Effects of Synchronized Neuromuscular Electrical Stimulation (NMES) on the Submental Muscles During Ingestion of a Specified Volume of Soft Food in Patients with Mild-to-Moderate Dysphagia Following Stroke

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Background: Neuromuscular electrical stimulation (NMES) is a method for producing regular contractions of muscles that have been paralyzed. This study aimed to evaluate the effects of synchronized NMES on the submental muscles during ingestion of a specified volume of soft food in patients with mild-to-moderate dysphagia following stroke.

Material/Methods: Eighty-three patients with mild-to-moderate dysphagia following stroke were enrolled and randomly divided into 3 groups: conventional training (CT) (n=28), eating training (ET) (n=28), and intensive swallowing training (IST) (n=27). The CT group received conventional swallow training, the ET group was given additional individual feedings with a specified volume of soft food, and the IST group received intensive swallowing training with synchronized NEMS. All of the patients were evaluated before and after the treatment with a modified barium swallow, and the Dysphagia Outcome and Severity Scale (DOSS); the numbers of patients with Stroke-Associated Pneumonia (SAP) and wet voice also were assessed.

Results: After 6 weeks, DOSS scores improved in patients in all 3 groups, and there were significant differences among the groups in their scores (*P*<0.001 for both measures). In the CT and ET groups, there was a statistically significant difference in the number of patients with SAP before and after treatment (*P*=0.010 and *P*<0.001, respectively). There also were fewer cases in the IST group than in the CT (*P*=0.042) and ET groups (*P*=0.011). After completion of treatment, compared with the first treatment, there were significantly fewer patients with wet voices in the CT (*P*<0.001) and IST groups (*P*<0.001).

Conclusions: Feeding a specified volume of soft food plus synchronized NMES of the submental muscles can improve the swallowing function of patients with mild-to-moderate dysphagia following stroke and it reduces their risk of food aspiration.

Keywords: Deglutition Disorders • Electric Stimulation Therapy • Feeding Methods • Stroke

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Background

Dysphagia is one of the most common symptoms following stroke. About 37% to 78% of patients who have an acute stroke develop dysphagia, and it is closely related to stroke-associated pneumonia (SAP), dehydration, and malnutrition [1]. Stroke also can result in a cognitive deficit, which is likely to affect other functions, such as swallowing. Tools such as the Abbreviated Mental Test Score (AMTS) can be used to evaluate cognitive deficit associated with stroke [2]. A composite score ≤7 on the 10 questions is indicative of a cognitive deficit and the scale has good reliability and validity for assessment of cognitive impairment [3-5].

A videofluorographic swallowing study, also known as a modified barium swallow, is one way to evaluate swallowing, and is considered the instrument of choice by many clinicians who specialize in swallowing disorders [6]. Various volumes and textures of food and liquid are administered and clinical impressions of the presence and degree of swallowing impairment are obtained from the radiographic images; with this method, judgments also are made regarding the coordination and timing of swallowing events [7].

The Dysphagia Outcome and Severity Scale (DOSS) is another evaluation method, based on a modified barium swallow. This scale can be used not only to assess swallowing function, but also to assess dietary, independence, and nutritional levels [8]. DOSS divides swallowing function into 7 levels, with lower levels indicating more severe dysphagia [9]. Level 1 represents severe dysphagia, wherein the patient cannot safely tolerate any oral nutrition, and has ≥1 of the following manifestations: severe pharyngeal residue or leakage and residue of oral bolus, which cannot be removed; asymptomatic aspiration when eating 2 or more types of sticky food; non-functional coughing; and an inability to complete swallowing. Level 7 represents normal swallowing function, wherein the patient can eat normally under any condition, with no compensation strategy or extra time needed. The 7 levels of swallowing function on the scale are further divided into 3 grades of dysphagia: Levels 5 and 4 for mild dysphagia; Levels 2 and 3 for moderate dysphagia; and Level 1 for severe dysphagia [9,10].

Patients who have a mild-to-moderate swallowing dysfunction often rely partially or completely on a nasogastric tube. Guidelines for clinical nutrition indicate that for patients who have insufficient oral intake of food during the acute phase of stroke, enteral nutrition should be given via a nasogastric tube. When no risk factors are present, intermittent boluses of food, given 6 times a day for 1 hour each, are just as safe [11]. Many experts recommend maintaining minimal oral intake, such as giving ice chips patients who are severely dysphagic, to promote oral hygiene and trigger swallowing ability, and they also recommend that patients with dysphagia be fed orally with food of a "safe texture" to promote oral hygiene and swallowing rehabilitation [12]. Guidelines from the European Society for Clinical Nutrition and Metabolism (ESPEN) provide 88 recommendations for feeding patients with stroke and indicate that diets in which the texture of the food is modified and liquids are thickened may reduce the incidence of aspiration pneumonia in patients who have experienced a stroke and have dysphagia [13], but such diets are associated with an increased risk for malnutrition compared to that in patients whose swallowing function is intact [13]. Therefore, in stroke rehabilitation, ways to promote effective oral intake and to reduce the incidence of complications are areas of significant study [14].

In dysphagia, the pharyngeal location is the area most prone to aspiration, which affects the safety and effectiveness of eating orally. The main manifestations of dysphagia are a decreased ability to use the mouth; a delay, lack, or prolongation of the initiation of the swallowing reflex; and a reduction in the lifting and forward movement ability of the tongue-throat complex.

Based on the principle of "plasticity" of the central nervous system, various external interventions can influence the plasticity of the nerves. These are defined as behavioral or non-behavioral interventions [15]. The former encompasses active and/or assisted athletic training and muscle-strengthening exercises that are used for patients with dysphagia; the therapeutic exercise commonly used in swallowing training; airway protection; compensatory swallowing training; biofeedback swallowing training; and behavioral interventions. A behavioral intervention is one that an individual accepts passively and for which a clear and direct response is not required to achieve the regulatory effect.

Neuromuscular electrical stimulation (NMES) is a non-behavioral therapy for dysphagia. Because an optimal NMES system uses the minimal stimulus frequency that produces a fused response, the typical frequency range is 10 to 50 Hz [16]. NMES induces muscle contraction or simulates normal autonomic movement through excitatory contraction to improve or restore the function of stimulated muscles or muscle groups [16]. Skeletal muscle contains "fast" and "slow" muscle fibers that are distinguished on the basis of contraction kinetics; these fiber types are generally categorized according to differences in histochemistry. Slow-twitch, oxidative Type I fibers generate lower forces, but are fatigue resistant; fast-twitch, glycolytic Type II fibers generate higher forces but fatigue more rapidly [17]. Because of the lower stimulation thresholds, NMES preferentially recruits Type II fibers, followed by recruitment of type I muscle fibers [18]. Pharyngeal muscle contraction increases the protein content and capillary density of muscle, resulting in an enhanced muscle training compensation effect, thereby improving the safety of swallowing [19].

Although NMES has several important advantages in the treatment of swallowing dysfunction, simple electrical stimulation training is entirely passive; there is no active participation of the patient during treatment process, which is contrary to the principle of muscle strength training. Thus, active ingestion training is an important behavioral intervention for the treatment of dysphagia. In keeping with food traits recommended by the European Society for Swallowing Disorders [20], in a previous study [21], we found that a 5-mL soft bolus produced greater activation and a longer contraction time in the submental muscles of patients with post-stroke pharyngeal dysphagia. In addition, because of the high viscosity of the soft bolus, swallowing also was safer. However, risks still existed, such as food sticking to the throat, and an increased risk of aspiration. We also found that the degree of activation of the submental muscles, which are the key muscles around the hyoid bone, was significantly and positively correlated with increased difficulty in swallowing [21].

Tongue-hold swallow is one part of the exercise protocol for intensive swallowing (IS), which targets the swallowing muscles that are desirable for reversing sarcopenia and age-related dysphagia [22]. In tongue-hold swallow, patients are asked to hold their tongue gently between their teeth and then swallow their saliva with their tongue in a straight position [23]. Recent research using simultaneous pharyngeal manometry and intramuscular electromyography has confirmed that this tongue-hold maneuver significantly increases the activation of the superior pharyngeal constrictor, as well as the genioglossus and the submental musculature [23].

In a study by Marilia et al that enrolled 83 patients with subacute stroke and dysphagia, 17 received traditional dysphagia therapy plus a swallow maneuver. At the same time that the swallow maneuver was performed, 2 Intelect VitalStim electrodes were placed just at or above the level of the thyroid notch over the thyrohyoid muscle. Combining the traditional dysphagia therapy with NMES improved the swallowing function and feeding in the patients with severe-to-profound post-stroke dysphagia [24].

Another study explored the effects of an intensive exercise-based swallowing program that incorporated lingual and respiratory exercises for patients with Parkinson disease (PD). The results suggested that an intensive exercise-based swallowing program had an overall positive and potentially additive or synergistic effect after a 4-week training period [25].

The aim of the present study was to evaluate the effects of synchronized NMES on the submental muscles during ingestion of a specified volume of soft food in patients with mild-to-moderate dysphagia following stroke.

Material and Methods

Subjects

The Declaration of Helsinki, which dictates ethics in clinical trials, was taken into consideration in development of the present study. The methods used were approved by the Ethics Committee of the Affiliated Hospital of Guizhou Medical University. All patients were asked to sign a written informed consent form before data collection.

Eighty-three patients with post-stroke pharyngeal dysphagia were enrolled at the Affiliated Hospital of Guizhou Medical University between June 1, 2018 and May 31, 2020. The inclusion criteria were as follows: clinical diagnosis of initial cerebral infarction or cerebral hemorrhage, confirmed by brain computed tomography or magnetic resonance imaging (MRI); disease course of 1 to 3 months; age 40 to 80 years old; stable vital signs; ability to swallow at least 50 mL of soft food in 30 min; a simple intelligence test scale AMTS score >7 points [2-5]; a DOSS score of 2 to 6, suggesting mild-to-moderate dysphagia [8-10]; pharyngeal dysphagia or oropharynx dysphagia diagnosed with a modified barium swallow [6,7]; and achievement of direct eating. The exclusion criteria were as follows: malignant tumors, serious medical diseases or other neurological diseases; mental disorders or cognitive dysfunction; dysphagia not triggered by stroke; head, neck, or gastroesophageal surgery; and dysphagia combined with an uncontrolled lung infection. Patients who met the inclusion criteria were divided into 3 groups, using the random number table method: conventional training (CT), eating training (ET), and intensive swallowing training (IST). The same experienced physician generated the random allocation sequence, enrolled the participants, and assigned them to the interventions. The therapist was aware of the allocation, but all the physicians who conducted the evaluation procedures – including all the scale measurements and analysis of the modified barium swallow data – were blinded to group assignment.

Treatment Protocol

CT Group

Each patient received the following conventional swallowing training: (1) oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (eg, lip, tongue, and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); (2) instruction in airway protection maneuvers (supraglottic swallow or supersupraglottic swallow); (3) thermal/tactile stimulation; (4) oral hygiene education; (5) direct eating training (ET) as per each individual's willingness; and (6) positioning strategies (eg, chin tuck, head turn, or head tilt) and practice with swallowing

maneuvers (eg, Mendelsohn maneuver). The choice of specific positioning strategies and swallowing maneuvers or exercises was based on DOSS score and clinical swallowing examination. Treatment sessions each lasted 30 min and were performed once a day for 5 days a week for 6 weeks, for a total of 30 training sessions.

In addition, NMES treatment with the Intelect VitalStim model 5900 was performed. Before treatment, a patient's neck skin was cleaned with 75% medical alcohol, or with physiological saline for those allergic to alcohol, to reduce interference and increase conductivity. The treatment electrode was placed on both sides of the anterior median line of the neck, between the submental and the upper part of the hyoid bone, and exposure was limited to the maximum contraction of the muscle with the electrode that a patient could withstand, which was usually 6.3 to 13.2 mA (average 11.6 mA). During direct ET, patients were kept relaxed and in a compensatory and safe eating position in a quiet environment. Suitable tableware was chosen, based upon a patient's tolerance for and choice of paste food to eat. During direct ET, patients were asked to swallow the first mouthful before taking the next one, and not to eat too fast [26].

ET Group

In addition to the conventional swallowing training, this group of patients was given direct ET with soft food (viscosity 4750 to 5113 cP) [27], depending on their willingness to eat it. The food was prepared with thickener and water at a temperature of 25°C. With a patient seated, the therapist applied a 5-mL food bolus onto the middle of the tongue using a spoon. The patient was allowed to swallow, and an additional 1 to 2 swallowing actions were performed to clean the food that remained in the pharynx. During the first week, the training time was gradually increased, based on patient tolerance; a maximum of 100 mL of food was fed. Each training session lasted for 30 min and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days.

IST Group

In addition to the conventional swallowing therapy, the patients in the IST group received intensive swallowing training with tongue-hold swallow [22,23]. During direct eating/swallowing training, a patient was asked to hold their tongue gently between their teeth. The therapist then applied a 5-mL food bolus onto the middle of the tongue using a spoon, and the patient swallowed it with their tongue in a straight position when they felt the maximum intensity of current stimulation in the submental muscles with synchronized electrical stimulation using the VitalStim neuromuscular stimulator. The NMES treatment was performed the same as in the CT group. The

patients in the IST group also were asked to finish swallowing the soft food bolus within 30 min, and they received no more than 100 mL of the food. Each training session lasted for 30 min and had 30 swallowing actions. The training sessions were held for 5 days per week for 6 weeks, for a total of 30 days.

Security Measures

Before and after ET, sputum and secretions in the mouths of patients in all 3 groups were cleaned up. When patients experienced bucking, eating was immediately stopped, the patients were instructed to cough, and the Heimlich technique was used, if necessary [28]. In cases of serious bucking, a fiberoptic bronchoscope was to be used to clear the foreign body from the airway; however, none of the patients had serious bucking.

Data Collection and Analysis

Adjustment of Viscosity of the Food Bolus

Food with 2 different viscosities was prepared, using a thickener (Urdiet, Guangzhou, China) that consisted of iohexol and water, and the viscosity value was measured with an NDJ-5S Rotational Viscometer (Shanghai Fangrui, Shanghai, China) at a temperature of 25°C. The 3 solutions were as follows: 1. iohexol aqueous solution: viscosity 5 to 10 mPa/s; 2. nectar-like bolus: viscosity 272 to 343 mPa/s; and 3. soft bolus: viscosity 4750 to 5113 mPa/s [27].

VitalStim Neuromuscular Electrical Stimulation

Electrical stimulation was performed with an Intelect VitalStim model 5900 (Chattanooga Group, Hixson, Tennessee, United States). The parameters set were bidirectional square wave, waviness width 300 μs, fixed-frequency 80 Hz, and galvanic stimulation intensity 0 to 25 mA.

Modified Barium Swallow

The modified barium swallow examination was performed using a remote-controlled, twin-bed PLD5000 X-ray machine (Perlead, Zhuhai, China). All subjects were examined in both a 90-degree sitting and a lateral position, according to the evaluation criteria for DOSS. For patients who could not sit still, the torso was fixed onto the examination chair using the waist fixation strap, with the patient's head fixed using a cushion behind the neck to avoid interference with the swallowing inspection. The video examination area was from the top of the nasal cavity down to the 7th cervical vertebra. During the examination, each patient was asked to swallow 5 mL of a nectar-like bolus, iohexol aqueous solution, and a soft bolus; 6 swallows were completed – 3 in a sitting position and 3 in a

lateral position. Each patient underwent this assessment before and after treatment. In the event of coughing, a patient was instructed to try to cough up the inhaled bolus, and before proceeding to the next step, a wet voice assessment and pharyngeal auscultation were performed to ensure that there was no wet voice or any buzzing or blisters heard in the throat.

Data from the patients' modified barium swallow recordings and on their oral eating abilities were graded using a DOSS scale [8-10] and their efficacy and total efficiency were calculated. Treatment was considered markedly effective if the DOSS score increased by >2 levels, effective if the score improved by ≤2 levels, and ineffective if there was no change in DOSS. The formula for the total rate of effectiveness in the 3 groups of patients was as follows: Total efficiency [10]=(number of cases with markedly effective outcome+number of cases with effective outcome)/(total number of cases)×100%

Stroke-associated Pneumonia

Stroke-associated pneumonia (SAP) refers to infective inflammation of the lung parenchyma (including the alveolar wellsite and the pulmonary interstitium) in patients who have had a stroke and had no prior pulmonary infection [29].The evaluation criteria for SAP were new findings of pulmonary invasive lesions on imaging; fever ≥38°C; new cough or exacerbation of original respiratory symptoms, with or without chest pain; signs of lung consolidation and/or moist rales; and peripheral blood leukocytes $≥10×10^9$/L or $≤4×10^9$/L. The diagnostic criteria were new findings of pulmonary invasive lesions on imaging plus ≥2 clinical indications of an infection. In the present study, none of the patients had SAP at enrollment and the number of cases of SAP in the 3 groups was assessed after 6 weeks of treatment.

Wet Voice Cases and Occurrences

Wet voice refers to a change in vocal pitch due to the attachment to or retention of a bolus or foreign body on the vocal cords. All of the patients were assessed for wet voice before and immediately after the end of each eating treatment. Before each treatment, the patients said their names or a paragraph at a normal volume. After completing the eating treatment, the names or the same paragraph were repeated to determine whether there were changes in tone such as hoarseness, reduced pitch, or humming in the voice. The number of patients in each group who had a wet voice between the end of the first and the 30th treatments was recorded.

Statistical Analysis

The data were analyzed and processed by SPSS statistical software, version 21.0. All data were tested for normal distribution before analysis. Data following a normal distribution were expressed as means±standard deviation. Data following a non-normal distribution were expressed as medians±quartile spacing, and were analyzed using a non-parametric median. Quartile data were analyzed using a chi-square test. Differences in age, disease course, neurological function score, and nutritional status among the 3 groups prior to treatment were analyzed with a 1-way analysis variance (ANOVA) and a Kruskal-Wallis test. Before and after treatment, the DOSS assessment, the number of SAP cases, the number of occurrences and cases of wet voice, the number of tube-feeding cases, and the differences before and after treatment were subject to a Wilcoxon rank sum test. The Kruskal-Wallis test (for multiple independent samples) was used to compare the treatment effects among the 3 groups. When the difference was statistically significant, Fisher's least significant difference *t* test was used for pairwise comparisons. Differences with *P*<0.05 were considered statistically significant.

Results

Baseline information for and characteristics of the 83 enrolled patients are listed in **Table 1**. There were no significant differences among the 3 groups (*P*>0.05) in their characteristics, including age, sex, duration of disease, type of paralysis, type of dysphagia, DOSS scores, or AMTS outcomes.

DOSS Scores

Median DOSS scores and interquartile ranges for swallowing function after treatment were 4 (3.75), 5 (4.75), and 6 (6) in the CT, ET, and IST groups, respectively. In all 3 groups, it was significantly better than before treatment (all *P*<0.001; **Table 2**). The IST group had the best swallowing function after treatment, followed by the ET group; the CT group had the worst swallowing function. Total efficacy, as assessed by DOSS score after treatment, was significantly better in the IST group (96.3%) than in the CT (67.9%, *P*<0.001) and ET groups (78.6%, *P*<0.001) (**Table 3**).

SAP Cases

There were no cases of acute lung infection in any of the patients at the time of enrollment. During the treatment period, patients in all 3 groups experienced SAP. There were significant differences before and after treatment in the CT (n=6, 21.4%; *P*=0.010) and ET groups (n=15, 53.6%; *P*<0.001) but not in the IST group (n=2, 7.4%; *P*=0.160). The rate of new SAP cases was the highest in the ET group. A pairwise comparison showed that there were statistically significant differences between the IST and ET groups (*P*=0.011) and between the IST and CT groups (*P*=0.042) after treatment (**Table 4**).

Table 1. Patient demographics.

Baseline characteristics	CT group N=28	ET group N=28	IST group N=27	P value*
Sex (F/M)	17/11	14/14	13/14	0.60
Age (mean±SD, years)	62.31±8.07	63.14±6.56	63.72±6.29	0.76
Course (mean±SD, months)	2.16±0.50	2.06±0.54	2.10±0.54	0.75
Type of paralysis (T/P)	11/17	10/18	8/19	0.75
Type of dysphagia (pharyngeal/opharynx)	13/15	12/16	11/16	0.91
DOSS median (IQR)	3 (2.75)	3 (2)	4 (3)	0.19
AMTS median (IQR)	9 (8.5)	9 (8)	9 (8)	0.55

AMTS – Abbreviated Mental Test Score; CT – conventional training; DOSS – Dysphagia Outcome and Severity Scale; ET – eating training; IST – intensive swallowing training; T – true bulbar palsy; P – pseudobulbar palsy; IQR – interquartile range. * Among the 3 groups.

Table 2. Differences in DOSS scores before and after treatment.

Group	Before median (IQR)	After median (IQR)	P value*	Improvement median (IQR)
CT N=28	3 (2.75)	4 (3.75)	<0.001	1 (0.75)
ET N=28	3 (2)	5 (4.75)	<0.001	2 (2)
IST N=27	4 (3)	6 (6)	<0.001	2 (2)
P value**	0.19	<0.001		<0.001
P value***	N/A	0.326		0.016
P value#	N/A	<0.001		<0.001
P value##	N/A	<0.001		<0.001

CT – conventional training; DOSS – Dysphagia Outcome and Severity Scale; ET – eating training; IST – intensive swallowing training; IQR – interquartile range. * Before vs after; ** Among the 3 groups; *** CT group vs ET group; # CT group vs IST group; ## ET group vs IST group.

Table 3. Evaluation of training effectiveness based on DOSS level scores after treatment.

Group	Markedly effective	Effective	Ineffective	Total efficiency
CT N=28	5	14	9	67.9%
ET N=28	14	8	6	78.6%
IST N=27	24	2	1	96.3%
P value*	<0.001	0.060	<0.001	<0.001
P value**	0.012	0.236	0.001	0.078
P value***	<0.001	0.002	<0.001	<0.001
P value#	<0.001	0.256	0.477	<0.001

CT – conventional training; DOSS – Dysphagia Outcome and Severity Scale; ET – eating training; IST – intensive swallowing training. * Among the 3 groups; ** CT group vs ET group; *** CT group vs IST group; # ET group vs IST group.

Table 4. Differences among groups in incidence of SAP before and after treatment.

Group	Before	After	P value*
CT N=28	0 (0.0%)	6 (21.4%)	0.010
ET N=28	0 (0.0%)	15 (53.6%)	<0.001
IST N=27	0 (0.0%)	2 (7.4%)	0.160
P value**	1.00	0.040	
P value***	N/A	0.589	
P value#	N/A	0.042	
P value##	N/A	0.011	

CT – conventional training; ET – eating training; IST – intensive swallowing training; SAP – stroke-associated pneumonia. * Before vs after; ** Among the 3 groups; *** CT group vs ET group; # CT group vs IST group; ## ET group vs IST group.

Table 5. Differences among the groups in incidence of wet voice before and after treatment.

Group	Incidence of wet voice		P value*
	After the first treatment	After the 30th treatment	
CT n=28	24 (85.7%)	7 (25.0%)	<0.001
ET n=28	23 (82.1%)	21 (75.0%)	0.480
IST n=27	25 (92.6%)	6 (22.2%)	<0.001
P value**	0.51	<0.001	
P value***	N/A	<0.001	
P value#	N/A	0.808	
P valueII	N/A	<0.001	

CT – conventional training; ET – eating training; IST – intensive swallowing training. * Before vs after; ** Among the 3 groups; *** CT group vs ET group; # CT group vs IST group; ## ET group vs IST group.

Wet Voice Cases

There was no statistically significant difference in the number of cases of wet voice among the 3 groups after the first training (P=0.51). After the 30th treatment, the number of cases of wet voice was significantly lower than before treatment in the CT (n=7, 25.0%; P<0.001) and the IST groups (n=6, 22.2%; P<0.001). There was no statistically significant difference in the number of cases in the ET group before and after treatment (n=21, 75.0%; P=0.480). There were statistically significant differences among the 3 groups (P<0.001), and the number of cases of wet voice was higher in the ET group than in the CT group (P<0.001) or the IST group (P<0.001) after 30 treatments (**Table 5**).

Discussion

The present study showed that after 6 weeks of treatment, dysphagia was improved in all 3 groups. The DOSS scores after treatment were significantly better in the IST group (96.3%)

than in the other 2 groups (CT group 67.9%, ET group 78.6%; P<0.001 for both; **Table 3**). These results indicated that, compared to conventional swallowing training or non-synchronous NMES, synchronized NMES of the submental muscles combined with swallowing training using a specified volume of a soft bolus could be more effective for improving the swallowing function in patients. The mechanism may be related to the fact that the soft food bolus (which has a suitable viscosity, a relatively slow flow, and is not easily diffused) can lead to full proprioceptive stimulation of the pharyngeal receptor and trigger significant activation of the group of swallowing muscles. A previous study of 17 patients who had dysphagia after subacute stroke showed that the effortful swallow maneuver therapy plus NMES improved swallowing function and feeding more than the effortful swallowing maneuver alone in individuals who had severe-to-profound post-stroke dysphagia [24]. Many guidelines for nutrition in patients with stroke, such as the ESPEN guideline, suggest minimal amounts of oral intake in patients with severe dysphagia, such as use of ice chips, which may promote oral hygiene and swallowing ability in and of itself and help reduce the risk of malnutrition

associated with a nasogastric tube [12,13]. The principle behind these recommendations is that of "reverse recruitment order," wherein the nerve stimulus threshold is inversely proportional to the diameter of the neuron. Thus, large-diameter nerve fibers, which innervate larger motor units, are recruited preferentially. Skeletal muscle contains "fast" and "slow" muscle fibers. Slow-twitch, larger-diameter nerve fibers and oxidative Type I fibers generate lower forces, but are resistant to fatigue; fast-twitch, smaller-diameter, glycolytic Type II fibers generate higher forces but fatigue more rapidly. The NEMS systems preferentially recruit Type II fibers because those fibers have lower stimulation thresholds [18].

Most of the main swallowing muscles have a high proportion of Type II muscle fibers [30]. NMES also has been shown to have a significant positive effect on muscle training by increasing the pharyngeal muscle contractile protein content and capillary density [31]. NMES is a non-behavioral therapy for dysphagia and the frequency range for the systems is 10 to 50 Hz, which induces muscle contraction or simulates normal autonomic movement through excitatory contraction to improve or restore the function of stimulated muscles or muscle groups [16]. A number of studies have confirmed that NMES treatment improves the degree of laryngeal elevation and of openness and coordination of the pharyngeal muscles, reduces aspiration, and improves swallowing function [32-36]. In addition to the kinesthetic response, the frequency can induce sensory stimulation below the electrodes, triggering reflexes in the pharynx, trigeminal, and vagal nerves, among others, which send sensory feedback to the central pattern generator (CPG) and the cortex and subcortical center. This accelerates the reorganization of nerve function and promotes the recovery of swallowing function [37,38]. Previous studies have suggested that sensory stimuli may have long-term effects on reorganization of the human cerebral cortex, enhancing the recovery and plasticity of brain function in swallowing control [39-41].

NMES also assists in preferentially recruiting Type II fibers in submental muscle; increases the number of muscles involved in contraction work; improves muscle and contraction strength and speed in the pharyngeal muscle group; and improves blood circulation in the stimulated area [42]. Combining the effortful swallowing maneuver with NMES doubles the activation of the swallowing center by activating different neural reflex pathways, facilitating functional reorganization or compensation of the cortical and medullary CPGs [43].

In the present study, the treatment program was more effective in the IST group than in the CT and ET groups. We believe that this is related to the intensity of swallowing training with a specified volume of soft food bolus swallowed within 30 min. According to the training principles of the McNeill Dysphagia Therapy Program [44], IST methods with intensive

exercise times, maximum exercise intensity, and an emphasis on speed and coordination can effectively and gradually improve swallowing function. This type of training has obvious effects on oral eating, and promotes detachment from tube feeding [44]. Recent research using simultaneous pharyngeal manometry and intramuscular electromyography also has confirmed that the tongue-hold maneuver, which was one of the IST methods used in the present study, significantly increases the activation of the superior pharyngeal constrictor, as well as the genioglossus and the submental musculature [23].

The safety evaluation in the present study showed that patients in all 3 groups experienced SAP during the treatment period. The number of new cases of SAP after treatment was the lowest in the IST group (n=2, 7.4%), compared with the CT (n=6, 21.4%; P=0.042) and ET groups (n=15, 53.6%; P=0.011). Also, the number of new SAP cases after treatment was the highest in the ET group (**Table 4**). Direct eating training is the only way for patients with dysphagia to resume oral feeding, and could contribute to removing a nasal feeding tube as soon as possible. Studies of SAP associated with stroke have shown that even with safe and effective direct ET, it is still not possible to completely eliminate SAP and bucking in these patients [45,46]. It is possible that in the present study the mobility of the boluses varied because they were non-homogeneous, which may have increased the risk of SAP and bucking in the CT group rather than in the ET group. Previous studies have suggested that a soft bolus may decrease the risk of aspiration and leakage, but there is still potential for pharyngeal retention after swallowing [47,48].

The number of cases of wet voice after treatment (n=21,75.0%) was higher in the ET group than in the IST (n=6, 22.2%, P<0.001) and CT groups (n=7, 25%, P<0.001). That may be because patients were asked to complete direct ET in 30 min, and because most of the main swallowing muscles have a high proportion of Type II muscle fibers, these fibers generate higher forces but fatigue more rapidly [18], especially with longer muscle fiber contractions [49]. These patients may appear to have muscle fatigue, which results in a decrease in muscle endurance and inadequate muscle strength and induces aspiration and leakage. Another related study also reported that patients with stroke-related dysphagia are presumed to have muscle atrophy or weakening because of disuse or long-term tube feeding, despite receiving NMES treatment for impairment in muscles involved in swallowing [50]. In the IST group, however, NMES may have improved contraction velocity and muscle strength because of the significant positive effects of training on submental muscles [31]. NMES stimulation of the submental muscles produced more powerful contractions when the bolus was in the pharyngeal cavity, reducing the bolus, which is in keeping with studies showing that use of NMES after muscle training and use of high frequencies of NMES

improve muscle contraction and activation and relieve muscle fatigue at the same time [51,52]. Therefore, as a therapy, NMES may have relieved muscle fatigue and improved muscle endurance, resulting in a decreased risk of SAP and bucking in the present study. As a consequence, in the present study, the incidence of wet voice was lower in the IST group than in the CT and ET groups.

Study Limitations

The present study had some limitations. First, the results cannot be generalized because of the small sample size. Also, the research was performed at a single center. Because the intervention period was only 6 weeks, it was not possible to evaluate long-term effects. Only patients with mild or moderate stroke were included, and none with severe dysphagia associated with stroke; therefore, the results cannot be generalized to every patient who has had a stroke. Bias could also be an issue because the patients enrolled were in the convalescence stage of stroke recovery and the possibility of natural recovery cannot be ruled out. Therefore, no definitive conclusions can be drawn about the treatment until a study is conducted with a true control group and that addresses the limitations previously described.

The mechanism underlying NMES also should be explored, not only to identify the actual swallowing function, but also to understand the relationship between neural activity in the brain and the muscles. In future studies, brain monitoring technologies such as functional near infrared spectroscopy, functional MRI, and diffuse tensor imaging should be employed to estimate brain function as a way to evaluate the proposed treatment methods.

Conclusions

Feeding a specified volume of soft food with synchronized NMES of the submental muscles can improve swallowing function in patients with mild-to-moderate dysphagia following stroke and it can reduce their risk of food aspiration.

Conflicts of Interest

None.

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