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Dysphagia

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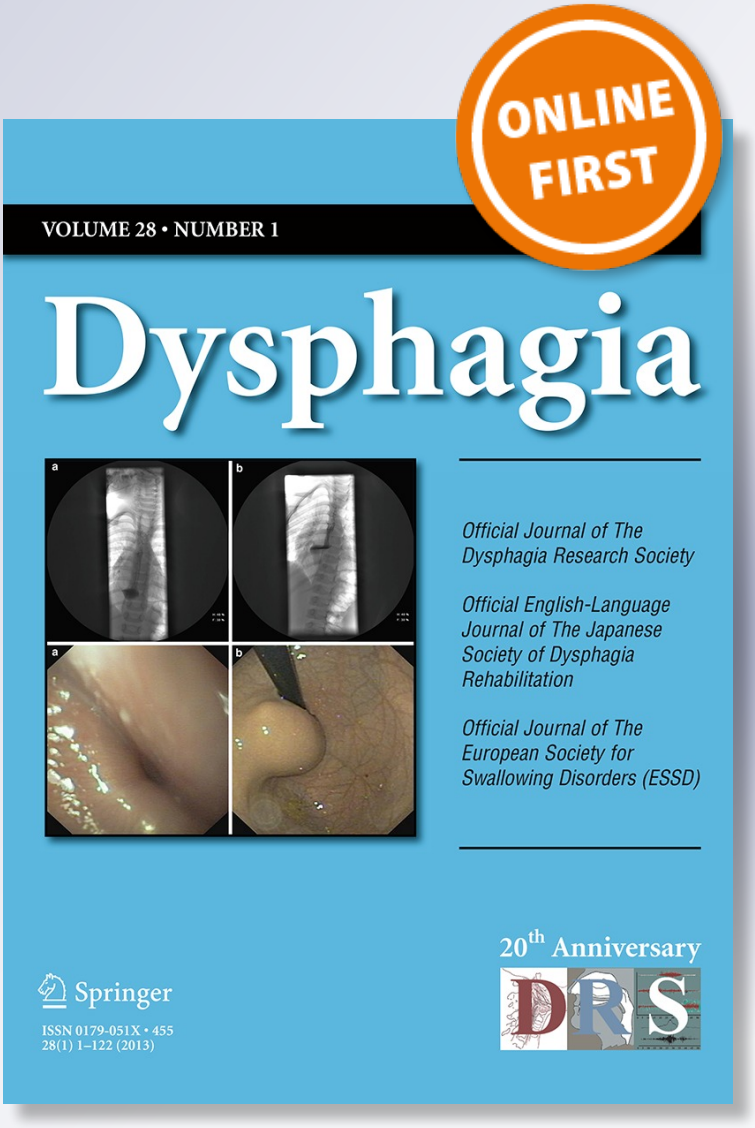

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ORIGINAL ARTICLE

Combined Neuromuscular Electrical Stimulation (NMES) with Fiberoptic Endoscopic Evaluation of Swallowing (FEES) and Traditional Swallowing Rehabilitation in the Treatment of Stroke-Related Dysphagia

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Abstract Dysphagia is common after stroke. Neuromuscular electrical stimulation (NMES) and fiberoptic endoscopic evaluation of swallowing (FEES) for the treatment of dysphagia have gained in popularity, but the combined application of these promising modalities has rarely been studied. We aimed to evaluate whether combined NMES, FEES, and traditional swallowing rehabilitation can improve swallowing functions in stroke patients with moderate to severe dysphagia. Thirty-two patients with moderate to severe dysphagia poststroke (≥3 weeks) were recruited. Patients received 12 sessions of NMES for 1 h/day, 5 days/week within a period of 2–3 weeks. FEES was done before and after NMES for evaluation and to guide dysphagic therapy. All patients subsequently received 12 sessions of traditional swallowing rehabilitation (50 min/day, 3 days/week) for 4 weeks. Primary outcome measure was the Functional Oral Intake Scale (FOIS). Secondary outcome measures included clinical degree of dysphagia, the patient's self-perception of swallowing ability, and the patient's global satisfaction with therapy. Patients were assessed at baseline, after NMES, at 6-month follow-up, and at 2-year follow-up. Twenty-nine patients completed the study. FOIS, degree of dysphagia, and patient's self-perception of swallowing improved significantly after NMES, at the 6-month follow-up, and at the 2-year follow-up ($p < 0.001$, each compared with baseline). Most patients reported considerable satisfaction with no serious adverse events. Twenty-three of the 29 (79.3 %) patients maintained oral diet with no pulmonary complications at 2-year follow-up. This preliminary case series demonstrated that combined NMES, FEES, and traditional swallowing rehabilitation showed promise for improving swallowing functions in stroke patients with moderate-to-severe dysphagia. The benefits were maintained for up to 2 years. The results are promising enough to justify further studies.

Keywords Dysphagia · Fiberoptic endoscopic evaluation of swallowing · Neuromuscular electrical stimulation · Rehabilitation · Stroke

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Introduction

Dysphagia is frequent after stroke, with a reported prevalence of between 29 and 65 % [1, 2]. Most dysphagia patients recover within 3 weeks of stroke onset, but it may take a more protracted course and give rise to serious complications such as pneumonia, malnutrition, or even death [3, 4]. The goal of dysphagia intervention is to increase safe and adequate oral intake of food and liquid. Current treatment options for dysphagia are limited.

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Swallowing exercises, dietary modification, therapeutic postures, and maneuvers continue to serve as the mainstays of therapy. A recent Cochrane review by Geeganage et al. [5] showed that although dysphagia treatment may be beneficial, more research is needed because there remains insufficient data on the effect of swallowing therapy on functional outcome in dysphagic patients who had acute or subacute stroke. Thus, development of effective interventions that improve swallowing after stroke are crucially important.

Neuromuscular electrical stimulation (NMES) is a well-documented method of augmenting muscle performance in both normal and paralyzed muscles [6, 7]. Freed et al. [8] first introduced transcutaneous NMES on the submental and laryngeal musculature, which provides controlled stimulation to strengthen the swallowing muscles. It has since become an increasingly popular treatment for oropharyngeal dysphagia. NMES recruits type II motor unit fibers before type I fibers, which is opposite the recruitment pattern that occurs during traditional rehabilitation exercise [9]. Prior studies have shown that NMES in conjunction with swallowing exercise seems to be more effective than traditional treatment alone [8, 10, 11]. Studies have also shown that oral and pharyngeal stimulation may cause reorganization of the motor cortex and enhance motor relearning [12, 13]. Satisfaction is reported to be high among patients and professionals [14].

Fiberoptic endoscopic evaluation of swallowing (FEES) is a newer, reliable, and valuable technique that can be used to assess pharyngeal dysphagia, determine aspiration risk, and guide the management of dysphagia [15–17]. FEES enables physicians or therapists to monitor patient evolution, make clinical decisions, and help prevent aspiration pneumonia. Diagnostic findings based on FEES are of paramount importance for determination of feeding status [18].

Combining a variety of technologies and therapies into a treatment plan to enhance functional outcomes is an emerging theme among innovative rehabilitation professionals. In clinical practice, a combination of several techniques, rather than one method, is often used to enhance the therapeutic effects on poststroke dysphagia. NMES is a novel strategy and has been proposed as an adjunctive modality for the treatment of oropharyngeal dysphagia. FEES is an excellent assessment and treatment tool. However, there is no literature on the effectiveness of combined application of these promising modalities in patients with poststroke dysphagia. Given the short-term effect of NMES, we considered that using NMES first, coupled with FEES at baseline and after NMES, for rigorous evaluation and to guide dysphagic management, followed by traditional swallowing rehabilitation may possibly improve the outcomes in stroke-related dysphagia patients.

The purpose of this study was to prospectively investigate whether combined NMES, FEES, and traditional swallowing rehabilitation can improve swallowing functions in patients with moderate to severe dysphagia after stroke.

Methods

Subjects

Between February 2007 and November 2008, volunteers were recruited through advertisements placed in a rehabilitation department of a university-affiliated tertiary-care medical center. Two research team members screened volunteers using the following inclusion criteria: (1) age between 20 and 85 years old, with first-time stroke confirmed by computed tomography or magnetic resonance image; (2) presence of dysphagia for more than 3 weeks, with preservation of the swallowing reflex, as revealed during clinical examination; (3) currently on a restricted diet, with a Functional Oral Intake Scale (FOIS) score of 5 or less (Appendix 1), indicating significant limitations in oral intake [19]; (4) the Mini-Mental State Examination (MMSE) score of 21 or higher, with no obvious mental depression, receptive aphasia, or cognitive impairment; and (5) the underlying disease process should have been stable.

Exclusion criteria for the trial were as follows: (1) progressive cerebrovascular disease or other neurologic diseases such as amyotrophic lateral sclerosis, multiple sclerosis, or Parkinson's disease; (2) unstable cardiopulmonary status, serious psychological disorder, or epilepsy; (3) tumors, extensive surgery, or radiotherapy of the head and neck region; (4) presence of a cardiac pacemaker; and (5) underwent swallowing therapy within 2 months before participation in the present study.

Forty-three volunteers were initially screened; 11 subjects were excluded as 6 subjects did not meet inclusion criteria and 5 met the exclusion criteria. Thirty-two patients met all eligible criteria and participated in the study. Three patients dropped out, two because of transportation problems and one because of uncontrolled hypertension. A total of 29 patients (24 men, 5 women) completed the study (Fig. 1). The study protocol was approved by the institutional review board of Kaohsiung Veterans General Hospital and each participant signed a written informed consent form.

Interventions

FEES

Baseline FEES was done within 1 week after recruitment, 1 day before the start of NMES. Follow-up FEES was done

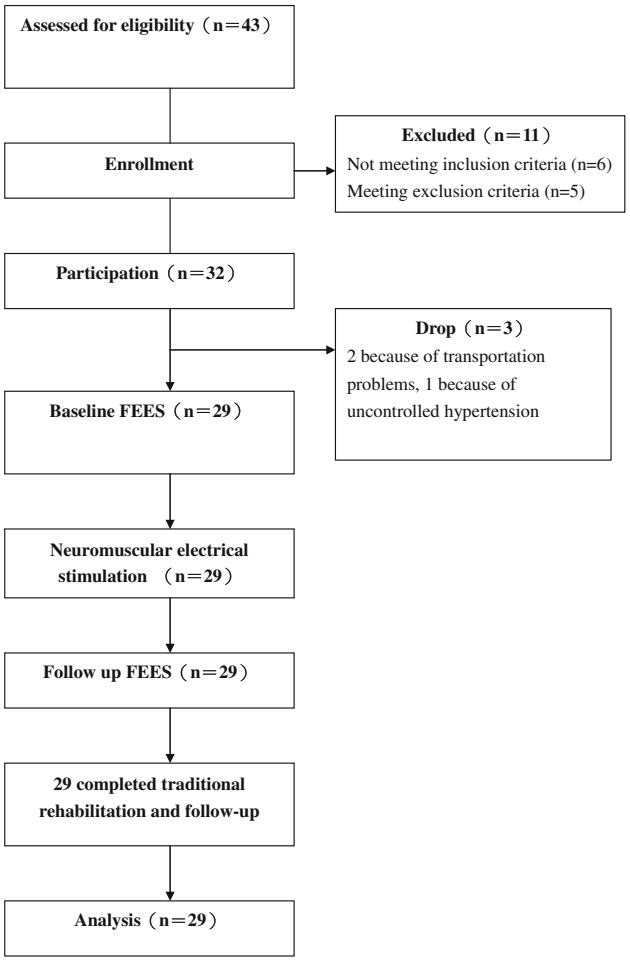

Fig. 1 Flow diagram of participants through the trial

within 2 days after completion of NMES. FEES was performed following the standard protocol with slight modification [17]. A physician skilled in endoscopy and a speech therapist (with several years of experience with FEES) jointly completed all FEES procedures. No topical anesthetic or vasoconstrictor was administered to the patients' nasal mucosa during FEES. Before the swallow, anatomy and functional movement of the tongue base, pharynx, and larynx were viewed and the presence of oropharyngeal secretions was assessed (Appendix 2). Swallowing was evaluated with food dyed green for contrast and began with standard volumes (approximately 3 ml) of puree consistency (pudding), followed by liquid (milk) and then soft solid food (white bread), if indicated. Pharyngeal stasis after swallowing was scored (Appendix 2). Different bolus consistencies and compensatory and posture strategies were attempted during FEES to determine if they affected swallowing success. If the patient aspirated (or there was penetration of) excessive amounts of any material, and spontaneous cough or cued cough could not effectively expel the remains of the bolus, we refrained from giving the next food consistency and the examination was terminated. Penetration was defined as any material entering the laryngeal vestibule but remaining at or above the vocal folds. Aspiration was defined as any material entering the larynx below the vocal folds. Scores for FEES were used for baseline and outcome measurement (Appendix 2).

NMES

NMES was delivered using a dual-channel electrotherapy system (VitalStim® electrical stimulator, frequency = 80 Hz, pulse width = 700 μs; Chattanooga Group, Hixson, TN, USA). Two pairs of electrodes were used, one pair placed horizontally in the submental region above the hyoid bone and the other pair over the thyroid cartilage on either side of the midline in the laryngeal region on the thyrohyoid muscles medial to sternocleidomastoid muscle [20]. The speech therapist involved in this study had attended the VitalStim® Certification Program and completed all requirements for certification as a VitalStim® therapy provider [21]. All patients received 12 treatment sessions of NMES, 1 h/day for five consecutive days per week within a period of 2–3 weeks. The highest electrical current level that the patient could tolerate, resulting in maximum underlying muscle contraction without discomfort, was applied. During electrical stimulation, the patients were encouraged to repeatedly swallow hard simultaneously. The start level of swallowed material used during NMES was identified by baseline FEES. The patients were progressively upgraded to swallowing various food consistencies as appropriate. If swallowing was deemed unsafe based on initial FEES findings, the patient would start with endogenous saliva (or ice chips) and dry swallows during NMES.

Rehabilitation

The traditional swallowing rehabilitation was done by the same speech therapist 1 day after the completion of follow-up FEES. Each session lasted about 50 min/day, 3 times a week for a total of 12 sessions. The program consisted of (1) oral-motor and pharyngeal swallowing exercises to strengthen the swallowing musculature (e.g., lip, tongue, and jaw exercises, Masako exercise, Shaker exercise, gargling or vocal cord adduction exercises); (2) airway protection maneuvers (supraglottic swallow or super-supraglottic swallow); (3) thermal/tactile stimulation; (4) oral hygiene education; (5) dietary modifications; and (6) positioning strategies (e.g., chin tuck, head turn, or head tilt) and practice of swallowing maneuvers (e.g., Mendelsohn maneuver or effortful swallow). The choice of specific positioning strategies and swallowing maneuvers or

exercises was based on the FEES findings and clinical swallowing examination.

Post-FEES feeding recommendations were made by the physician and speech therapist. Recommendation of future feeding status was determined by combining data from the clinical swallowing evaluations and FEES findings, the results of rehabilitation strategies, the patient's medical condition and cognitive functioning, and clinical judgment.

Outcome Measures

Outcome measures were done by another experienced speech therapist who was unaware of the swallowing status of each patient on all evaluations and who had no information on pre- or postintervention or patient progress during the study period. The primary outcome measurement was the FOIS. Secondary outcome measures included the clinical evaluation of the degree of dysphagia, the patient's self-perception of swallowing ability and global satisfaction with the combination therapy. The outcome measurements were described as follows:

1. The FOIS is a 7-point ordinal scale reflecting the dietary intake of patients with dysphagia (Appendix 1) [19]. It has adequate reliability and validity and has been used extensively in clinical studies of dysphagia to measure functional oral intake.
2. The degree of dysphagia was graded 1–4 after a detailed clinical swallowing evaluation, including cranial nerve assessment, observations of swallowing and related movements, and swallowing trials using various volumes and consistencies of food (Appendix 1) [22].
3. Each patient completed a perceptual evaluation of his/her swallowing ability using a 10-cm visual analog scale (VAS) [11]. It was rated by answering a single question: "How do you qualify your swallowing ability?" Scores can vary from 0 (no difficulty at all) to 10 (unable to swallow).
4. Patients were asked to rate the level of global satisfaction with the combination therapy. The rating was based on a 7-point categorical scale weighted from completely satisfied, satisfied, somewhat satisfied, no change, somewhat unsatisfied, unsatisfied, to completely unsatisfied.

FOIS, degree of dysphagia, and VAS were evaluated at baseline, 3 days after completion of NMES, and at 6 months and 2 years after completion of traditional swallowing rehabilitation. Patients' global satisfaction was evaluated at the 6-month and the 2-year follow-up.

Apart from the above-mentioned evaluation, data on FEES were gathered at baseline and after NMES. When evaluating handling of puree consistency, pharyngeal stasis was graded (Appendix 2). Laryngeal penetration or aspiration was scored using a simplified 5-point penetration-aspiration scale [23]. If penetration or aspiration occurred, the presence of protective cough reflexes was recorded.

The occurrence of adverse events or pneumonia was recorded during the study period. Pneumonia was diagnosed by the clinician and was based on the detection of three or more of the following features: fever (>38 °C), productive cough with purulent sputum, abnormal respiratory examination (tachypnea > 22 breaths/min, tachycardia, inspiratory crackles, bronchial breathing), arterial hypoxemia ($PaO_2 < 70$ mmHg), isolation of a relevant pathogen (positive gram stain and culture), and abnormal chest radiograph [24]. The occurrence of adverse events or pneumonia was looked for from multiple overlapping sources, such as asking patients, the caregiver, relatives, and staff at each follow-up assessment. Complications were verified, if necessary, by the patient's doctor and reviewed by chart at each follow-up assessment.

Statistical Analysis

Sample size was estimated using Statistical Software G*Power 3.1.2, and all other statistical procedures were performed with the SPSS ver. 12.0 (SPSS Inc., Chicago, IL). Based on the Statistical Software G*Power 3.1.2 and the statistical method used for the study's purpose, the Wilcoxon signed-rank test, the required sample size was estimated to be 26 (power = 0.95; $\alpha = 0.01$; effect size = 0.92). The calculation of effect size was based on the pilot study data of our first five patients after NMES (mean of FOIS difference = 2.40, standard deviation of FOIS difference = 2.61) as the parameter estimation. Anticipating a dropout rate of 20 %, we then increased the decided sample size to 32.

Descriptive statistics for the data were presented as mean ± standard deviation, median (interquartile range), or number (percentage) as appropriate in the text and tables. Differences between post-tests data and baseline data were tested by Wilcoxon signed-rank tests. Wilcoxon signed-rank tests were also used to test differences between any two consecutive measurements. Bonferroni's corrections were used for multiple comparisons. A $p < 0.05$ was regarded as statistically significant.

Results

Participant Demographics

The demographic data and clinical characteristics of patients are given in Table 1. The mean age was 70.1 ± 8.9 years (range = 46–81 years). Fifteen patients

Table 1 Demographic data and clinical features of study patients

Characteristics	Study group ($n = 29$)	Range
Age (years)	70.1 ± 8.9	46–81
Female [n (%)]	5 (17.2)	
Diagnosis of hemispheric stroke [n (%)]	15 (51.7)	
Diagnosis of brainstem stroke [n (%)]	14 (48.3)	
Weight (kg)	64.5 ± 9.7	44–83
Height (cm)	165.2 ± 6.0	150–174
MMSE	26.7 ± 2.0	23–30
Dysphagia duration (months)	2.9 ± 2.4	0.75–8
FOIS = 1 [n (%)]	11 (37.9)	
FOIS = 2 [n (%)]	8 (27.6)	
FOIS = 3 [n (%)]	2 (6.9)	
FOIS = 4 [n (%)]	2 (6.9)	
FOIS = 5 [n (%)]	6 (20.7)	
Degree of dysphagia grade 3 [n (%)]	8 (27.6)	
Degree of dysphagia grade 4 [n (%)]	21 (72.4)	

Values are mean ± standard deviation, number (percentage) or range

MMSE Mini-Mental State Examination, *FOIS* Functional Oral Intake Scale

(51.7 %) suffered from hemispheric stroke and 14 patients (48.3 %) suffered from brainstem stroke. All participants were outpatients. The mean MMSE score was 26.7 ± 2.0 (range = 23–30). The mean duration of dysphagia was 2.9 months (range = 3 weeks to 8 months). Before intervention, 21 of the 29 patients (72.4 %) were dependent on tube feeding (FOIS levels 1-3). The degree of dysphagia was evaluated as grade 3 in 8 patients (27.6 %) and grade 4 in 21 patients (72.4 %).

Functional Outcomes

Significant improvements were demonstrated in FOIS, degree of dysphagia, and patient self-perception of swallowing ability after the combination therapy. Table 2 presents the median and the 25th and 75th percentiles of patients' baseline and post-treatment follow-up scores. The median FOIS scores improved significantly from 2 at baseline to 6 after NMES ($p < 0.001$), and no patients decreased functional oral intake. The improvements were maintained at the 6-month and the 2-year follow-ups ($p < 0.001$, each compared with baseline).

The median degree of dysphagia improved significantly from grade 4 at baseline to grade 3 after NMES ($p < 0.001$). An additional improvement to grade 2 was seen at the 6-month follow-up ($p = 0.014$, compared data after NMES with 6-month follow-up) and the effect was maintained at the 2-year follow-up ($p < 0.001$, compared with baseline) (Table 2).

The median VAS score of patients' self-perception of swallowing ability improved from 5.5 at baseline to 3 after NMES ($p < 0.001$). It further improved to 2 at the 6-month follow-up ($p = 0.009$, compared data after NMES with 6-month follow-up), and the effect was maintained at the 2-year follow-up ($p < 0.001$, compared with baseline). No patient rated post-therapy perception of swallowing ability as lower than his/her baseline score.

Figure 2 shows changes in FOIS scores during the study period, and Table 3 gives the detailed changes in FOIS scores from baseline after NMES and at 6-month and 2-year follow-up. Most patients (69 %, 20/29) improved at least two levels on the FOIS after NMES. At the 6-month follow-up, 8 patients improved two or three levels and 12 patients improved four to six levels. At the 2-year follow-up, 9 patients improved two or three levels and 12 patients improved four to six levels. Overall, 15 of the 21 (71.4 %) initial tube-feeding patients (FOIS levels 1–3) improved enough to no longer require a feeding tube and they progressed to total oral intake (FOIS levels 4–7). No pneumonia was found in any of the patients who successfully resumed an oral diet. Twenty-three of the 29 (79.3 %) patients maintained an oral diet with no pulmonary complications at 2-year follow-up. However, six patients still required a feeding tube for long-term nutrition. Among them, two patients remained partially dependent on nonoral feeding and four patients eventually took nothing by mouth.

Table 4 presents the results of comparisons of FEES findings at pre- and post-NMES. Most patients showed improvement in the pharyngeal phase of swallowing. Compared with baseline, pharyngeal secretion, pharyngeal stasis, and penetration-aspiration scale improved significantly after NMES ($p < 0.001$, each compared with baseline). However, cough score did not change significantly after NMES ($p = 0.236$).

Patients' global satisfaction was high. Twenty-five (86.2 %) patients reported satisfaction at 6-month follow-up and 24 (82.8 %) patients reported satisfaction at 2-year follow-up (Table 5).

Table 2 Comparisons of outcomes at baseline and post-tests ($n = 29$)

Scale	Visit	Median	Corrected[a] p[b]	Corrected[a] p[c]	Corrected[a] p[d]
FOIS	Baseline	2 (1;4)			
	After NMES	6 (5;6)	<0.001		
	6 months	6 (5;6)	<0.001	0.244	
	2 years	6 (5;6)	<0.001		1.000
Degree of dysphagia	Baseline	4 (3;4)			
	After NMES	3 (2;3)	<0.001		
	6 months	2 (1.5;3)	<0.001	0.014	
	2 years	2 (1.5;3)	<0.001		1.000
VAS	Baseline	5.5 (4.8;8.0)			
	After NMES	3 (2.5;4.8)	<0.001		
	6 months	2 (2.0;3.0)	<0.001	0.009	
	2 years	2 (2.0;3.0)	<0.001		1.000

Values are median with 25th and 75th percentiles in parenthesis

FOIS Functional Oral Intake Scale, *VAS* visual analog scale for the patient's self-perception of swallowing ability

[a] Bonferroni's correction for multiple comparisons

[b] When comparing each follow-up data with baseline data

[c] When comparing post-NMES data and 6-month follow-up data

[d] When comparing 6-month follow-up data and 2-year follow-up data

All patients tolerated the treatment sessions with no obvious discomfort. Two patients complained of minor skin irritation at the site of the electrodes during NMES, but they completed the protocol. Minor epistaxis occurred in one case during FEES. Three (10.3 %) patients had pneumonia at 4, 7, and 10 months after recruitment and one developed a recurrent pneumonia at 15 months after recruitment.

Discussion

This preliminary investigation demonstrated that combined NMES, FEES, and traditional swallowing rehabilitation showed potential to improve FOIS scores, clinical degree of dysphagia, and self-perception of swallowing ability of stroke patients with moderate to severe dysphagia. These benefits were maintained at 6 months and 2 years after therapy. Patients' global satisfaction was high with no serious adverse events. The results are promising enough to justify further studies.

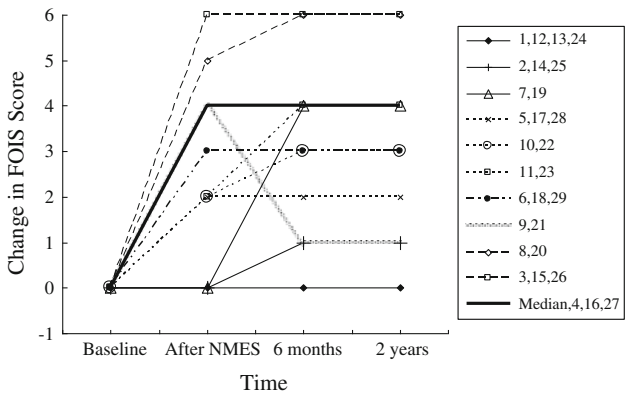

Fig. 2 Change in Functional Oral Intake Scale score during the study period. *FOIS* Functional Oral Intake Scale, *NMES* neuromuscular electrical stimulation

The study results are in agreement with previous research that has documented the effectiveness of NMES on swallowing [10, 11, 14]. However, direct comparison between our study's data and that of others is difficult because of the difference in treatment techniques and time poststroke. The mechanisms of action of NMES have not been fully elucidated. In patients with stroke-related dysphagia, voluntary control of the muscles involved in swallowing was impaired, and it might be presumed that these muscles were atrophied or lost strength because of disuse or long-term tube feeding. Oropharyngeal sensation and the timing in triggering the pharyngeal swallow could be impaired. NMES is postulated to improve hyolaryngeal elevation, restore motor function of weak muscles, combat disuse atrophy, enhance sensory awareness, and facilitate muscle contractions [20, 25, 26]. Studies have shown that cortical representation areas can be modified by sensory and motor stimulation, suggesting that NMES may improve swallowing via cortical reorganization [27]. NMES recruits more motor units than volitional contraction and may produce greater gains in muscle strength than exercise alone [9, 28]. DeKroon et al. [29] reported that NMES administered during execution of a purposeful

Table 3 Changes in FOIS scores from baseline during the study periods ($n = 29$)

FOIS change	After-NMES	6 months	2 years
0	8	4	4
1	1	5	4
2	7	3	4
3	4	5	5
4	4	7	6
5	2	0	2
6	3	5	4

Values are numbers of patients

FOIS Functional Oral Intake Scale

motor task may be superior to NMES administered when the target muscle is at rest. In our study, NMES was applied simultaneously with volitional swallowing exercise for task-oriented intense training and enhancing motor relearning.

In this study, most patients improved swallowing functions rapidly and significantly after NMES. Final feeding status had improved significantly, even after the combination intervention was discontinued. Various factors might account for the clinical and functional gains after the combination therapy ended. However, these results did not address the relative contribution of each therapy procedure. For stroke patients, the goals of dysphagia treatment are to return the individual to safe oral feeding and to prevent any medical complications. At 2-year follow-up, 15 of the 21 (71.4 %) initial tube-feeding patients improved enough to no longer require a feeding tube, and the majority (79.3 %) of patients maintained an oral diet with no pulmonary complications. To the best of our knowledge, there have been no other reports that revealed persistent and significant swallowing improvements after such a long follow-up period. Given the short-term effect of NMES, we believe that the strategy of intensive rehabilitation training soon after NMES and the use of FEES to guide dysphagic management contributed substantially to the improvement of the swallowing function and assuring a long-term benefit. However, part of the improvement might have been the result of spontaneous recovery.

In this study, FEES was used to objectively evaluate pharyngeal dysphagia, guide dietary recommendations before and after NMES, and provide information to help decide on the therapeutic strategies that promote safe and efficient eating. The results corroborated previous reports using FEES [5, 15, 16, 18]. We demonstrated that FEES can be used successfully to determine the appropriate food consistency and help resume safe oral feeding with no adverse outcome. To our knowledge, this study is also the first that prospectively used FEES to examine swallowing change after NMES in patients with poststroke dysphagia. We observed that pharyngeal secretion, pharyngeal stasis, and penetration or aspiration decreased significantly after NMES and confirmed a recovery of the oropharyngeal phase of swallowing by FEES.

Results of the study were promising and encouraging, as we found that patients with moderate and severe dysphagia may improve swallowing functions and feeding status and the incidence of feeding tube placements decreased after the combined intervention. The information from this case series not only may add to the body of literature on the efficacy of NMES and FEES for swallowing rehabilitation, it also helps focus on future research efforts in the area of combination therapy. Interestingly, three patients in this case series, who despite having relied on nonoral feeding for more than 6 months, returned to independent oral feeding at the 6-month and 2-year follow-ups. Our findings suggest that even long-standing dysphagia (>6 months)

Table 4 Comparisons of FEES findings at pre- and post-NMES ($n = 29$)

Time	Pharyngeal secretion	Pharyngeal stasis	Penetration-aspiration scale	Cough score
Pre-NMES	2 (1;2)	3 (3;4)	3 (2;5)	1 (1;1)
Post-NMES	0 (0;2)	2 (1;3)	2 (1;2)	1 (1;1)
Corrected[a] p	<0.001	<0.001	<0.001	0.236

Values are median with 25th and 75th percentiles in parenthesis

[a] Bonferroni's correction for multiple comparisons

Table 5 Patients' global satisfaction ($n = 29$)

Visit	Completely satisfied	Satisfied	Somewhat satisfied	No change	Satisfaction rate
6 months	15 (51.7)	8 (27.6)	2 (6.9)	4 (13.8)	86.2
2 years	12 (41.4)	9 (31.0)	3 (10.3)	5 (17.2)	82.8

Values are number of patients and percentage in parentheses. The number of patients refers to those who reported their level of global satisfaction with regard to the combination therapy when comparing the situation with that before the therapy. No patients reported dissatisfaction throughout the study period

can improve dramatically in selected patients after the combination treatment. However, the predictive factors for good response were not delineated in this small-case-number study.

Despite improvements in most of the patients, six patients still required a feeding tube for long-term nutrition at the 6-month and 2-year follow-ups. Nonoral status was necessary for these patients because they either aspirated or were at high aspiration risk (e.g., they had severe pooling or retention in the pyriform sinuses not cleared with subsequent dry swallows and severe or consistent laryngeal penetration, and they did not benefit from therapeutic strategies to improve swallowing). One interesting point we found in these patients was that they all showed saliva penetration and/or aspiration and did not have an effective cough by initial FEES. This point has to be examined more closely in a future study to investigate whether there is an association between initial FEES findings and final feeding outcomes. In line with our experience, Shaw et al. [30] previously showed that NMES seems to help patients with mild to moderate dysphagia, but those with the most severe dysphagia did not gain independence from tube feeding. One possible explanation for the poor response in these patients might be that the treatment period is probably not long enough to observe significant improvement. Besides, the fixed stimulation variables (frequency and pulse width) of the VitalStim® electrical stimulator might not have been optimal for treatment of severe swallowing disorders.

The strengths of this study included the minimization of observer bias in outcome evaluation by the blinding the assessor to treatment progression, and the inclusion of several outcome measures, which reduces the potential to influence the obtained outcomes. Moreover, patients with cognitive impairment were excluded from this study because their ability to learn swallowing maneuvers could be impacted, and previous research has demonstrated a relationship between cognitive abilities and swallow outcomes [31]. Satisfaction was taken into consideration when judging the beneficial effects of the combination therapy.

Although this preliminary investigation yielded many findings of interest, conclusions drawn from this case series must be tempered by the many limitations inherent in its design. This was a single-center study with a small sample size and limited to patients with moderate to severe dysphagia after stroke. The ability to generalize the results to other dysphagic populations remains uncertain. Besides, participants were recruited by advertisement, which means they were self-referred and a very motivated cohort is not necessarily representative of the general patient population. Some patients were still in acute or subacute stage after stroke, and this study did not include a control group; part of the improvements might have been the result of spontaneous recovery. Patients who received NMES also performed the effortful swallow exercise simultaneously; thus, it is not clear whether the effortful swallow or the NMES led to the benefit. We acknowledged that the 6-month and 2-year outcomes were interesting, but the long-term outcomes might be subject to more confounders. The optimal time to perform NMES, FEES, or rehabilitation in stroke-related dysphagia patients remains unknown. To date, there is no universally accepted NMES protocol for dysphagia, including intensity of the current, frequency, and length of the treatment. Optimization of electrical stimulation parameters to improve dysphagia treatment is needed. Furthermore, we did not repeat FEES periodically to monitor swallowing change in patients who still required long-term feeding access after therapy. The issue of when to reevaluate and when to advance the diet in these severely dysphagic patients is challenging and the cost:benefit ratio needs careful consideration.

Future studies should replicate and extend this study with rigorously controlled designs and a larger sample size. The potential effects on the central cortical representation of swallowing remain an area of interest. Comparison studies with other potential therapeutic combinations are needed to determine the optimal treatment for dysphagia, and such research trials should assist in the identification of specific populations that may have a greater response to therapy, if such subgroups exist.

Conclusion

This preliminary investigation demonstrated that combined NMES, FEES, and traditional swallowing rehabilitation showed the potential to improve swallowing function in stroke patients with moderate to severe dysphagia. These benefits could be maintained for 6 months and up to 2 years. Patient satisfaction rate was high and there were no serious adverse events. The results from this case series provide support for introducing this promising combination into clinical practice and further studies are warranted to help establish the future clinical utility of this novel combination therapy in dysphagic patients.

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Conflict of interest The authors have no conflicts of interest to declare.

Appendix 1

See Table 6.

Table 6 Functional Oral Intake Scale and degree of dysphagia

FOIS	
Level 1	Nothing by mouth
Level 2	Tube-dependent with minimal attempts at food or liquid intake
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 foods limitation
Level 7	Total oral diet with no restrictions
Degree of dysphagia	
1	No clinical signs and symptoms of dysphagia
2	Very mild dysphagia suspected from clinical examination, but the patient never complained of any swallowing difficulty
3	Patient had complaints of dysphagia that were supported by other clinical signs, but nonoral feeding was not necessary at the time of investigation
4	Patient had distinct clinical signs and symptoms of dysphagia, including aspiration, and dysphagia was sufficiently severe to necessitate nonoral feeding

Appendix 2

See Table 7.

Table 7 Scores for fiberoptic endoscopic evaluation of swallowing

FEES	Scoring
Pharyngeal secretion level	0 = normal (moist)
	1 = pooling without penetration or aspiration
	2 = pooling with penetration or aspiration
Pharyngeal stasis	0 = no stasis or trace stasis
	1 = mild bolus retention
	2 = moderate bolus retention (approximate 1/2 cavity)
	3 = severe bolus retention (fill > 1/2 cavity)
	4 = major stasis with bolus overflow onto laryngeal vestibule
Penetration-aspiration scale	1 = no penetration or aspiration
	2 = penetration with protective reflex
	3 = penetration without protective reflex
	4 = aspiration with protective reflex
	5 = aspiration without protective reflex
Cough score	0 = can not cough
	1 = somewhat effective cough
	2 = very effective cough

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