Effect of direct feeding training with xanthan gum-based thickener modified food on the recovery of swallowing safety and efficacy in Chinese patients with post-stroke dysphagia: a randomized controlled study

Yao Wang  
Nanjing Brain Hospital

Jiang Rao  
Nanjing Brain Hospital

Jie Zhang  
Nanjing Brain Hospital

Hui-min Zhu  
Nanjing Brain Hospital

Li Liu  
Nanjing Brain Hospital

Shao-chun Huang (✉ hsc70518@126.com)  
Nanjing Brain Hospital

Research Article

Keywords: Stroke, Dysphagia, Volume-viscosity swallow test, Direct feeding training, Xanthan gum-based thickener.

DOI: https://doi.org/10.21203/rs.3.rs-426723/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

Background: Increasing the bolus viscosity of food can protect patients with post-stroke dysphagia (PSD) from aspiration. However, conventional starch thickeners increase post-deglutition residue. The aim of this study was to assess the therapeutic effect of direct feeding training with xanthan gum-based thickener (Softia G, NUTRI Co., Ltd., Yokkaichi, Japan) modified food in Chinese PSD patients with a nasogastric tube.

Methods: This randomized controlled study enrolled PSD patients with a gastric tube, who were equally divided into the experimental group (E-group) and the control group (C-group) according to a random number table. Both groups were given traditional training for dysphagia. The E-group cases received additional direct feeding training with Softia G-modified training food. 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 for four weeks. The nasogastric tube removal rate was calculated in both groups post-training.

Results: A total of 167 participants completed the study, 82 cases in the E-group and 85 in the C-group. After treatment, the FOIS score of the E-group (median = 5) was better than that of the C-group (median = 3) ($p < 0.001$). In the E-group, the incidence of coughing, voice changes, and oxygen desaturation of 3% or more was 7.32%, 4.88%, and 2.44%, significantly lower than in the C-group (37.65%, 16.47%, and 11.76%, $p < 0.05$). The incidence of pharyngeal residue and piecemeal deglutition were 0% and 2.44%, respectively, in the E-group; the differences between the groups were statistically significant (The C-group: 28.24% and 16.47%, $p < 0.05$). Moreover, the gastric tube removal rate was 100% in the E-group and 28.24% in the C-group ($p < 0.001$).

Conclusion: Direct feeding training with xanthan gum-based thickener Softia G-modified food can effectively promote swallowing safety and efficacy in Chinese patients with PSD. M-VVST is more applicable to the Chinese population than conventional V-VST.

Trial registration: Chinese Clinical Trail Registry ChiCTR2100043352, 11/02/2021, Retrospectively registered.

Background

Post-stroke dysphagia (PSD), or difficulty swallowing after stroke, is a common complication affecting about 28% to 65% of patients in the acute period [1-4]. Nearly half of these patients recover their swallowing ability within two weeks, but up to 15% of patients have long-term swallowing dysfunction [5]. Dysphagia 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 [6, 7].

Unfortunately, so far, there is limited data that can be used to predict dysphagia, and the efficacy of many rehabilitation treatments remains uncertain [7, 8]. Direct feeding training is one method of direct
rehabilitation swallowing training commonly used in clinical practice. Still, blind ingestion increases the risk of aspiration and aspiration pneumonia in patients with dysphagia. To ensure patients’ safe intake, the use of texture-modified foods and thickened liquids, combined with intensive swallowing training, has become a cornerstone of clinical practice to address dysphagia [9]. However, to date, ingestion training has often been conducted based on individual recovery of swallowing function, which delays the removal of the nasal feeding tube and oral feeding to a certain extent. Therefore, if the patient can transition from direct feeding training to oral feeding as soon as possible under the premise of ensuring safety and effectiveness, they may improve their swallowing function in a short period, and it will be of great significance for reducing the incidence of dysphagia complications.

Videofluoroscopy (VFS) is the gold standard for studying the oral and pharyngeal mechanisms of dysphagia and aspiration [10]. However, it is unfeasible to perform VFS on every patient at risk for or with suspected dysphagia. The volume-viscosity swallow test (V-VST) [11] 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 [12]. 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 VFS [11]. Nevertheless, the bolus volume seems large for Chinese people 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 [13, 14].

It is essential to provide patients with suitable liquids or foods for effective and safe swallowing. There are a variety of guidelines for food preparation [13, 15-17]. There are patient benefits associated with thickening liquids in terms of reducing penetration and aspiration. 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 [9]. A new type of thickener, xanthan gum-based thickener (XG), can be dissolved in food to increase bolus viscosity, improving swallow safety without increasing residue [18-20].

Limited evidence shows the therapeutic effect of texture-modified foods or liquid with XG as direct feeding training material for PSD patients with a nasal feeding tube. This study aims to determine the suitable volume of food for direct ingestion training with the new thickener XG to observe the safety and efficacy changes before and after training using modified V-VST to evaluate swallowing functional recovery in patients with PSD.

**Methods**

**Study design**

This was a randomized controlled study. The enrolled patients were divided into the experimental group (E-group) and the control group (C-group) according to the random number table method. All the participants received the traditional training for dysphagia for four weeks, five days per week, twice a day,
30 minutes each time. The E-group received the additional direct feeding training twice a day, 20 minutes each time, for a total of four weeks. All participants were evaluated using the Functional Oral Intake Scale (FOIS) and the modified V-VST before and after training. The nasogastric tube removal rate was calculated in both groups post-training. **Participants**

This prospective analysis enrolled 214 patients with PSD recruited consecutively from Nanjing Brain Hospital between January 2016 and September 2020.

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 seven days to three 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) 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.

In total, 34 patients were excluded from the study. According to the random number table method, the remaining 180 patients were divided into the experimental group (E-group) and the control group (C-group), with 90 patients in each group. Eight participants in the E-group and five 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).

**Procedure**

**Modified Volume Viscosity Swallow Test (M-VVST)**

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). The differences between V-VST [11] and M-VVST were that we used a lower sip volume to begin with, different viscosities, and a new generation of thickener.

**Training materials and process**

*Traditional training*
Oral sensation and motor training include oral muscle training, sucking, larynx lifting training, pharyngeal ice stimulation, empty swallowing training, and Mendelssohn training.

Breathing and cough training was performed.

We also performed language, writing, gesture stimulation, and pronunciation training.

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 extralingual 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.

**Direct feeding training**

- **Training food preparation**

The training food 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.

- **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.

**Clinical measurements**

**Functional Oral Intake Scale (FOIS)**

According to the patient’s oral intake, the FOIS was used for swallowing function grade (Table 2).

**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 [21]. The incidence of safety and efficacy changes were compared between the two groups.

**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 signs of aspiration, the nasal feeding tube could be removed.

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. The training was supervised by a senior speech 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.

**Statistical analysis**

Categorical variables were presented in number (percentage), continuous variable 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 $\chi^2$ 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 considered to be statistically significant.

**Results**

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 \((p < 0.001, p = 0.001, p = 0.012, \text{respectively})\) (Table 3).

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 \((p < 0.001)\). Compared with the C-group, the incidence of changes in safety in the E-group was lower after treatment \((p < 0.001, p = 0.023, p = 0.032, \text{respectively})\) (Table 3).

**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 \((p = 0.005, 0.005, 0.045, \text{respectively})\) (Table 3). After 4 weeks of additional ingestion training in E-group, oral residue, pharyngeal residue, and piecemeal deglutition decreased from 12 to 0, 44 to 0, and 28 to 2, respectively \((p < 0.001)\). Meanwhile, after treatment, the occurrence of pharyngeal residue and piecemeal deglutition in the E-group was significantly lower than that of C-group after training \((p < 0.001, p = 0.003, \text{respectively})\). However, we found no significant differences in the occurrence of oral residue between the two groups post-training \((p = 0.497)\) (Table 3).

**Removal of nasal feeding tube**

After treatment, all 82 patients in the E-group removed their nasogastric tubes, a rate of 100.00%. In the C-group, the rate was 26.67%. The difference was statistically significant \((p < 0.001)\) (Table 3).

**Discussion**

Post-stroke dysphagia (PSD) is a common complication of acute stroke and is associated with increased mortality, morbidity, and institutionalization due in part to aspiration, pneumonia, and malnutrition [22]. An indwelling nasogastric tube is routinely given in the clinic to ensure nutrition and oral drug intake and prevent aspiration. However, compared to avoiding artificial nutrition, early nasogastric tube feeding in dysphagic stroke patients has no significant effect on death or disability and may lead to increased rates of complications [23], including nasopharyngeal discomfort, sore mouth or thirst, gastro-esophageal reflux, gastrointestinal symptoms [24], tube blockage [25], tube misplacement or dislodging [26], and
increasing incidence of aspiration pneumonia [27]. Therefore, removing the tube as soon as possible and resuming independent eating has become the goal of various PSD rehabilitation treatments.

The use of thickeners makes it possible for PSD patients to eat by mouth as soon as possible. Texture modification, such as an increase in bolus viscosity using thickeners—mainly modified starch (MS) granules—has become one of the most common forms of intervention for PSD and is widely considered essential for promoting safe and efficient swallowing [9, 19]. Increased bolus viscosity is associated with increased swallowing safety and reduced pneumonia episodes [9, 12]. On the other hand, the increasing thickness may impair swallowing efficacy by increasing oropharyngeal residue prevalence [9]. 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].

This study’s test thickener was xanthan gum-based thickener (XG), which has recently been developed. In contrast with MS, XG has a better taste and a stable viscosity over time and is not affected by amylase [29]. Other studies found that increasing bolus viscosity with this XG thickener significantly improved swallowing safety in post-stroke patients with oropharyngeal dysphagia in a viscosity-dependent manner without increasing the prevalence of pharyngeal residue [18-20].

However, these studies were performed in only one single visit, 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.

In this study, patients with dysphagia after stroke with a nasal feeding tube were enrolled as the research subjects. A new type of xanthan gum-based thickener that caused less residue was used for direct ingestion training. We selected two observation points before and four weeks after treatment for the assessments. The modified volume-viscosity swallow test and Functional Oral Intake Scale were administered. The results showed that compared with the control group, which received conventional swallowing function training, the experimental group, which received Softia G for direct feeding training, had improved swallowing safety and efficacy, which was manifested by significant reductions of cough, voice changes, and oxygen desaturation by ≥ 3%. The residue in the pharyngeal phase and piecemeal deglutition also decreased significantly. The results were similar to those of previous studies [18-20], but we did not significantly improve the residue in the oral phase. After four weeks of direct feeding training, all the patients in the experimental 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 (20.7%), 5 (48.8%), or 6 (24.4%), and only seven patients resumed a total oral diet with no restrictions, which suggested that four weeks’ training may not be long enough to achieve satisfactory results.

Unlike the V-VST that Clave [11] suggested, our study used a modified volume-viscosity swallow test according to the Chinese eating habits. The modified parts included changes in solute, volume, and viscosity. The advantages of thickener XG have been described above.
During the V-VST process, the participant is required to take 5 ml, 10 ml, and 20 ml bites in sequence when the safety indicators are not compromised to choose the safest and most effective bite size for the patient. In clinical applications, some patients still experience aspiration even if they take the smallest bite of 5 ml during the test, and it is difficult to clear or absorb slowly, which increases the rates of complications [30, 31]. Therefore, this study changed the initial bite size to 3 ml, 5 ml, and 10 ml as the maximum bite size considering the Chinese people's preference for small-bite eating and careful tasting.

V-VST uses water, nectar, and pudding samples as the viscosity test liquids. However, owing to the differences between Chinese and Western cultures, food form words such as nectar or pudding often mislead clinicians and therapists, resulting in inconsistent food viscosity for patients in different institutions. Therefore, this study referred to the viscosity of xanthan gum products specified by the Japanese Society of Swallowing in the 2013 edition [17] and quantified it into three viscosity levels (1%, 2%, and 3%). Each character had a corresponding viscosity value. The range interval provided a reference basis for different 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. Both the traditional and the direct ingestion training had ideal therapeutic effects in reducing oral residue in PSD patients. On the other hand, we did not find special superiority of direct feeding training for PSD patients in improving the swallow efficacy function of oral residue compared with traditional training.

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 VFS, 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 VFS with the present methodology to observe the safety and efficacy of swallowing function after adding xanthan gum-based thickeners based on M-VVST. Except for the thickening of liquids, according to the new guidelines [13], 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 need further investigation. Third, we set two visits for evaluation in this study. More follow-up should be performed to observe long-term effects. Fourth, this training method's mechanism of swallowing function recovery will be the next area for us to explore.

Conclusions
Compared with traditional training for dysphagia, using xanthan gum-based thickener Softia G to prepare direct feeding training food allows PSD patients with nasal feeding tubes to reduce the incidence of safety and effectiveness (except oral residue) changes in swallowing, conducive to removing the nasal feeding tube and resuming independent eating as soon as possible. The modified V-VST as an assessment for Chinese people is more in line with their dietary habits.

**List Of Abbreviations**

PSD: Post-stroke dysphagia; VFS: Video-fluoroscopy; V-VST: Volume viscosity swallow test; MS: modified starch; XG: Xanthan gum-based thickeners; FOIS: Functional oral intake scale; E-group: The experimental group; C-group: The control group. M-VVST: Modified Volume Viscosity Swallow Test.

**Declarations**

**Ethics approval and consent to participate**

All participants received verbal and written information about our research's purpose and process, that were carried out in accordance with relevant guidelines and regulations, approved by the Ethical Committees of Nanjing Brain Hospital. All individuals provided written, informed consent to participate in the study before the trial.

**Acknowledgements**

We thank the concerned patients, nurses, and doctors for their support. We also thank LetPub (www.letpub.com) for its linguistic assistance during the preparation of this manuscript.

**Availability of data and material**

The dataset may be made available by the corresponding author on reasonable request, subject to permission from the relevant ethics committees at the hospital and university.

**Authors’ contributions**

SCH and LL were responsible for the study design. JZ participated in the intervention training of research nurses. JZ implemented the intervention. SCH, JR, and HMZ collected the data. YW was responsible for the statistical analysis. YW wrote the first draft of the article. All authors read and approved the final manuscript.

**Funding**

This study was funded by Health Science and Technology Development Special Fund Projects of Nanjing (Grant No. YKK18119).

**Consent for publication**
Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

**References**


6. FT C. Poor Nutritional Status on Admission Predicts Poor Outcomes After Stroke. Stroke. 2003; 346:1450-1456; doi:10.1161/01.STR.0000074037.49197.8C.


Tables

Table 1. Patient characteristics at baseline
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Experimental Group ($n = 82$)</th>
<th>Control Group ($n = 85$)</th>
<th>$t/\chi^2$ value</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years old</td>
<td>$67.39 \pm 7.81$</td>
<td>$66.92 \pm 8.65$</td>
<td>0.370</td>
<td>0.712</td>
</tr>
<tr>
<td>Gender, male</td>
<td>45 (54.9)</td>
<td>50 (58.8)</td>
<td>0.256</td>
<td>0.607</td>
</tr>
<tr>
<td>Disease duration, days</td>
<td>$43.06 \pm 15.20$</td>
<td>$41.28 \pm 15.24$</td>
<td>0.755</td>
<td>0.451</td>
</tr>
<tr>
<td>Duration of retention nasogastric tube, days</td>
<td>$41.48 \pm 14.40$</td>
<td>$39.99 \pm 14.54$</td>
<td>0.664</td>
<td>0.508</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>64 (78.0)</td>
<td>60 (70.6)</td>
<td>1.215</td>
<td>0.270</td>
</tr>
<tr>
<td>Diabetic</td>
<td>56 (68.3)</td>
<td>49 (57.6)</td>
<td>2.026</td>
<td>0.155</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>12 (12.6)</td>
<td>15 (17.6)</td>
<td>0.280</td>
<td>0.597</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>50 (61.0)</td>
<td>57 (67.1)</td>
<td>0.671</td>
<td>0.431</td>
</tr>
<tr>
<td>Smoking</td>
<td>34 (42.5)</td>
<td>33 (38.8)</td>
<td>0.121</td>
<td>0.728</td>
</tr>
<tr>
<td>Drinking</td>
<td>19 (23.2)</td>
<td>23 (27.1)</td>
<td>0.335</td>
<td>0.563</td>
</tr>
<tr>
<td>Type of stroke</td>
<td></td>
<td></td>
<td>0.113</td>
<td>0.736</td>
</tr>
<tr>
<td>Ischemic</td>
<td>51 (61.2)</td>
<td>55 (64.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>31 (38.8)</td>
<td>30 (35.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke lesions</td>
<td></td>
<td></td>
<td>0.741</td>
<td>0.864</td>
</tr>
<tr>
<td>Cerebral lobe</td>
<td>23 (28.0)</td>
<td>24 (28.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basal ganglia</td>
<td>34 (41.5)</td>
<td>31 (36.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebellum</td>
<td>7 (8.5)</td>
<td>10 (11.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain stem</td>
<td>18 (22.0)</td>
<td>20 (23.5)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2.** 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

Table 3. 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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Experimental Group</th>
<th>Control Group</th>
<th>$\chi^2$ value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td>Changes in safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coughing [n (%)]</td>
<td>60 (73.17)</td>
<td>6 (7.32)</td>
<td>65 (64.71)</td>
<td>32 (37.65)</td>
</tr>
<tr>
<td>Voice changes [n (%)]</td>
<td>32 (39.02)</td>
<td>4 (4.88)</td>
<td>34 (40.00)</td>
<td>14 (16.47)</td>
</tr>
<tr>
<td>Oxygen desaturation by ≥ 3% [n (%)]</td>
<td>20 (24.39)</td>
<td>2 (2.44)</td>
<td>23 (27.06)</td>
<td>10 (11.76)</td>
</tr>
</tbody>
</table>

| Changes in efficacy | | | | |
| | | | | |
| Residue | | | | |
| Oral residue [n (%)] | 12 (14.63) | 0 (0) | 13 (15.29) | 2 (2.35) | - | 0.497 b |
| Pharyngeal residue [n (%)] | 44 (53.66) | 0 (0) | 42 (49.41) | 24 (28.24) | - | <0.001 b* |
| Piecemeal deglutition [n (%)] | 28 (34.15) | 2 (2.44) | 25 (29.41) | 14 (16.47) | - | 0.003 b |

| Removal of nasal feeding tube [n (%)] | - | 82 (100) | - | 24 (28.24) | 92.157 | <0.001* |

a: Comparison of index between the experimental group and the control group after training.
b: Fisher exact test. Fisher exact test has no $\chi^2$ value.
*: The difference was statistically significant.
Pre: before training; Post: after training.

Figures

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