

Original Article

Effectiveness of transcranial magnetic stimulation plus resistive tongue pressure feedback for improving swallowing function in patients with post-stroke dysphagia: a retrospective cohort study

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Abstract: Objective: To investigate the efficacy of repetitive transcranial magnetic stimulation (rTMS) combined with tongue pressure biofeedback training on swallowing function in patients with post-stroke dysphagia. Methods: A retrospective analysis was conducted on 120 patients with post-stroke dysphagia admitted to our hospital between January 2021 and December 2023. Based on actual treatment received, patients were divided into three groups (n = 40 each): combined therapy (rTMS + tongue pressure training), rTMS-only, and tongue pressure-only. All groups received basic treatment and standard swallowing rehabilitation for 4 weeks. Outcome measures included the Water Swallowing Test (primary), Standardized Swallowing Assessment (SSA), Functional Oral Intake Scale (FOIS), maximum tongue pressure, hyoid displacement, Swallowing Quality of Life (SWAL-QOL), and adverse events. Results: The combined therapy group showed significantly greater improvement in SSA grades compared to the other groups (Kruskal-Wallis H = 8.56, P = 0.014). After 4 weeks of treatment, the combined group demonstrated superior outcomes compared to both control groups: lower SSA scores (F = 18.645, P < 0.001), higher FOIS grades (F = 15.329, P < 0.001), increased maximum tongue pressure (F = 22.781, P < 0.001), larger hyoid displacement (F = 12.347, P < 0.001), and higher SWAL-QOL scores (F = 14.257, P < 0.001). The incidence of adverse events did not differ significantly across groups ($\chi^2 = 1.254$, P = 0.534). Conclusion: A 4-week program combining rTMS and tongue pressure biofeedback is more effective than either therapy alone in improving swallowing safety, physiological function, and quality of life in patients with post-stroke dysphagia, with acceptable safety profiles.

Keywords: Stroke, deglutition disorders, transcranial magnetic stimulation, tongue pressure biofeedback, rehabilitation, controlled trial

Introduction

Post stroke dysphagia (PSD), is one of the most disabling complications after stroke, and it has a high clinical incidence. PSD not only significantly reduces patients' quality of daily life and hinders the overall rehabilitation of neurological and physical functions, but it also worsens long-term prognosis and imposes substantial caregiver and socioeconomic burden [1]. Given the profound impact of PSD on full-cycle rehabilitation outcomes, the development of a standardized swallowing rehabilitation program that is safe, effective, and clinically applicable has

long been a hotspot in neurorehabilitation [2]. Currently, clinical rehabilitation approaches for PSD are undergoing fundamental changes. Previously, single isolated interventions were commonly applied, and these interventions are gradually being replaced by comprehensive, multi-dimensional treatment paradigms. Traditional interventions in clinical practice typically focus on behavioral strategies (e.g., oral and facial sensorimotor training, compensatory swallowing technology) and various physical therapies. These programs mostly rely on peripheral stimulation and repetitive task training to achieve compensatory recovery of swal-

lowing function and neural circuit remodeling [3].

Recent clinical studies have increasingly explored the clinical value of central nervous system regulation therapies, with non-invasive brain stimulation emerging as a novel approach for the intervention of PSD [4]. Repetitive transcranial magnetic stimulation (rTMS) is one of the most widely used non-invasive methods for modulating cortical excitability. By targeting the swallowing motor cortex of the stroke-affected hemisphere, rTMS can promote functional reorganization and excitability balance in swallowing-related neural networks, or inhibit abnormal hyperexcitability of the contralateral hemisphere, thereby enhancing cortical-driven swallowing function [5]. Alongside the development of central regulation technologies, targeted functional training for key peripheral effector organs of the swallowing pathway has gradually become a research hotspot in PSD rehabilitation. As the core organ responsible for shaping and propelling the food bolus, the tongue muscle, known as the “power pump” of swallowing, directly determines swallowing safety. Its function is highly dependent on sufficient strength, endurance, and coordinated movement of the muscle group [6]. Tongue pressure biofeedback training, based on biofeedback technology, can directly correct core functional deficits of the tongue muscle by quantitatively targeting tongue elevation force. This precise peripheral intervention can significantly improve the efficiency of oral phase of swallowing and is supported by high-level clinical evidence [7]. Previous studies have confirmed that multiple precise targeted interventions, including acupuncture, can effectively improve swallowing function in post-stroke patients. For instance, clinical research by Li et al. showed that a specific acupuncture program (“five neck needles” technique) provided significant clinical benefits for patients with dysphagia secondary to bulbar palsy after stroke [1].

Although rTMS and tongue pressure biofeedback training have shown promising clinical prospects, inherent limitations exist in single interventions when addressing the complex, multi-level neurological deficits observed in PSD patients [8]. rTMS can effectively modulate cortical excitability; however, the translation of this modulation into improvement in swallowing function depends highly on the

integrity of descending pathways such as the corticospinal and corticomedullary tracts, as well as the structural and functional integrity of peripheral neuromuscular effectors. In other words, the “motor command” generated centrally must be transmitted through intact pathways to the spinal cord and peripheral motor units to execute the final swallowing action [9].

Swallowing is a complex motor behavior requiring precise coordination of multiple muscle groups. A single central intervention is insufficient to fully optimize contraction timing, motor coordination, and force output across all muscles involved in swallowing [10]. Peripheral targeted training, represented by tongue pressure biofeedback, can directly and efficiently improve tongue muscle strength. However, the effects of such interventions are typically confined to the trained muscle groups, with limited influence on central neural networks governing the timing and coordination of the entire swallowing sequence [11]. Previous studies predominantly focused on verifying the clinical effectiveness of individual interventions or simply superimposing emerging technologies onto conventional behavioral training programs [12]. Currently, there remains a significant gap in high-quality clinical research designed around the theoretical framework of “central regulation combined with peripheral targeted reinforcement”, especially studies that rigorously isolate the independent contributions of each component within a combined intervention. This gap leaves an unresolved fundamental question in PSD rehabilitation: does the combination of rTMS and tongue pressure biofeedback produce merely additive effects, or is there a true synergistic interaction, whereby the overall effect exceeds the sum of the individual interventions [13-15].

To address this gap, we conducted a retrospective cohort study employing a distinct three-arm, sham-controlled design. We hypothesized that a 4-week regimen of combined active rTMS and tongue pressure biofeedback training would produce significantly greater improvements in swallowing function compared to either active intervention alone. The unique advantage of this study design lies in its ability to precisely isolate and compare the net clinical effects of the combined protocol against each individual components. Additionally, this study aimed to provide a preliminary exploration of the potential neurophysiological

mechanisms underlying the combined effect, thereby offering higher-level evidence for a comprehensive, non-invasive rehabilitation strategy for PSD in clinical practice.

Materials and methods

Study design and sample size calculation

This study was a single-center, retrospective cohort study. Medical records of patients with post-stroke dysphagia admitted to the Qingdao Special Servicemen Recuperation Center of PLA Navy between January 2021 and December 2023 were reviewed. All patients meeting the inclusion criteria during this period were included, resulting in a total of 120 patients. A post-hoc power analysis was performed using G*Power software (version 3.1.9.7) to assess the statistical power achieved with the final analytic sample of 113 patients. The primary outcome was the Water Swallowing Test (WST) grade, an ordinal variable analyzed using the Kruskal-Wallis test. To inform the effect size for the power analysis, an internal audit of the first 30 consecutively enrolled patients was performed, revealing a standardized effect size (Cohen's d) of approximately 0.35 for the comparison among three independent groups, corresponding to a moderate-to-large effect.

Using the Kruskal-Wallis test with three groups, an alpha level of 0.05, and a total sample size of 113 ($n_1 = 37$, $n_2 = 37$, $n_3 = 39$), the achieved power was calculated to be 0.84, exceeding the conventional threshold of 0.80. This confirms that the study was adequately powered to detect observed differences in WST grade distribution.

Based on the treatments actually received during hospitalization, patients were divided into three groups: Group A (combined therapy) received both rTMS and tongue pressure training; Group B (rTMS-only) received rTMS alone; Group C (tongue pressure-only) received tongue pressure training alone. Treatment allocation was at the discretion of the attending physicians according to clinical judgment and patient preferences, and no randomization was performed.

Inclusion and exclusion criteria

Inclusion criteria: (1) First ischemic or hemorrhagic stroke confirmed by brain CT or MRI,

meeting standard diagnostic criteria of stroke; (2) Stable vital signs and clinical condition, with stroke onset within the subacute phase (2 weeks to 6 months); (3) Age ranged from 40 to 80 years old; (4) Clinically significant dysphagia confirmed by clinical evaluation, defined as a positive clinical swallowing assessment and a Functional Oral Intake Scale (FOIS) score ≤ 4 , suggesting tube dependence or limited oral intake of a single food consistency; (5) Clear consciousness, with a Glasgow Coma Scale (GCS) score ≥ 13 , and ability to understand and follow simple instructions.

Exclusion criteria: (1) Severe cognitive impairment or sensory aphasia, defined as Mini-Mental State Examination (MMSE) score < 17 , precluding cooperation with assessments and therapy; (2) Severe comorbidities, including cardiac, hepatic, or renal insufficiency, or major life-limiting conditions such as malignancy; (3) Contraindications to TMS, including history of epilepsy, intracranial metallic implants, cardiac pacemakers, or elevated intracranial pressure; (4) Non-neurogenic dysphagia due to structural abnormalities of the oral cavity, pharynx, or esophagus (e.g., tumors, post-surgical changes); (5) Documented psychiatric disorders; (6) Concurrent participation in other clinical trials that might influence swallowing rehabilitation outcomes.

Study procedures

(1) Data source and grouping: Data were extracted from electronic medical records by two independent researchers blinded to the study hypothesis. Demographic characteristics, stroke-related information, and treatment details were recorded. Patients were categorized into three groups according to the interventions they received during hospitalization: Group A (combined therapy incorporating both rTMS and tongue pressure training), Group B (rTMS-only), and Group C (tongue pressure-only). This study was conducted in accordance with the Declaration of Helsinki and approved by the Qingdao Special Servicemen Recuperation Center Of PLA Navy (Approval No. QDTLL2026-055). The requirement for written informed consent was waived due to the retrospective nature of the study, which involved analysis of de-identified data. The approval report is provided as a supplementary file.

(2) Intervention protocols: All patients underwent 4 weeks of standard neurological medication and conventional swallowing rehabilitation therapy (30 minutes per day, 5 days per week), which included oral sensory stimulation, active/passive exercises for lip, tongue, and jaw muscles, the Mendelsohn maneuver, and supra-glottic swallowing exercises. In addition, patients in different groups received the following targeted interventions as documented in their medical records:

rTMS protocol (for Groups A and B): Repetitive transcranial magnetic stimulation was delivered using an Yiruide CCY-I magnetic stimulator with a figure-of-eight coil. The resting motor threshold (RMT) was first determined for the first dorsal interosseous muscle of the affected hand. The stimulation target was the cortical representation area for swallowing in the affected hemisphere, localized 2 cm anterior and 4 cm inferior to the C3 or C4 point, following the international 10-20 electroencephalography (EEG) system. Stimulation was applied at a frequency of 5 Hz, with an intensity of 80% RMT. Each train lasted 5 seconds, with an inter-train interval of 55 seconds. Each daily session comprised 40 trains (totaling 2,000 pulses), administered 5 days per week for 4 weeks.

Tongue pressure training protocol (for Groups A and C): The IOPI PRO system (USA) was used. Maximum tongue pressure (MTP) was first measured. During training, patients were seated and positioned the device's bulb between the anterior tongue and hard palate. The target pressure was set at 70% of individual MTP. Patients were instructed to press their tongue against the bulb for 5 seconds to reach the target bar, followed by a 10-second rest. Each set included 20 repetitions, with 3 sets per session and a 1-minute rest between sets, administered 5 days per week for 4 weeks.

To ensure the validity of our three-arm design, sham interventions were meticulously implemented. For Group C (tongue pressure-only), sham rTMS was administered using a sham coil that produces identical auditory and mild somatosensory sensations (scalp tapping) without generating a significant magnetic field. The intensity was set at 5-10% of the RMT, which is physiologically inert, below the threshold for neuronal depolarization, and does not elicit motor-evoked potentials (MEPs) [16]. For

Group B (rTMS-only), sham tongue training was performed using the same IOPI PRO device, with the visual target fixed at a constant, low pressure of 5 kPa. Patients were instructed to maintain tongue-to-palate contact to keep a bar on the screen illuminated, requiring negligible effort. This paradigm provides the visual and sensory feedback of using the device, without progressive training.

A post-hoc analysis of MTP data confirmed that patients in Group B showed the inert nature of sham tongue training. Specifically, the median MTP in Group B increased modestly from 21.8 kPa (IQR, 16.2-26.9) at baseline to 28.4 kPa (IQR, 23.1-33.6) after treatment, representing a median increase of 6.6 kPa (95% CI, 4.1 to 9.1), consistent with standard rehabilitation effects. In contrast, Group C (active tongue pressure training) demonstrated a substantially larger median increase of 11.9 kPa (95% CI, 9.2 to 14.6), from a baseline median of 23.1 kPa (IQR, 18.4-27.3) to 35.0 kPa (IQR, 29.8-39.5) after treatment. Between-group comparison of MTP change confirmed that the improvement in Group C was significantly greater than that in Group B (Mann-Whitney U test, $P < 0.001$).

(3) Quality control and safety monitoring: To maintain blinding, several measures were implemented. Patients were informed that they would receive one of several active or sham treatment combinations but were not told their specific group allocation. Outcome assessors (certified clinicians who did not participate in delivering interventions) were blinded to group assignment throughout the study and conducted all baseline and post-treatment assessments. The statistician performing the data analysis was also blinded to group identities (coded as A, B, and C).

Therapists delivering the interventions could not be blinded due to the nature of the interventions (e.g., handling the rTMS coil or the IOPI device). However, they were strictly instructed to maintain a neutral demeanor, avoid discussing group allocation or treatment rationale with patients, and prevent any inadvertent unblinding during therapy sessions. The success of patient blinding was not formally assessed with a questionnaire, which constitutes a limitation of this study.

TMS equipment was calibrated monthly according to manufacturer specifications. The IOPI device bulbs were disinfected after each use per infection control guidelines. During the treatment period, adverse events, including TMS-related discomfort such as headache, scalp discomfort, tinnitus, and training-related discomfort such as tongue muscle fatigue or temporomandibular joint pain, were systematically recorded in medical charts and were extracted for analysis.

Outcome measures

All outcome measures were assessed by trained clinicians following standard protocols, and the results were documented in the medical records. For this retrospective study, data were collected at two time points: baseline (within 3 days before intervention initiation) and immediately after the 4-week treatment period (within 3 days after completion).

Primary outcome measure: The Water Swallowing Test (WST) was conducted with patients in a comfortable posture. Patients were guided to drink 30ml of warm water according to their normal swallowing habits. Assessors observed the swallowing process and recorded signs of swallowing disorders, such as choking and delayed swallowing. Swallowing performance was evaluated using a 5-level grading system: Grade 1, successful swallowing without any abnormality; Grade 2, swallowing requires two or more attempts without choking; Grade 3, swallowable in a single attempt but accompanied by choking; Grade 4, two or more swallows accompanied by coughing; Grade 5, frequent choking and inability to complete the drinking task. Higher grades indicate more severe impairment of swallowing safety and efficiency.

Secondary outcome measures: (1) Standardized swallowing assessment (SSA), a comprehensive clinical tool for evaluating swallowing function, was conducted, covering consciousness level, respiratory status, and voluntary control of lips and tongue, followed by three sequential tests evaluating swallowing of different volumes of water. Total SSA scores range from 18 to 46, with higher scores indicating worse swallowing function and greater aspiration risk. A score ≥ 25 points is considered an important threshold indicating increased risk of aspiration. (2) Functional Oral Intake Scale

(FOIS): The scale is a 7-level scale assessing patients' oral intake ability, ranging from 1 (completely unable to eat by mouth) to 7 (completely unrestricted normal diet). In this study, the highest dietary level at which the patient could safely and consistently eat was recorded for analysis. (3) Maximum tongue pressure (MTP): IOPI PRO system was used to measure MTP, which reflects objective and quantitative data on tongue muscle contraction force, a core parameter of oral-phase swallowing function. During testing, patients were seated in an upright position and guided to place the inflatable balloon of the device against the hard palate. They pressed the bulb with the tip of the tongue at maximum force for 2-3 seconds. The procedure was repeated three times with sufficient rest between trials. The highest value (kPa) among the three measurements was recorded as the representative MTP. (4) Hyoid Bone Displacement (HBD): HBD was assessed using a diagnostic ultrasound system (e.g., Mindray M9) with a high-frequency linear array transducer. Patients were placed supine with the neck slightly extended. The transducer was placed longitudinally along the anterior midline to visualize the hyoid bone, thyroid cartilage, and pre-epiglottic space. Patients performed a dry swallow, and the vertical distance between the hyoid bone and thyroid cartilage was measured on ultrasound images at rest and at the peak of swallowing. The displacement (mm) was calculated as the difference between these measurements, and the average of three measurements was used for analysis. (5) Swallowing Quality of Life (SWAL-QOL): This 44-item questionnaire encompassing 11 domains, including eating desire, eating duration, food selection, and psychological burden. Each item is rated on a 5-point scale. The total score was transformed to a 0-100 scale, with higher scores indicating better swallowing-related quality of life. (6) Incidence of Aspiration Pneumonia: New cases of aspiration pneumonia occurring during the treatment period were recorded. Diagnosis required meeting at least two of the following criteria: ① Fever (temperature $> 38^{\circ}\text{C}$); ② New or worsened cough/sputum; ③ Presence of moist rales on lung auscultation; ④ New pulmonary infiltrates on chest X-ray or CT. (7) Motor Evoked Potentials (MEPs): As an exploratory mechanistic outcome, pharyngeal MEPs were recorded to assess the integrity and excitability of the corticobulbar pathway.

The study was not specifically powered for MEP analyses; therefore, results are considered hypothesis-generating. MEP recordings were performed using the Yiruide CCY-I magnetic stimulator equipped with a figure-of-eight coil. Single-pulse TMS was delivered to the swallowing motor cortex of the affected hemisphere, localized 2 cm anterior and 4 cm inferior to the C3 or C4 point according to the international 10-20 EEG system. Stimulation intensity was set at 120% of the RMT, which was determined from the first dorsal interosseous muscle of the affected hand prior to MEP recording. Stimuli were delivered at 0.2 Hz (one pulse every 5 seconds) to prevent cumulative effects on cortical excitability.

Recording electrodes (Ag/AgCl surface electrodes, 10 mm diameter) were placed in a bipolar montage over the submental muscle group on the affected side: the active electrode was positioned 2 cm lateral to the midline and 1 cm posterior to the mandibular symphysis, the reference electrode over the ipsilateral mandibular angle, and a ground electrode on the ipsilateral clavicle. Electromyographic signals were acquired using a Neuropack MEB-9400 system (Nihon Kohden, Tokyo, Japan) with a bandpass filter of 20 Hz - 2 kHz, sampling rate of 5 kHz, and sweep time of 100 ms (including 20 ms pre-stimulus baseline). For each assessment session, ten consecutive MEPs were recorded with the patient at rest to avoid facilitation effects from voluntary muscle activation. The average of the five largest responses was used for analysis. MEP latency was defined as the time (ms) from stimulus onset to the first negative waveform deflection, and MEP amplitude was measured as the peak-to-peak voltage difference (μ V).

Statistical analysis

Statistical analyses were performed using SPSS (version 26.0) and R (version 4.3.1). Continuous variables were presented as mean $\pm$ standard deviation (SD) for normally distributed data, or median (interquartile range [IQR]) for non-normally distributed data. Categorical variables were presented as frequency and percentage. Baseline characteristics among the three groups were compared using one-way ANOVA or the Kruskal-Wallis H test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables. For

the primary outcome (WST grade, an ordinal variable), overall group comparisons were conducted using the Kruskal-Wallis H test. If a significant difference was observed, post-hoc pairwise comparisons were performed. Clinical response rates were defined as the proportion of patients demonstrating at least a one-grade improvement in WST grade from baseline to post-treatment. All statistical tests were two-sided, with $P < 0.05$ considered statistically significant. To control for potential confounding due to the retrospective study design, sensitivity analyses were performed using multivariable linear regression models adjusting for baseline variables with $P < 0.10$. The results of these sensitivity analyses were consistent with the primary analyses.

Results

A total of 120 patients met the inclusion criteria and had complete medical records for the 4-week treatment period. Based on the treatments received, 40 patients were allocated to Group A (combined therapy), 40 to Group B (rTMS-only), and 40 to Group C (tongue pressure-only). During the treatment period, 2 patients in Group A discontinued treatment due to personal reasons, and 1 patient was transferred to another facility (lost to follow-up); In Group B, 1 patient discontinued due to a mild skin rash (attributed to TMS coil contact) and 2 were transferred; In Group C, 1 patient discontinued due to acute gastroenteritis, and 1 was transferred. Consequently, 113 patients (Group A: $n = 37$, Group B: $n = 37$, Group C: $n = 39$) completed the full 4-week treatment and had complete outcome data. All analyses were performed on these 113 patients using a complete-case approach, as missing data were minimal and not imputed.

Baseline characteristics

The three groups were comparable in terms of demographic data, stroke-related factors, and baseline swallowing function measures. No statistically significant differences were observed among groups for age, sex, stroke type, lesion side, time since stroke onset, or NIHSS score. Baseline swallowing assessments, including WST grade, SSA score, FOIS grade, MTP, HBD, SWAL-QOL score, and pharyngeal MEP latency and amplitude, were also similar across groups (all $P > 0.05$; **Table 1**).

Table 1. Comparison of baseline characteristics among the three groups (n = 120)

Variable	Group A (n = 40)	Group B (n = 40)	Group C (n = 40)	Statistic	P-value
Demographics					
Age (years, mean $\pm$ SD)	62.35 $\pm$ 8.17	60.89 $\pm$ 7.43	61.72 $\pm$ 8.65	F = 0.309	0.735
Male [n (%)]	22 (55.0)	25 (62.5)	23 (57.5)	χ^2 = 0.509	0.775
Stroke Characteristics					
Ischemic Stroke [n (%)]	32 (80.0)	30 (75.0)	31 (77.5)	χ^2 = 0.287	0.866
Left Hemisphere Lesion [n (%)]	18 (45.0)	22 (55.0)	19 (47.5)	χ^2 = 0.800	0.67
Time Since Stroke Onset (days, mean $\pm$ SD)	45.63 $\pm$ 22.41	48.90 $\pm$ 24.67	43.85 $\pm$ 21.08	F = 0.532	0.588
NIHSS Score (mean $\pm$ SD)	8.45 $\pm$ 3.12	8.93 $\pm$ 3.40	8.20 $\pm$ 2.98	F = 0.606	0.547
Baseline Swallowing Function					
WST Grade [median (IQR)]	4.0 (3.0, 4.0)	4.0 (3.0, 4.0)	4.0 (3.0, 4.0)	H = 0.132	0.936
SSA Score (mean $\pm$ SD)	32.18 $\pm$ 4.25	33.05 $\pm$ 4.70	32.60 $\pm$ 4.33	F = 0.400	0.671
FOIS Grade [median (IQR)]	3.0 (2.0, 4.0)	3.0 (2.0, 3.0)	3.0 (2.0, 4.0)	H = 0.415	0.812
MTP (kPa, mean $\pm$ SD)	22.47 $\pm$ 6.58	21.83 $\pm$ 7.01	23.10 $\pm$ 6.24	F = 0.347	0.707
HBD (mm, mean $\pm$ SD)	8.92 $\pm$ 2.31	9.15 $\pm$ 2.44	8.78 $\pm$ 2.17	F = 0.251	0.779
SWAL-QOL Score (mean $\pm$ SD)	48.32 $\pm$ 10.56	46.95 $\pm$ 11.23	49.01 $\pm$ 9.87	F = 0.365	0.695
Pharyngeal MEP Latency (ms, mean $\pm$ SD)	12.89 $\pm$ 1.75	13.12 $\pm$ 1.68	12.71 $\pm$ 1.82	F = 0.583	0.56
Pharyngeal MEP Amplitude (μ V, median (IQR))	45.6 (32.1, 58.9)	42.8 (30.5, 55.3)	47.2 (35.0, 60.1)	H = 0.794	0.672

Notes: NIHSS, National Institutes of Health Stroke Scale; WST, Water Swallowing Test; SSA, Standardized Swallowing Assessment; FOIS, Functional Oral Intake Scale; MTP, Maximum Tongue Pressure; HBD, Hyoid Bone Displacement; SWAL-QOL, Swallowing Quality of Life; MEP, Motor Evoked Potentials; SD, Standard Deviation; IQR, Interquartile Range.

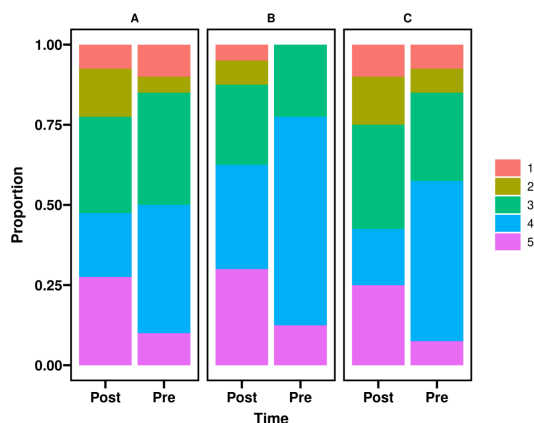


Figure 1. Distribution of water swallowing test grades before and after treatment in the three groups. Bar charts depict the proportion of patients in groups (A), (B), (C) achieving each WST grade (1 to 5) at baseline (Pre-Tx) and after the 4-week intervention (Post-Tx). Lower grades indicate better swallowing function. The Kruskal-Wallis H test showed a significant between-group difference in post-treatment WST grade distribution (H = 8.56, P = 0.014).

Primary outcome analysis

The distribution of WST grades was similar among the three groups before treatment. After 4 weeks of intervention, all groups showed significant improvement in WST grade compared to baseline (P < 0.05). A Kruskal-Wallis H test

revealed a significant difference in post-treatment WST grade distribution among the three groups (H = 8.56, P = 0.014). Post-hoc pairwise comparisons using Dunn's test with Bonferroni correction showed that Group A had significantly lower (better) WST grades than Group B (P = 0.021) and Group C (P = 0.018), with no significant difference between Groups B and C (P = 0.71), as shown in **Figure 1**.

Secondary outcome analysis (functional and physiological measures)

No significant differences were found among the three groups at baseline for any of the secondary functional and physiological measures, including SSA score, FOIS grade, MTP, and HBD (all P > 0.05). All measures showed significant improvement from baseline within each group after treatment (all P < 0.05). A significant time $\times$ group interaction effect was observed for all secondary outcomes (all P < 0.05), indicating differential treatment effects over time.

Post-treatment between-group comparisons revealed statistically significant differences among the three groups for all secondary outcomes. For the ordinal variable FOIS, a Kruskal-Wallis H test showed a significant difference in post-treatment grades among the

Table 2. Comparison of secondary functional and physiological measures among the three groups before and after treatment (mean $\pm$ SD)

Measure	Group	n	Before Treatment	After Treatment	Within-Group t/Z-value	P-value	Interaction Effect F-value	P-value	Between-Group F-value (Post-Tx)	P-value
SSA Score	A	40	32.18 $\pm$ 4.25	24.63 $\pm$ 3.89	11.237	< 0.001	9.873	< 0.001	18.645	< 0.001
	B	40	33.05 $\pm$ 4.70	28.45 $\pm$ 4.12	8.456	< 0.001				
	C	40	32.60 $\pm$ 4.33	29.10 $\pm$ 4.05	7.891	< 0.001				
FOIS Grade	A	40	3.0 (2.0, 4.0)	5.0 (5.0, 6.0)	-5.420	< 0.001	8.912	< 0.001	15.329	< 0.001
	B	40	3.0 (2.0, 3.0)	4.0 (4.0, 5.0)	-4.981	< 0.001				
	C	40	3.0 (2.0, 4.0)	4.0 (4.0, 5.0)	-5.012	< 0.001				
MTP (kPa)	A	40	22.47 $\pm$ 6.58	36.82 $\pm$ 7.15	-12.893	< 0.001	12.456	< 0.001	22.781	< 0.001
	B	40	21.83 $\pm$ 7.01	28.41 $\pm$ 6.83	-7.245	< 0.001				
	C	40	23.10 $\pm$ 6.24	34.95 $\pm$ 6.90	-11.234	< 0.001				
HBD (mm)	A	40	8.92 $\pm$ 2.31	13.45 $\pm$ 2.78	-10.567	< 0.001	7.894	0.001	12.347	< 0.001
	B	40	9.15 $\pm$ 2.44	11.23 $\pm$ 2.56	-5.432	< 0.001				
	C	40	8.78 $\pm$ 2.17	10.89 $\pm$ 2.34	-6.123	< 0.001				

Note: SSA, Standardized Swallowing Assessment; FOIS, Functional Oral Intake Scale; MTP, Maximum Tongue Pressure; HBD, Hyoid Bone Displacement; SD, Standard Deviation.

Table 3. Comparison of quality of life and adverse events among the three groups

Item	Group A (n = 40)	Group B (n = 40)	Group C (n = 40)	Statistic	P-value
SWAL-QOL Score (mean $\pm$ SD)				F = 14.257	< 0.001
Before Treatment	48.32 $\pm$ 10.56	46.95 $\pm$ 11.23	49.01 $\pm$ 9.87		
After Treatment	78.45 $\pm$ 9.12	65.38 $\pm$ 10.45	67.89 $\pm$ 9.78		
Within-Group t (P) value	-15.234 (< 0.001)	-9.876 (< 0.001)	-10.567 (< 0.001)		
Adverse Events [n (%)]				$\chi^2 = 1.254$	0.534
Aspiration Pneumonia	1 (2.5)	3 (7.5)	2 (5.0)		
TMS-related Discomfort	0 (0)	1 (2.5)	0 (0)		
Training-related Discomfort	0 (0)	0 (0)	0 (0)		

Note: SWAL-QOL, Swallowing Quality of Life; TMS, Transcranial Magnetic Stimulation.

groups ($H = 14.21$, $P < 0.001$). Post-hoc Dunn's tests indicated that Group A had significantly higher (better) FOIS grades than both Group B ($P < 0.001$) and Group C ($P < 0.001$), while no significant difference was found between Groups B and C ($P = 0.45$). Detailed results are presented in **Table 2**.

Quality of life and safety analysis

No significant differences were observed in baseline SWAL-QOL scores among the three groups ($P > 0.05$). All groups showed a significant increase in SWAL-QOL scores after treatment compared to baseline ($P < 0.05$). Post-treatment between-group comparison revealed a statistically significant difference in SWAL-QOL scores among the three groups ($P < 0.05$), with Group A showing the greatest improvement. The overall incidence of adverse events did not differ significantly among the

three groups ($P > 0.05$). The details are shown in **Table 3**.

Exploratory neurophysiological measures analysis

Pharyngeal MEPs could not be obtainable in all patients at baseline (**Table 4**), which is a common limitation in PSD research due to the severity of corticobulbar tract injury. Consequently, the sample size for this exploratory analysis was reduced (Group A: $n = 28$, Group B: $n = 26$, Group C: $n = 29$). Baseline characteristics of this subgroup were comparable to the overall cohort (data not shown), though selection bias cannot be fully excluded as patients with measurable MEPs may present milder impairment.

Within this subgroup, no significant differences were found among the three groups at baseline for pharyngeal MEP latency or amplitude (both

Table 4. Comparison of pharyngeal motor evoked potential parameters among the three groups before and after treatment (mean $\pm$ SD)

Parameter	Group	n	Before Treatment	After Treatment	Change (Post - Pre)	Within-Group t-value	P-value	Between-Group F-value (Change)	P-value
Latency (ms)	A	28	12.79 $\pm$ 1.71	11.23 $\pm$ 1.45	-1.56 $\pm$ 1.23	6.712	< 0.001	2.187	0.119
	B	26	13.05 $\pm$ 1.65	11.85 $\pm$ 1.52	-1.20 $\pm$ 1.18	5.324	< 0.001		
	C	29	12.66 $\pm$ 1.79	11.58 $\pm$ 1.49	-1.08 $\pm$ 1.31	4.567	< 0.001		
Amplitude (μ V)	A	28	48.23 $\pm$ 15.67	68.45 $\pm$ 18.34	20.22 $\pm$ 10.15	-10.567	< 0.001	6.543	0.002
	B	26	44.12 $\pm$ 14.89	55.78 $\pm$ 16.23	11.66 $\pm$ 9.87	-6.123	< 0.001		
	C	29	49.01 $\pm$ 16.12	60.34 $\pm$ 17.45	11.33 $\pm$ 8.96	-6.789	< 0.001		

Table 5. Comparison of clinical response rates based on water swallowing test improvement among the three groups [n (%)]

Analysis Set	Group	n	Responder	Non-responder	Response Rate (%)	χ^2 value	P-value
ITT Set	A	40	37	3	92.5	8.125	0.017
	B	40	29	11	72.5		
	C	40	30	10	75		
PPS Set	A	37	35	2	94.6	9.843	0.007
	B	37	27	10	73		
	C	39	30	9	76.9		

Notes: ITT, Intention-To-Treat; PPS, Per-Protocol Set; WST, Water Swallowing Test.

$P > 0.05$). After treatment, MEP latency significantly decreased and amplitude significantly increased within each group (both $P < 0.05$). Between-group comparison showed no significant difference in latency change ($P > 0.05$), while the change in amplitude differed significantly among groups ($P < 0.05$). Results are presented in **Table 4**.

Response rate

Based on improvement in the WST, the clinical response rates differed significantly among the three groups in the intention-to-treat (ITT) analysis set ($P < 0.05$). Similarly, a statistically significant difference in response rates was observed among the groups in the per-protocol set (PPS) analysis ($P < 0.05$). See **Table 5**.

Discussion

This retrospective cohort study demonstrates that a 4-week regimen of combined rTMS and tongue pressure biofeedback training is associated with significantly greater improvements in swallowing function compared to either intervention alone in patients with post-stroke dysphagia. The combined therapy showed superior outcomes across clinical, physiological, and quality-of-life measures, supporting our hypothesis of a synergistic effect. These findings pro-

vide real-world evidence for a promising non-invasive treatment strategy. This core result suggests that the combination of central nerve regulation and peripheral effector-targeted functional training appears to produce clear synergy, providing an efficient and non-invasive rehabilitation pathway for PSD [17].

In this study, improvement in swallowing safety, indicated by changes in WST grades, was most prominent in the combined intervention group. This effect likely reflects the complementary mechanisms of the two interventions on remodeling swallowing-related neural circuits. rTMS can optimize neural initiation and temporal control of the swallowing sequence by regulating the excitability of cortical area governing swallowing and corticomedullary tract function [18]. Tongue pressure biofeedback training can directly enhance the contraction strength and coordinated movement of the tongue, the core effector of swallowing, thereby improving the biomechanical efficiency of bolus formation and propulsion [19].

From a neurorehabilitation perspective, the simultaneous application of central and peripheral interventions promotes functional recovery at two critical levels: "central command generation" and "peripheral action execution". The combined effect is substantially greater

than that achieved by either intervention alone. This observation is consistent with the general principle presented in previous rehabilitation research, whereby joint intervention programs, such as neuromuscular electrical stimulation combined with behavioral training, often produce better clinical outcomes compared with single-mode interventions [20]. Although the specific technologies differ among various joint schemes, the underlying principle of integrating central regulation with peripheral reinforcement remains consistent and theoretically sound.

The multi-dimensional positive results further reinforce the core findings of this study across different levels. Improvements in SSA and FOIS scores directly translate into enhanced swallowing safety and recovery of oral intake ability in real-life context, highlighting the clinical translational value of the interventions [21]. MTP and BHD, as objective physiological indicators, provide direct biomechanical evidence of improved swallowing function. The increase in MTP reflects the targeted strengthening effect of tongue resistance training, while the increase in hyoid bone lifting amplitude reflects enhanced overall swallowing dynamics. This effect may stem from the synergistic effect of rTMS-mediated cortical drive and the functionally enhanced suprahyoid muscle group following resistance training [22]. The concurrent improvement of multiple outcome measures across different dimensions suggests that the joint intervention exerts broad regulatory effects on various subfunctions of swallowing, rather than being limited to a single swallowing component.

Building upon these objective physiological and functional improvements, SWAL-QOL in patients receiving combined therapy was also significantly improved. This finding holds core clinical value, as the ultimate goal of neurorehabilitation is to improve patients' daily survival experience and social participation. The significant advantages of the combined intervention in this measure suggest that functional gains can be effectively translated into improvements in daily life. Safety data demonstrated no statistical difference in the incidence of serious complications, such as aspiration pneumonia, or minor adverse events, among the three groups. These results indicate that adding tongue pressure biofeedback train-

ing to rTMS does not introduce new safety risks. Overall, the combined intervention exhibits a favorable safety profile, which is a crucial consideration for the clinical promotion of rehabilitation programs [23, 24].

Our findings align with and extend previous research on combination therapies for PSD, for instance, combining rTMS with peripherally-focused intervention such as neuromuscular electrical stimulation. In contrast, our study employed a more physiologically relevant peripheral task (tongue pressure training) and crucially incorporated sham controls to isolate the independent contributions of each intervention component, an aspect often lacking in previous studies. To explore the underlying mechanisms, MEPs were collected as an exploratory outcome. These findings, while suggestive, must be interpreted with caution due to the reduced sample size and exploratory nature of the analysis. A significant increase in MEP amplitude was observed in the combined therapy group, suggesting enhanced excitability and synchronization of the corticobulbar pathway. In contrast, MEP latency, reflecting conduction speed, did not differ among groups. This dissociation is neurophysiologically plausible: amplitude increases are often early marker of synaptic efficacy and cortical map reorganization, while latency changes typically reflect remyelination or recruitment of faster-conducting fibers, processes that may require longer than 4 weeks to manifest. These results suggest that the primary short-term benefit of the combined intervention lies in strengthening neural drive (amplitude) rather than altering conduction velocity (latency).

The observed increase in MEP amplitude indicates that the combined intervention can specifically enhance the neural excitability of the swallowing related corticomedullary tract. Elevated MEP amplitude generally reflects enhanced synchronous firing of cortical neurons or improved neural excitability at the brainstem and spinal cord levels, representing a core marker of plasticity in the central nervous system [25]. This finding provides a reasonable neurophysiological explanation for the clinical advantages of the combined intervention: rTMS induces neuroplasticity changes at the cerebral cortex level, while task-oriented peripheral tongue resistance training consolidates and amplifies this plasticity effect

through enhanced sensory afferent feedback and motor learning process. Notably, the increase in MEP amplitude in the combined group exceeded the expected additive effect of the two single interventions, suggesting a synergistic interaction beyond simple summation and pointing toward new avenues for mechanistic research. Nevertheless, the mechanistic hypothesis require further validation in multi-center studies with larger sample sizes and advanced neuroimaging technology [26].

The combined intervention group showed a significant clinical efficacy, a result comparable to the high efficiency level reported by other active PSD interventions, such as specific acupuncture regimens [27]. The two single-intervention control groups also showed considerable clinical efficiency, consistent with recent studies on isolated rTMS and targeted tongue muscle training [28]. Importantly, the clinical effective rate of the combined intervention group was significantly higher than that of the two single intervention groups, suggesting that the combined program does not merely produce additive effects, but rather achieves a “1+1 > 2” synergistic effect. This finding has practical implications for optimizing rehabilitation resource allocation and improving the cost effectiveness of PSD rehabilitation intervention in clinical practice [29].

Several limitations of this study should be acknowledged. First, its single-center, retrospective design and moderate sample size, while statistically powered, limit generalizability of our findings and introduce potential selection bias and unmeasured confounding, despite comparable baseline characteristics and sensitivity analyses. Second, the absence of long-term follow-up (e.g., at 3 and 6 months) precludes conclusions regarding the durability of treatment effects. Third, we did not assess nutritional indicators such as serum albumin or BMI, which are relevant to swallowing safety and overall patient health. Fourth, although the tongue pressure training was standardized at 70% of each patient’s baseline maximum, it was not progressively individualized based on their daily performance, which might have optimized the training stimulus. Finally, despite our use of sham-controlled interventions to mitigate placebo effects, perfect blinding in complex multimodal interventions is inherently challenging, and patients’ percep-

tions of group allocation cannot be entirely excluded. Future studies should incorporate longer-term follow-up to evaluate the persistence of treatment effects, expand outcome measures to broader dimensions such as nutritional status, length of hospital stay, and overall medical costs [30].

From a clinical translation perspective, the combined protocol used in this study is feasible for implementation in well-equipped rehabilitation centers. The 4-week duration (5 sessions/week) aligns with standard inpatient rehabilitation course, facilitating integration into existing care pathways. The equipment required - a figure-of-eight rTMS device and a biofeedback tongue pressure device such as the IOPI PRO - entails a notable but justifiable capital investment for centers aiming to provide comprehensive dysphagia care. Operational difficulty is moderate, necessitating therapists trained in both rTMS administration and instrument-based dysphagia therapy.

Our findings suggest that this combined approach may be particularly beneficial for subacute stroke patients (2 weeks to 6 months post-stroke) with moderate-to-severe dysphagia (baseline FOIS ≤ 4). The observed increase in MEP amplitude in the combined group indicates that patients with some preserved corticobulbar integrity (i.e., those in whom MEPs could be elicited) might be ideal candidates, as they possess the neural substrate capable of responding to and consolidating the central and peripheral stimulation. Future prospective studies should aim to validate these preliminary subgroup observations to refine patient selection criteria.

Conclusion

This retrospective cohort study indicates that a 4-week regimen of repetitive transcranial magnetic stimulation combined with tongue pressure resistance biofeedback training is associated with significantly better improvement in swallowing function in post-stroke dysphagia patients compared to either intervention alone. These findings provide real-world evidence supporting the combined approach and highlight the need for confirmatory randomized controlled trials to establish efficacy and generalizability.

Disclosure of conflict of interest

None.

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