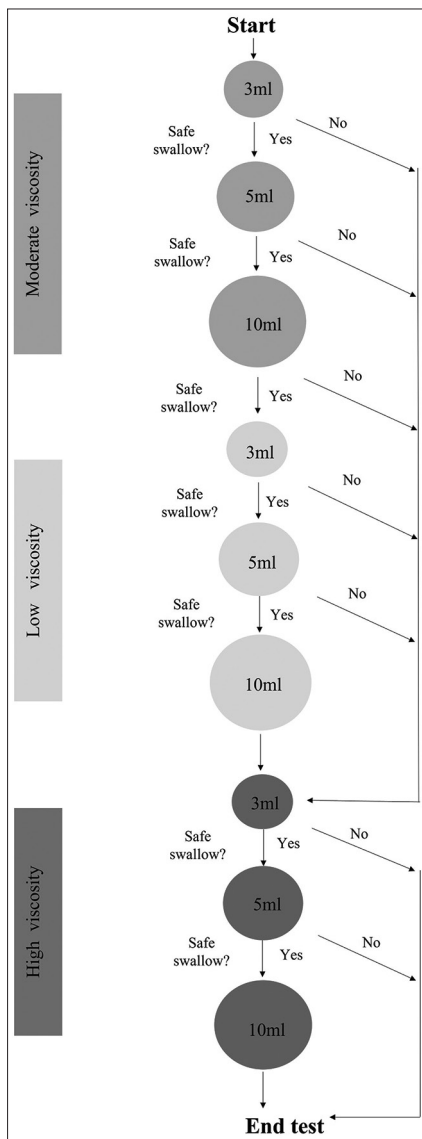


Figure 2: The procedure of bolus volume and viscosity administration during the Modified V-VST. V-VST: volume-viscosity swallow test

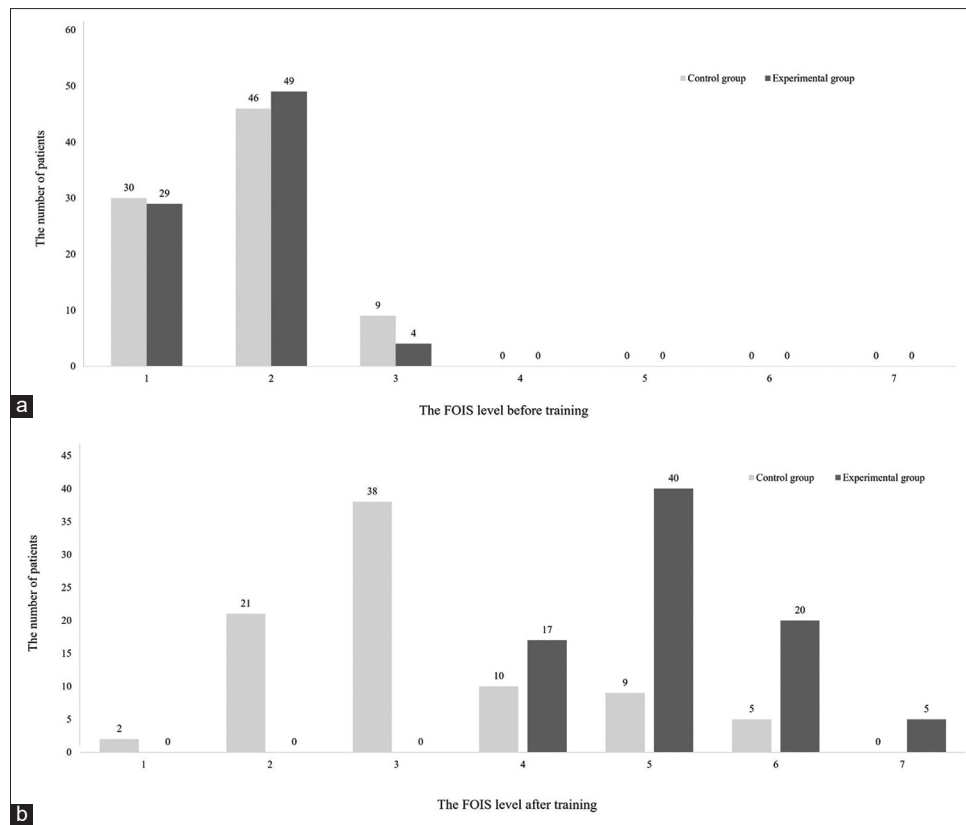


Figure 3: The FOIS level distribution in the control and the experimental group before (a) and after (b) training. The median level in the experimental group was higher than that in the control group, with a statistically significant difference after training ($P < 0.001$). FOIS: Functional Oral Intake Scale

Table 2: The incidence of safety and efficacy changes in the experimental group and the control group before and after training according to M-VVST and the rate of nasal feeding tube removal after training in the two groups.

Characteristic	Experimental Group (n=82)		Control Group (n=85)		p ^{a,b}	χ ² value ^c	p ^c
	Pre	Post	Pre	Post			
<i>Changes in safety</i>							
Coughing [n (%)]	60 (73.17)	6 (7.32)	65 (76.47)	32 (37.65)	<0.001 ^{a*} , <0.001 ^{b*}	21.843	<0.001 [*]
Voice changes [n (%)]	32 (39.02)	4 (4.88)	34 (40.00)	14 (16.47)	0.001 ^{a*} , <0.001 ^{b*}	-	0.023 ^{d*}
Oxygen desaturation by ≥3% [n (%)]	20 (24.39)	2 (2.44)	23 (27.06)	10 (11.76)	0.012 ^{a*} , <0.001 ^{b*}	-	0.032 ^{d*}
<i>Changes in efficacy</i>							
<i>Residue</i>							
Oral residue [n (%)]	12 (14.63)	0 (0)	13 (15.29)	2 (2.35)	0.005 ^{a*} , <0.001 ^{b*}	-	0.497 ^d
Pharyngeal residue [n (%)]	44 (53.66)	0 (0)	42 (49.41)	24 (28.24)	0.005 ^{a*} , <0.001 ^{b*}	-	<0.001 ^{d*}
Piecemeal deglutition [n (%)]	28 (34.15)	2 (2.44)	25 (29.41)	14 (16.47)	0.045 ^{a*} , <0.001 ^{b*}	-	0.003 ^{d*}
Removal of nasal feeding tube [n (%)]	-	82 (100)	-	24 (28.24)	-	92.157	<0.001 [*]

a: Comparison of index for the control group before and after training. b: Comparison of index for the experimental group before and after training. c: Comparison of index between the experimental group and the control group after training. d: Fisher exact test. Fisher exact test has no χ² value. *: The difference was statistically significant. Pre: before training; Post: after training

with the goal of removing tubes as soon as possible, ensuring security and effective swallowing, and restoring transthoracic feeding.

Texture modification, such as an increase in bolus viscosity using thickeners—mainly MS granules—has become one of the most common forms of intervention for PSOD and is widely considered essential for promoting safe and efficient

swallowing.^[18,20] Increased bolus viscosity is associated with increased swallowing safety and reduced pneumonia episodes.^[18,24] On the other hand, the growing thickness may impair swallowing efficacy by raising oropharyngeal residue prevalence.^[18] Moreover, starches easily decomposed into sugars after entering the human body to cause changes in blood sugar, so they are not suitable for diabetic patients.^[28]

In contrast with MS, XGT used in this study has a better taste and a stable viscosity over time and is not affected by amylase.^[19] Previous studies found that increasing bolus viscosity with this XGT significantly improved swallowing safety in post-stroke patients with oropharyngeal dysphagia in a viscosity-dependent manner without increasing the prevalence of pharyngeal residue^[17,20-22]. However, these studies were performed in only one single visit, which meant that they were not longitudinal studies, and there was no mention of whether the patients had a nasogastric tube or not, so the findings could not be regarded as a valid treatment effect. We are also the first to propose using a Softia G thickener and water mixture as a swallowing training material, and we are investigating if combining this swallowing-Softia G training with the CDT improves therapeutic efficacy over the CDT alone.

In this study, patients with oropharyngeal dysphagia after a stroke with a nasogastric tube were enrolled as the research subjects. Additional swallow training was conducted using a new type of XGT that produced less residue. We designed only two groups due to the potential increased risk of oropharyngeal retention and aspiration pneumonia from swallowing traditional thickeners for concentrated training in patients with nasogastric tubes as well as the difficulty of removing traditional swallowing treatments in actual clinical practice. We selected two observation points before and 4 weeks after treatment for the assessments. The modified volume-viscosity swallow test (M-VVST) and FOIS were administered. The results showed that, when compared to the C-group, which only received conventional swallowing function training, the E-group, which also received Softia G for swallow training, had improved swallowing safety and efficacy, as reductions in cough, voice changes, and oxygen desaturation by $\geq 3\%$. The residue in the pharyngeal phase and piecemeal deglutition also decreased significantly. After 4 weeks of swallow training, all the patients in the E-group removed the nasogastric tube and resumed oral feeding, and the FOIS scale rating was significantly improved. Nevertheless, most cases in the E-group recovered to FOIS level 4 (20.73%), 5 (48.78%), or 6 (24.39%), and only five patients resumed a total oral diet with no restrictions, which suggested that 4 weeks' training may not be long enough to achieve satisfactory results.

Our study used a VVST tailored for Chinese eating patterns, which was unlike Clavé suggested.^[17] Solute, volume, and viscosity were changed. The new thickener was also performed as the test material.

During the V-VST process, the participant is required to take 5 ml, 10 ml, and 20 ml bites in sequence in sequence to pick the safest and most effective bite size for the patient. Some patients still aspirate even if they take the smallest mouthful of 5 ml during the test, and it's tough to clear or absorb slowly, which increases the rates of complications.^[29,30] Considering Chinese people's predilection for small bites and meticulous tasting, this study modified the initial bite size to 3, 5, and 10 ml.

Due to cultural differences, food form terminology like nectar or pudding often misleads doctors and therapists, resulting in

varying food viscosity across institutions. This study referred to the Japanese Society of Swallowing's 2013 version^[31] for xanthan gum viscosity levels (1%, 2%, and 3%). Each character's viscosity was different. The range interval helped compare xanthan gum products.

This study did not find significant differences in oral residue incidence between the two groups post-training. However, the prevalence of oral residue decreased significantly in both groups before and after treatment. In order to reduce oral residue in PSOD patients, both the CDT by itself and the CDT in conjunction with swallow training produced optimal therapeutic outcomes. In other words, we did not discover any distinct advantages of additional swallow training with XGT for PSOD patients over only performing conventional training in terms of enhancing the efficacy function of the oral residual.

This study has several limitations: First, we only compared the results assessed by the rating scale and M-VVST and did not systematically evaluate patients by VFSS, which is not available and relatively expensive for most Chinese patients, meaning that the collection of subject data took longer, and the smaller sample size inevitably caused bias and affected the reliability of the results. In the future, we will combine VFSS with the present methodology with a larger sample size to observe the safety and efficacy of swallowing function after adding XGTs based on M-VVST. Except for the thickening of liquids, according to the new guidelines,^[25] we will add an evaluation of swallowing texture-modified foods to guide the formulation of subsequent dietary plans. Simultaneously, the evaluation of swallowing function and recovery indicators, such as the incidence of pneumonia, serum nutritional indicators, quality of life, and mentality, is warranted. Second, the V-VST is a bedside screening method, recognized as an assessment of superior sensitivity and specificity for detecting dysphagia, but few publications have studied the sensitivity and specificity of the M-VVST, modified for Chinese eating habits, which urge further analysis. Third, we set two visits for evaluation in this study. More follow-ups should be performed to observe long-term effects. Fourth, the method by which the CDT is paired with Softia G-swallowing training, as well as whether it is the additional swallowing training itself that plays a specific role, or the specific training material, or both of them, merits further investigation.

In conclusion, the findings of this longitudinal study fill a clinical knowledge gap and suggest that swallow training with XGT Softia G added to CDT is safer and more effective (except for oral residue) in patients with stroke who have feeding tube-dependent dysphagia and is more conducive to removing the nasogastric tube and resuming independent eating than CDT alone. The M-VVST as an assessment for Chinese people is more in line with their dietary habits. Given the scarcity of published studies on this clinical problem, swallow training with XGT Softia G combined with CDT deserves further investigation in patients with PSOD carrying nasogastric tube and have profound to severe feeding tube-dependent dysphagia

because it is safe when administered according to the protocol used in this study and it appears to be efficacious; also it is simple to implement via trained therapists.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Statements of ethics

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethical Committees of Nanjing Brain Hospital on Feb.28th 2018.

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Conflicts of interest

There are no conflicts of interest.

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Supplemental Table 1: Functional Oral Intake Scale (FOIS)

Levels	Criteria
Level 1	Nothing by mouth
Level 2	Tube-dependent with minimal attempts of food or liquid
Level 3	Tube-dependent with consistent oral intake of food or liquid
Level 4	Total oral diet of a single consistency
Level 5	Total oral diet with multiple consistencies but requiring special preparation or compensations
Level 6	Total oral diet with multiple consistencies without special preparation but with specific food limitations
Level 7	Total oral diet with no restrictions

SUPPLEMENTAL FILE 1

Training materials and process

Classical dysphagia training

- Oral sensation training: Cold stimulation training; Olfactory stimulation training; Taste stimulation training; Oral and facial vibration stimulation; Air-pulse stimulation; K-point stimulation.
- Oral motor training: Lip and tongue exercise; Tongue pressure resistance training; Tongue suction device; Masako therapy; Shaker exercise.
- Airway protection training: Mendelssohn swallow exercise; Supraglottic swallow exercise; Super-supraglottic swallow exercise.
- Low-frequency electrical stimulation therapy: A low-frequency electrical device named VitalStim was purchased from the United States. The neuromuscular electric stimulator was used for treatment, and the stimulation electrode was placed in the lower jaw of the patient. To stimulate the extra lingual and pharyngeal muscles of the neck, the bidirectional square wave width was 700 ms, the frequency range was 30–80 Hz, and the intensity was 7–10 mA.

SUPPLEMENTAL FILE 2

Notes for swallow training with Softia G:

- Sip volume
The intake of food training started from 3 to 5 ml based on the results of M-VVST, and then increased to 10 ml to 20 ml. Ingestion was stopped as soon as safety changes occurred.
- Total food intake volume
The total volume started from 50 to 80 ml. It gradually increased about 60 ml each time, every two days, until the patient reached regular food intake, at which 200–300 ml is appropriate.
- Eating speed
The patients needed to eat carefully to prevent food from entering the trachea; 30–40 min was suitable for the whole process, with sufficient rest time. If safety or efficacy changes occurred, the patient was asked to stop eating immediately.
- Posture
Sitting is the ideal posture. When it was not possible, we rolled the head of the bed 30–60°, tilted the neck forward, and padded the shoulders on the hemiplegic side, and the feeder was on the healthy side.
- How to eat
We assisted the patient in putting food on the middle and back part of the tongue and gently pressed the tongue with the back of a spoon to stimulate swallowing. After swallowing food each time, we had the patient do empty eating several times or drink a little water (<1 ml) after each swallowing, and then we fed the second mouthful after confirming that the first one had been swallowed completely.