Dysphagia
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ORIGINAL ARTICLE

The Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Post-stroke Dysphagia: A Randomized Controlled Trial

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Abstract

The study aimed to evaluate the effects of traditional dysphagia therapy (TDT) and neuromuscular electrical stimulation (NMES) combined with TDT on functionality of oral intake, dysphagia symptom severity, swallowing- and voice-related quality of life, leakage, penetration–aspiration, and residue levels in patients with post-stroke dysphagia (PSD). Thirty-four patients with PSD were included in our prospective, randomized, controlled, and single-blind study. The patients were divided into two groups: (1) TDT only (control group, $n = 17$) and (2) TDT with NMES (experimental group, $n = 17$). TDT was applied to both groups for three consecutive weeks, 5 days a week, 45 min a day. Sensory NMES was applied to the experimental group for 45 min per session. Patients were evaluated by the functional oral intake scale (FOIS), the eating assessment tool (EAT-10), the swallowing quality of life questionnaire (SWAL-QOL), and the voice-related quality of life questionnaire (VRQOL) at baseline, immediately post-intervention, and at the 3rd month post-intervention. Fiberoptic endoscopic evaluation of swallowing (FEES) with liquid and semi-solid food was performed pre- and post-intervention. A significant post-intervention improvement was observed on all scales in both groups, and these improvements were maintained 3 months post-intervention. Leakage and penetration–aspiration levels with semi-solid food declined only in the experimental group. In conclusion, TDT is a non-invasive and inexpensive method that leads to improvement in many swallowing-related features in stroke patients; however, NMES as an adjunct therapy is costly but can provide additional benefits for improving features, such as penetration–aspiration and residue levels.

Keywords Stroke · Rehabilitation · Dysphagia · Neuromuscular electrical stimulation · Traditional dysphagia therapy · Penetration–aspiration

Introduction

The most frequent cause of neurogenic dysphagia is post-stroke dysphagia (PSD), which is characterized by problems in the oropharyngeal stage [1]. PSD has been described as a difficulty in swallowing that affects most patients in the first few hours and days after a cerebrovascular accident, CVA [2]. The prevalence of PSD has been reported as up to 60%, and this rate can reach up to 100% when minor swallowing disorders are considered [3]. PSD can increase morbidity and mortality in stroke patients due to prolonged hospital stays, delays in the rehabilitation process, malnutrition, dehydration, aspiration pneumonia, increased risk of infection, and even death. Early evaluation of PSD and initiation of dysphagia therapy prevent PSD complications [4].

According to stroke rehabilitation guidelines, patients with dysphagia should receive swallowing rehabilitation 1 week after a CVA [5]. Swallowing rehabilitation comprises traditional dysphagia therapy (TDT) and other rehabilitative approaches, such as neuromuscular electrical stimulation (NMES). TDT includes patient education, oral hygiene, diet regulation, nutritional support, and compensatory and rehabilitative approaches [6, 7].

Since the first article investigating the use of NMES in PSD rehabilitation was published (2001), few trials have investigated the effects of NMES on PSD [8]. In studies investigating the application of NMES to swallowing

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muscles, sensory or motor stimulation was applied to the suprahyoid or infrahyoid regions [9–12]. Different protocols have been studied regarding stimulation features and session frequency. In previous studies, intervention durations were 1–8 weeks, 2–5 days a week, for 10 min to 1 h. The stimulation frequency was 30–80 Hz, and the pulse duration was 300 µs to 800 ms [9, 13–17]. The optimum NMES application has not been determined.

Previous studies have shown conflicting results regarding the use of NMES alone in PSD therapy. Although some show that the use of NMES along with TDT will provide additional benefits, others have the opposite opinion [9, 10, 14, 15, 18].

The consensus in PSD trials to date is that there is insufficient evidence for the NMES use alone in swallowing therapy and that NMES may contribute more to the improvement of swallowing than TDT alone [9, 10, 19]. Studies evaluating NMES use in PSD have provided inconsistent results; therefore, the efficacy and safety of this method remain controversial. To determine whether NMES is effective and in which patients NMES may be more effective, high-quality studies are needed to evaluate electrode placement, application methods, and the short- and long-term effects of NMES on swallowing function [14].

Using standardized scales and instrumental assessment methods, we investigated and compared the effects of TDT and the addition of NMES to TDT in PSD. To the best of our knowledge, our study is the first to compare the effects of TDT and TDT–NMES on the severity of dysphagia symptoms, the physiology of swallowing, and patients' quality of life related to swallowing and voice, as well as the effects of these therapies on functional swallowing.

Methods

Our study was designed as a randomized, controlled, prospective, single-blind study. Thirty-eight stroke patients were eligible for our study, which was conducted from April 2020 to October 2020. The inclusion and exclusion criteria are presented in Table 1.

Participants were randomized into two groups: the TDT with NMES group (experimental) and the TDT group (control). Randomization was provided via a code generator program on the computer using the permuted block randomization method. The researcher (E.T.C.) who prepared the randomization list applied the treatment program to the patients. Another researcher (S.S.) was blinded to the intervention that measured the functional oral intake scale (FOIS), the eating assessment tool (EAT-10), the swallowing quality of life questionnaire (SWAL-QOL), and the voice-related quality of life questionnaire (VRQOL) pre-, post-, and in the 3rd month after the intervention. Pre- and post-intervention fiberoptic endoscopic evaluations of swallowing (FEES) measurements were recorded by an otorhinolaryngologist (C.S.) blinded to the treatment, and the records were evaluated by another otorhinolaryngologist (C.D.) who was also blinded to the treatment. All extracted data were analyzed by the data analyst who was blinded to the study.

Table 1 Inclusion and exclusion criteria of the participants

Inclusion criteria
• Diagnosis of stroke by MRI or CT scans
• Over the age of 18
• Detection of dysphagia by bedside water swallow test in patients who have passed 1 week or longer after stroke
• Having unassisted sitting balance
• A score above 20 on the MMSE
• No swallowing problems before stroke
Exclusion criteria
• Having had multiple strokes
• Presence of global aphasia or cognitive impairments that would affect comprehension of the instructions
• Having major medical issues that may affect participation in the program
• Presence of tracheostomy or cardiac pacemaker
• History of epilepsy
• Having had a previous surgical operation or radiotherapy to the head or neck are

MRI magnetic resonance imaging, *CT* computerized tomography, *MMSE* mini-mental state examination

Our study was approved by the Institutional Review Board and followed the principles of the Declaration of Helsinki. The study protocol was approved by the Istanbul University Istanbul Faculty of Medicine Clinical Research Ethics Committee (Approval Number 75346), and all methods were performed following the relevant guidelines and regulations. This study was also approved by the National Agency for Medicines and Medical Devices. Each patient signed an informed consent form, and the study was registered on clinicaltrials.gov (Registration Number NCT04421937).

Figure 1 presents the Consolidated Standards of the Reporting Trials flow diagram.

Intervention

TDT was used in both groups for three consecutive weeks at 5 days per week for 45 min per day. In addition to TDT, 45 min of NMES was applied to the experimental group.

TDT was a standardized program that included diet modification according to the patients' oral intake levels, oral hygiene education, compensatory methods, and exercises. The TDT program was overseen by a physiatrist (E.T.C.). Compensatory methods comprised postural techniques, such as chin tuck and rotation lateral flexion of the head, and oral sensorimotor enhancement techniques, such as

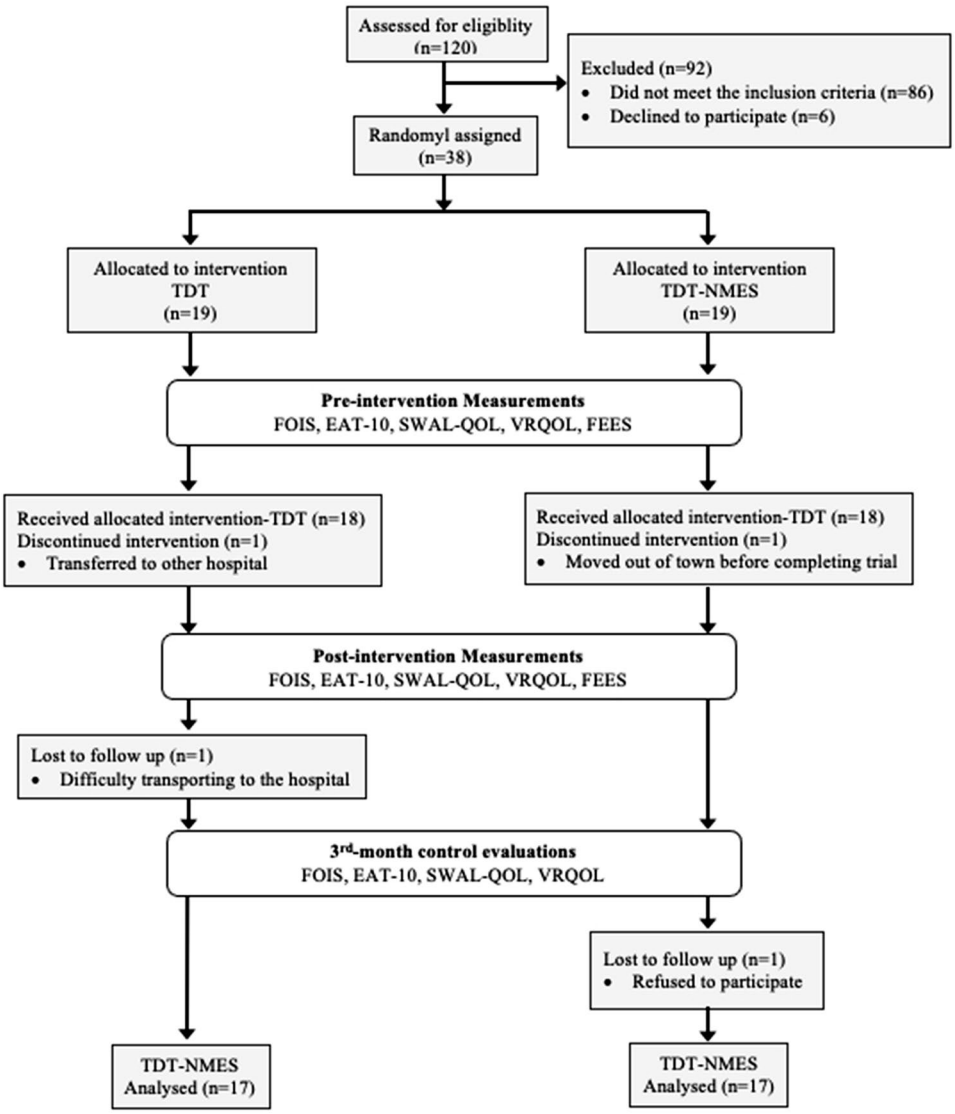


Fig. 1 Participant flow and study profile. *TDT* traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, FOIS functional oral intake scale, *EAT-10* the eating assessment tool, *SWAL-QOL* the swallowing quality of life questionnaire, VRQOL the voice-related quality of life questionnaire, *FEES* fiberoptic endoscopic evaluation of swallowing

thermal-tactile stimulation (TTS). Oral motor control exercises consisting of jaw, tongue, and lip range of motion (ROM) exercises were performed for eight repetitions in each direction for three sets, minimum. The Masako maneuver, which is a pharyngeal ROM exercise, was performed with 10 repetitions for three sets, minimum. The chin tuck against resistance exercise, which provides suprahyoid muscle contraction and is also a pharyngeal ROM exercise, was performed at maximum patient toleration in three sets. The TDT program comprised exercises implemented in similar studies investigating PSD rehabilitation and recommended in current guidelines [5, 7, 14, 20]. During the exercise sessions, the patients were given short rest periods of less than 5 min in line with their requests.

NMES was applied via using a modified hand-held battery-powered electrical stimulator (VitalStim® Dual Channel Unit and Electrodes, Chattanooga Group, Hixson, TN, USA). The application protocols of NMES in PSD vary. Therefore, NMES session duration and frequency and the total number of sessions in this study were created by evaluating previous studies [9, 14–17, 21–35]. NMES was applied in 15 sessions for 3 weeks, 5 consecutive days per week, with each session lasting 45 min.

By reviewing previous studies, the NMES application method was determined as an 80 Hz pulse rate with a biphasic pulse duration of 700 µs and stimulation intensity not exceeding 25 mA [12, 14, 15, 19, 25, 36–39].

Proper electrode placement targeting the suprahyoid or infrahyoid muscles during electrotherapy of swallowing muscles is difficult due to the small and overlapping locations of these muscles. Given that the function of the suprahyoid muscles is to pull the hyoid upward and toward the mandible, the suprahyoid muscles are targeted during stimulation to prevent hyolaryngeal excursion in those with PSD. It is important for the thyrohyoid muscle to contract with sufficient force to protect the airway during swallowing;

therefore, this muscle was also targeted in the stimulation [12, 40]. Based on these factors, the upper electrodes were placed on the mylohyoid muscle just above the hyoid bone, and the lower electrodes were placed horizontally on the thyrohyoid muscle (Fig. 2). The stimulation intensity level started at 2 mA, increased by 0.5 mA intervals, and stabilized when the patient felt vibration in their neck. During the application, the patient was observed by a physiatrist (E.T.C).

Evaluation Measurements

The patients' clinical and demographic information was recorded at the beginning of the study. The patients were evaluated by outcome measures at baseline, immediately after the intervention, and at the 3rd month after the intervention. The FOIS was the primary outcome measure. The EAT-10, SWAL-QOL, and VRQOL were the secondary outcome measures. FEES was performed as a quantitative measure before and immediately after the intervention.

The FOIS is a seven-level scale that indicated oral intake level. This demonstrates a change in functional oral intake in stroke patients [41]. The EAT-10 is a 10-item scale that evaluates dysphagia symptom severity to monitor dysphagia treatment effectiveness [42]. An EAT-10 total score of ≥ 3 indicates the presence of oropharyngeal dysphagia [43], whereas ≥ 15 indicates the risk of aspiration [44]. The SWAL-QOL evaluates the quality of life of those who have swallowing disorders and comprises burden, communication, eating desire, eating duration, fatigue, fear, food selection, mental health, sleep, social functioning, and symptom frequency subsections [45–47]. The VRQOL assesses quality of life by questioning the emotional and functional effects of voice problems [48]. The outcome measures used in our study have national validity and reliability [45, 49, 50].

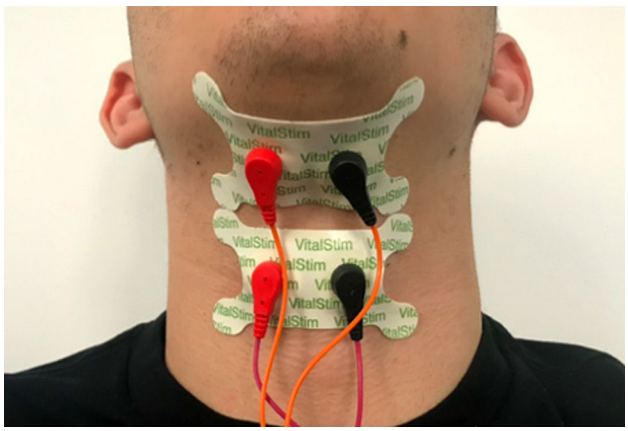


Fig. 2 Application of electrodes

FEES was performed by an otorhinolaryngologist blinded to the study with boluses with different consistencies, including liquid (90 ml of a mixture of water and green food coloring) and semi-solid food (yogurt). The patients were first given 10 ml of fluid, and their oral capacity was evaluated, followed by a bolus of 90 ml of liquid using a straw. Subsequently, the patients were given one tablespoon of yogurt twice. A leakage assessment was performed during bolus intake. A score was given according to the localization where the bolus escaped: 0 = no leak, 1 = at the base of the tongue or vallecula, 2 = moves to lateral channels or the tip of the epiglottis, 3 = in the piriform sinuses or touches the laryngeal rim on the sides or back, and 4 = falls into the laryngeal vestibule or is aspirated before swallowing [51]. After swallowing, the patients were evaluated according to the eight-item penetration–aspiration scale, PAS [52]. A score was given according to the localization of the residue formed after swallowing: 0 = no residue, 1 = oropharyngeal, 2 = in the pyriform sinuses, and 3 = in the aditus larynx [53].

Statistical Analysis

Taking into account the results of a previous study [54] and assuming an α error of 0.05% and a power of 80%, the required sample size was estimated to be 17 patients per group. Assuming a dropout rate of 10%, 19 participants in total would be needed in each group.

In the evaluation of the data, besides descriptive statistical methods (mean, standard deviation, median, interquartile range), the normality of the distribution was determined with the Shapiro–Wilk test. Independent sample *t*-test was used to compare the normally distributed variables in paired groups. Friedman Test was used for multiple time comparisons of non-normally distributed variables, Dunn's multiple comparison test was used for subgroup comparisons, and Wilcoxon test was used for time comparisons. For variables without normal distribution, the Mann–Whitney *U* test was used to compare paired groups and the χ^2 test to compare qualitative data. The significance of the results was evaluated at the $p < 0.05$ level. All analyses were conducted using the NCSS 2021 Statistical Software (Number Cruncher Statistical System, Utah, USA).

Results

There was no significant difference between the two groups in terms of the patients' initial demographic and clinical characteristics (Table 2). There was no significant difference at the baseline assessment between the two groups in terms of all outcome measures (Table 3). No adverse effects were observed during the interventions or 3 months after the interventions.

Table 2 Clinical and demographic characteristics of patients

	TDT ($n=17$)	TDT–NMES ($n=17$)	p
Age (years)	63.6 ± 10.0	62.9 ± 9.8	0.717*
Gender (male/female)	9/8	11/6	0.486^{+}
Length of stay in hospital after stroke (days)	12.0 ± 11.2	12.7 ± 10.8	0.640**
Time from stroke to enrollment (weeks)	52.2 ± 92.2	48.3 ± 92.6	0.640**
Presence of aphasia	3 (17.7%)	4 (23.5%)	0.671^{+}
Presence of dysphonia	14 (82.4%)	15 (88.2%)	0.628+
Stroke etiology (ischemic/hemorrhagic)	15/2	16/1	0.545^{+}
Stroke lesion site (hemisphere/brainstem)	10/7	11/6	0.724^{+}
Affected side in stroke (right/left)	5/12	6/11	0.714^{+}
Post-stroke nutritional support status (absent/NGT/PEG)	5/11/1	6/10/1	0.933^{+}
History of post-stroke pneumonia (yes/no)	5/12	6/11	0.714^{+}
Barthel index			
Total dependency	3	3	0.983^{+}
Severe dependency	1	2	
Moderate dependency	6	6	
Slight dependency	5	4	
Total independent	2	2	

Values are presented as mean ± standard deviation or number (%)

TDT traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, *NGT* nasogastric tube, *PEG* percutaneous endoscopic gastrostomy

*Independent *t*-test, $^{+}\chi^2$ test, **Mann–Whitney *U* test

Table 3 Outcome measures, comparisons pre-, post-intervention and 3rd month after the intervention

Outcome measures	Group	Measures			Changes	Between groups	
		Pre	Post	3rd-month	Freidman test		Mann–Whitney *U* test
FOIS	TDT	4.5 ± 1.8 5 (3–6)	5.8 ± 1.6 6 (5.5–7)	6 ± 1.4 6 (5.5–7)	0.0001	Pre Post	0.857 0.685
	TDT–NMES	4.3 ± 1.9 5 (2–6)	6 ± 1.5 6 (6–7)	6.2 ± 1.4 7 (6–7)	0.0001	3rd-month	0.449
EAT-10	TDT	24 ± 9.4 23 (16.5–32.5)	11.5 ± 8.8 9 (6–16)	11.6 ± 9.7 12 (2–16)	0.0001	Pre Post	0.809 0.103
	TDT–NMES	24.8 ± 9.2 23 (17.5–33.5)	7.7 ± 7.9 6 (2–11.5)	6.7 ± 8.3 3 (1.5–10)	0.0001	3rd-month	0.083
SWAL-QOL	TDT	116.6 ± 28.8 126 (96–136.5)	163.4 ± 28.3 175 (144–181.5)	164.8 ± 32.5 170 (147–188)	0.0001	Pre Post	0.743 0.129
	TDT–NMES	115.2 ± 27.7 119 (96.5–134.5)	177.2 ± 22.4 184 (162–193.5)	182.1 ± 22.9 189 (172.5–198)	0.0001	3rd-month	0.065
VRQOL	TDT	30.5 ± 13.1 30 (17.5–43)	20.6 ± 11.7 18 (10–31)	21 ± 12.0 15 (10.5–33.5)	0.0001	Pre Post	0.959 0.777
	TDT–NMES	30.6 ± 14.1 30 (16–46)	19.6 ± 11.1 17 (10–29)	19 ± 10.2 15 (10–30)	0.0001	3rd-month	0.543

Values are presented as mean ± standard deviation and median (range)

TDT traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, *Pre* pre-intervention, *Post* post-intervention, *3rd month* 3rd month after the intervention, *FOIS* functional oral intake scale, *EAT-10* eating assessment tool, *SWAL-QOL* swallow quality of life questionnaire, *VRQOL* voice-related quality of life questionnaire

Table 4 Dunn's multiple comparison test results of outcome measures

Pairwise	FOIS		EAT-10		SWAL-QOL		VRQOL	
	TDT	TDT–NMES	TDT	TDT–NMES	TDT	TDT–NMES	TDT	TDT–NMES
Pre/Post	0.001	0.0001	0.0001	0.0001	0.0001	0.0001	0.001	0.001
Pre/3rd month	0.001	0.0001	0.0001	0.0001	0.0001	0.0001	0.001	0.001
Post/3rd month	0.180	0.102	0.795	0.221	0.999	0.027	0.527	0.472

Values presented are *p*-values

FOIS functional oral intake scale, *EAT-10* eating assessment tool, *SWAL-QOL* swallow quality of life questionnaire, *VRQOL* voice-related quality of life questionnaire, *TDT* traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, *Pre* pre-intervention, *Post* post-intervention, *3rd month* 3rd month after the intervention

Statistically significant changes were observed pre- and post-intervention, and in the 3rd month after the intervention. FOIS levels and EAT-10, SWAL-QOL, and VRQOL scores in both groups are shown in Table 3. In all outcome measures, the post-intervention and 3rd month control evaluations were found to be statistically significantly improved compared to the pre-intervention evaluations in both groups. There was no significant change in the outcome measures, except SWAL-QOL, in the post-intervention and the 3rd month after the intervention in either group. In the TDT–NMES group, there was an improvement in SWAL-QOL in the 3rd month after the intervention compared to the post-intervention ($p=0.027$), while there was no significant change in the TDT group (Table 4).

There was no significant change in the presence of oropharyngeal dysphagia (EAT-10 score ≥ 3) or aspiration risk (EAT-10 score ≥ 15) in either group. While not statistically significant, aspiration risk was detected in 78.6% and 88.2% of the patients in the pre-intervention TDT and TDT–NMES groups, respectively, and these rates decreased to 29.4% and 5.9%, respectively, after the intervention (Table 5).

There was no significant difference at the baseline assessment between the two groups in terms of FEES findings (Table 6). In the TDT group, there was significant improvement in all parameters in FEES with liquid, but improvement was observed only for post-swallowing residues with semi-solid food. Conversely, in the TDT–NMES group, significant improvement was achieved in all parameters in FEES with both liquid and semi-solid food. Leakage levels with semi-solid food were significantly lower in the TDT–NMES group than in the TDT group post-intervention.

Discussion

This study found improvement in swallowing function, dysphagia symptom severity, and quality of life in patients with PSD using both TDT and TDT–NMES, and these improvements were preserved at the 3rd month after the intervention. Additionally, improvements in PAS and leakage scores were better with semi-solid food in the group in which NMES was added to the therapy regimen.

Functionality of Oral Intake

FOIS, which was the primary outcome measure, improved in both groups. This improvement was maintained in both groups at the 3rd month after the intervention, and there was no significant difference between the groups.

Huang et al. [16] divided 29 patients with PSD who had suffered a stroke less than 3 months prior into 3 groups: TDT

Table 5 EAT-10 scores, comparisons pre-, post-intervention and 3rd month after the intervention

	EAT-10 score	TDT ($n=17$)	TDT–NMES ($n=17$)	p*
Pre	$<3/\geq 3$	0 (0.0)/17 (100.0)	0 (0.0)/17 (100.0)	1
	$<15/\geq 15$	3 (21.4)/14 (78.6)	2 (11.8)/15 (88.2)	0.999
Post	$<3/\geq 3$	2 (13.3)/15 (86.7)	7 (41.2)/10 (58.8)	0.118
	$<15/\geq 15$	12 (70.6)/5 (29.4)	16 (94.1)/1 (5.9)	0.175
3rd month	$<3/\geq 3$	5 (29.4)/12 (70.6)	8 (47.1)/9 (52.9)	0.413
	$<15/\geq 15$	11 (64.7)/6 (35.3)	16 (94.1)/1 (5.9)	0.085

Values are presented as number (%)

EAT-10 eating assessment tool, *TDT* traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, *Pre* pre-intervention, *Post* post-intervention, *3rd month* 3rd month after the intervention

*χ^2 test

Table 6 FEES (fiberoptic endoscopic evaluation of swallowing) findings, comparisons pre- and post-intervention

FEES findings	Food consistency	Group	Measures			Between groups	
			Pre	Post	Wilcoxon test		Mann–Whitney *U* test
Leakage	Liquid	TDT	2.6 ± 1.1 3 (2–3)	2.1 ± 1.1 2 (1–3)	**0.024**	Pre	0.666
		TDT–NMES	2.7 ± 1.3 3 (2–4)	1.4 ± 1.2 1 (0–2)	**0.002**	Post	0.08
	Semi-solid	TDT	1.4 ± 1.2 1 (0.5–2)	1.1 ± 1.1 1 (0–1.5)	0.102	Pre	0.843
		TDT–NMES	1.3 ± 1.2 1 (0–2)	0.5 ± 0.7 0 (0–1)	**0.011**	Post	**0.048**
PAS	Liquid	TDT	3.5 ± 2.9 2 (1–6)	2.3 ± 2.4 1 (1–3)	**0.016**	Pre	0.677
		TDT–NMES	4 ± 3 4 (1–7)	2.6 ± 2.4 1 (1–4.5)	**0.007**	Post	0.756
	Semi-solid	TDT	2 ± 1.9 1 (1–25)	1.5 ± 1.5 1 (1–1)	0.059	Pre	0.663
		TDT–NMES	2.4 ± 2.2 1 (1–35)	1.4 ± 1.5 1 (1–1)	**0.043**	Post	0.325
Residue	Liquid	TDT	2 ± 1 2 (1–3)	1.2 ± 1.1 1 (0–2)	**0.003**	Pre	0.394
		TDT–NMES	2.3 ± 0.9 3 (1.5–3)	0.9 ± 1.1 0 (0–2)	**0.001**	Post	0.410
	Semi-solid	TDT	1.5 ± 1.1 1 (1–3)	0.9 ± 1.0 1 (0–1)	**0.031**	Pre	0.613
		TDT–NMES	1.7 ± 1.1 2 (1–3)	0.9 ± 1.1 1 (0–2)	**0.023**	Post	0.855

Values are presented as mean ± standard deviation, median (range) and *p*-value. Bold values denote statistical significance at the $p < 0.05$ level

TDT traditional dysphagia therapy, *NMES* neuromuscular electrical stimulation, *PAS* penetration–aspiration scale, *Pre* pre-intervention, *Post* post-intervention

($n = 11$), NMES ($n = 8$), and TDT–NMES ($n = 10$). NMES was applied for 10 sessions at 60 min per session for 3 sessions per week. The dual-channel electrodes were placed in one vertical line, with channel one above the thyroid notch and channel two below the thyroid notch. TDT comprised a combination of oral exercise, compensation methods, TTS, and swallowing maneuvers. The patients were evaluated using FOIS, PAS, and the functional dysphagia scale (FDS). They had hemispheric lesions and were at stage 4 or lower according to FOIS. Although there were differences in NMES application features and the clinical characteristics of the participants in this study, a similar significant improvement in FOIS was achieved with interventions in all three groups, and no significant difference was found among the groups in terms of results. However, PAS levels with dense foods were significantly better in the TDT–NMES group [16]. These results, similar to the results of our study, show that TDT and TDT–NMES both improve swallowing functionality, and that NMES added to TDT may further improve the physiology of swallowing dense foods.

Unlike our study, patients in studies showing greater improvement in the functionality of oral intake with the addition of NMES to TDT were in the acute [36, 37, 55], acute/subacute [25], or subacute phases [38]. These studies included patients who were tube-fed [36–38, 55], had aspiration [37], or could not tolerate all food consistencies without restriction [25]. Therefore, in acute or subacute patients with PSD and in patients with a FOIS of 5 or lower, NMES, in addition to TDT, may improve swallowing functionality more than TDT alone.

Dysphagia Symptom Severity

In our study, comprehensive TDT was effective in reducing the severity of dysphagia symptoms, and the addition of NMES did not provide additional benefits. In former studies, NMES as an adjunct therapy reduced dysphagia symptom severity by reducing the EAT-10 [34, 56]. To the best of our knowledge, no study has compared the effects

of TDT and TDT–NMES on dysphagia symptom severity using the EAT-10. Our study showed that, although not statistically significant, according to the EAT-10 scores, patients at risk of aspiration had a reduced risk after dysphagia rehabilitation. To reveal statistically significant results, new studies with a larger sample sizes are needed.

Quality of Life

Swallowing includes not only physiological food intake but also social, psychological, and cultural experiences. Given that most studies have investigated physiological swallowing function, more studies on the quality of life of patients with PSD are needed. In our study, the SWAL-QOL of all patients increased with dysphagia rehabilitation. The 3rd-month evaluations indicated that the SWAL-QOL continued to increase after the treatment was terminated in the group with NMES added to the treatment regimen. This may have been due to the cortical reorganization effects of NMES [12].

Zhang et al. [39] divided 82 patients with PSD who had a medullary stroke less than 1 month prior into 3 groups: traditional swallowing therapy (TT, $n=27$), the sensory approach combined with TT ($n=28$), and the motor approach combined with TT ($n=27$). TT included postural adjustment, diet modification, TTS, oropharyngeal strengthening exercises, and swallowing maneuvers. Electrical stimulation sessions were conducted for 20 min, 2 times per day, 5 days per week over a 4-week period; two electrodes were placed parallel to the digastric muscle in the submental region. Zhang et al. revealed improvement in the SWAL-QOL in all groups, similar to our study, but the improvement was greater with NMES and TT than with TT alone, unlike our study. The greatest improvement in SWAL-QOL was in the group that applied the sensory approach [39], which was the method used in our study. Unlike our study, the fact that NMES provided additional benefits for SWAL-QOL may have been due to the clinical characteristics of the patients included, who were in the acute phase after medullary stroke.

Unlike our study, Xia et al. [28] reported that the SWAL-QOL in PSD improved more when NMES was added to the swallowing rehabilitation program [28]. Xia et al. defined the swallowing rehabilitation program they applied as basic training and direct food intake training, which was simpler than the TDT in our study and lacked many exercise types [28]. Accordingly, a well-designed swallowing rehabilitation program consisting of a sufficient number and variety of exercises can improve SWAL-QOL in patients with PSD.

Byeon [57] divided patients with PSD into three groups: the Mendelsohn maneuver and NMES ($n=15$), the Mendelsohn maneuver alone ($n=15$), and NMES alone ($n=13$). Evaluations were conducted with FDS and SWAL-QOL both before and after treatment. The NMES with the Mendelsohn maneuver group had the highest FDS and SWAL-QOL scores, followed by the Mendelsohn maneuver alone group and the NMES alone group. The results of Byeon's study showed that NMES may be more effective when combined with exercises than a single intervention method [57]. Byeon did not provide long-term results; however, in our study, in the long-term SWAL-QOL evaluation, similar to Byeon et al.'s study, there was a greater improvement in SWAL-QOL in the TDT–NMES group compared to the TDT group. This result suggests that NMES, as an adjunct therapy, provides further improvements in SWAL-QOL.

Swallowing and phonation share a common structure in the form of the respiratory–digestive system [58]. Therefore, according to the location and size of the lesion, voice changes that reduce the quality of life can be seen in patients with PSD [59]. According to our research, this study is the first to evaluate the effects of dysphagia rehabilitation programs on VRQOL. The results of this study showed that dysphagia therapy provides an increase in VRQOL, and this was maintained at the 3rd month post-intervention.

Fiberoptic Endoscopic Evaluation of Swallowing

FEES is a gold-standard test for the objective evaluation of PSD and is successful in demonstrating leakage, residue, penetration, and aspiration [60, 61]. We have demonstrated that FEES is an appropriate tool for dysphagia evaluation. Our FEES findings suggest that comprehensive swallowing therapy alone can reduce the levels of leakage, penetration, aspiration and residue in patients with PSD, and that NMES added to TDT may provide additional benefits in selected patient groups with worse functionality in oral intake.

Lim et al. [32] randomized 28 patients with PSD into 2 groups: TTS ($n=12$) and TTS–NMES ($n=16$). The intervention, defined as traditional therapy in their study, had weaker content than ours. Lim et al. administered TTS to the control group, while we applied TDT, which we created by combining many exercises used in dysphagia rehabilitation, to the control group. Unlike our study, Lim et al. revealed that NMES as an adjunct therapy, reduced PAS, but traditional therapy alone did not [32]. This difference may have been due to the different methods we applied to the control groups. Dysphagia rehabilitation, which comprises well-designed exercises in combination, is more beneficial than using a single type of exercise and improves PAS levels.

Simonelli et al. [37] divided their patients with PSD into two groups: TDT ($n=15$) and TDT–NMES ($n=16$). Similar to our study, they applied a comprehensive combination of various exercises (oral, tongue, and laryngeal motor exercises; laryngeal adduction elevation; TTS;

tongue strengthening; effortful swallowing; the Mendelsohn and Masako maneuvers; and the Shaker exercise) to the TDT group and performed FEES before and after treatment. While our study included subacute and chronic stroke patients, Simonelli et al. included only patients with subacute strokes. In Simonelli et al., TDT–NMES was more effective at reducing PAS than TDT in patients with subacute PSD, all of whom were fed via a feeding tube [37]. This finding supports our theory that NMES, as an adjunct therapy, may provide more successful results in reducing PAS in patients with low functionality in oral intake.

Neuromuscular Electrical Stimulation Application

There is no standard for electrode placement or stimulation parameters for NMES in PSD. Electrode placement on the suprahyoid muscles and thyrohyoid provides hyolaryngeal excursion in dysphagic patients with reduced hyolaryngeal elevation and weak muscles [12, 40, 62]. We placed two sets of electrodes to target the mylohyoid and thyrohyoid muscles. Similarly, Terré and Mearin [38] used two sets of electrodes and targeted these muscles. Sensory NMES, in which the stimulation threshold depended on the lowest current level at which the patients felt tingling in their necks, was applied in our study. Considering the effects of sensory stimulation on the long-term reorganization of the human cortex, the use of sensory electrical stimulation is recommended to improve swallowing function [12]. Sensory NMES applied in patients with PSD resulted in significant improvement in various dysphagia parameters, such as delayed swallowing response time and aspiration prevalence [63]. Motor NMES selectively activates type II muscle fibers, while type I muscle fibers are activated in voluntary contractions [9, 12]. Although this difference is accepted as a way to strengthen the muscles and develop their functions, it may not be enough to carry the results into functional activities.

In previous studies, the NMES session durations were 10 [17], 20 [21–23], 30 [24–29], 40 [30], and 60 [16, 31–34] min. The number of sessions varied between 3 [17] and 30 [35] in total; there were frequently 10 [16, 26, 34], 12 [22], 15 [25, 30, 31], 20 [24], 24 [23], and 28 [29] sessions. The sessions were completed in 2–6 weeks, and the session frequency varied between 2 and 5 per week [9, 14, 15]. In some studies, sessions were conducted twice per day [24, 29]. Similar to our method Diéguez-Pérez et al. found that NMES was most effective at 60–80 Hz, with a 700 µs pulse duration. However, unlike our method, for Diéguez-Pérez et al. NMES was most effective at motor intensity threshold and stimulations of 20–30 min [11]. Although our NMES application method was well tolerated, the optimum administration procedure needs to be determined.

Strengths and Limitations

The strengths of this study are the 3-month follow-up period, all evaluations were done completely blind to the intervention, and standardized scales and methods were used as primary and secondary outcome measures for evaluating the effectiveness and the safety of swallowing. This is the first study to investigate the effects of dysphagia rehabilitation on VRQOL. FEES, allowing evaluation of the safety of swallowing, was repeated with different food consistencies. The standardized TDT, organized with the combination of various exercises, was applied to all patients. Another strength is that the distribution of demographic and clinical characteristics that may affect the results of our study and the pre-treatment values of treatment evaluation parameters were homogeneous between the two groups.

The main limitation is the relatively small sample size. The second limitation is the study population heterogeneity. Given that stroke patients with hemisphere or brain stem lesions were included in the study, swallowing functions may be affected differently in these patients. Third, since both subacute and chronic patients were included in the study, the natural effect of post-stroke recovery may have contributed to the recovery provided by the intervention. However, we did not include an untreated control group in the study because it would not have been ethically appropriate. Another limitation of our study is that it was not double-blind. The application of electrical stimulation may have a placebo effect, which should be considered when interpreting the results. Finally, the lack of consensus on optimum electrode placement and stimulation settings also limited the study.

Conclusion

The current study demonstrated that NMES as an adjunct therapy provides additional benefits in some swallow-related conditions. On the other hand, an inclusive dysphagia therapy combined with patient education, diet modification, and compensatory and rehabilitative techniques can improve all swallowing-related particularities and is an inexpensive, device-free, and non-invasive method compared to NMES. The NMES is more costly due to the need for a stimulation device and specific electrodes. There is a need for a standardized guideline for the treatment of PSD. To carry out a cost-effective treatment, patients who will benefit most from NMES should be determined.

In conclusion, additional benefits of NMES have been demonstrated by the limited data obtained with a small sample size in our study. There is a need for additional larger studies to confirm these findings.

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Declarations

Conflict of interest None of the authors have a conflict of interest to report.

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