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Evaluation of Quality of Life and Treatment Outcome among Stroke Patients with Dysphagia

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Objectives: Dysphagia occurs in 37-78% of stroke patients. We aimed to study the effect of three treatments on the quality of life of stroke patients with dysphagia. **Methods:** The study was a hospital-based, cross-sectional study. Participants were enrolled from the Affiliated Hospital of Inner Mongolian University for the Nationalities between July 2018 and March 2019. All patients were randomly divided into three treatment groups. One hundred forty-nine patients with post-stroke dysphagia were evaluated by Swallowing-Related Quality of Life (SWL-QOL) Scale before and after the treatment. **Results:** The mean age of the patients was 59.70 ± 9.55 years, with no difference between treatment groups. There was a statistically significant improvement in scores for all three treatments compared to pretreatment (p=.0001). The SWAL-QOL score was 39.25 ± 3.50 after sensory treatment combined with conventional swallowing therapy, 39.10 ± 3.54 following motor treatment combined with conventional therapy, and 42.12 ± 4.55 in neuromuscular stimulation combined with conventional therapy with latter's scores significantly higher than the other treatments (p<.01). **Conclusions:** Conventional therapy combined with neuromuscular electrical simulation provided a better outcome than conventional therapy combined with nerve or muscular stimulation in stroke patients with dysphagia.

Keywords: Rehabilitation, Nerve Stimulation, Muscular Stimulation, Standardized Swallowing Assessment

Introduction

Worldwide, 16.9 million cases of stroke were reported in 2010[1]. The incidence has increased by 68% since 1990[1]. In 2016, there were 5.5 million deaths attributable to cerebrovascular disease worldwide (2.7 million deaths from ischemic stroke and 2.8 million deaths from hemorrhagic stroke)[1]. Dysphagia is one of the most common sequelae of stroke and occurs 35-78% of patients with stroke[2-3]. Specifically, dysphagia occurs in 51-100% of the brain stem stroke patients[4-8]. It directly impacts the quality of life and decreases the social activity of those afflicted.

The incidence of cardiovascular disease and stroke have

been increasing related to economic uncertainty, urbanization, poor lifestyles, and stress. As a result, dysphagia has increased and is becoming one a pressing issue in health care because it results in pneumonia, malnutrition, and prolonged the hospital stays[6-7]. Unfortunately, its diagnosis and optimal treatment are still not clearly defined.

Many researchers have investigated post-stroke dysphagia treatment outcomes a single treatment device to conventional swallowing therapy, such as electric stimulation. For example, Zhang et al. compared traditional swallowing therapy and neuromotor electrical stimulation in two different modes, acting on the sensory input or the motor muscle, seperately[7]. In another study, Power et al. applied electrical stimulation at three frequencies (0.2, 1 and 5 Hz) and found that stimulation at 0.2 Hz did not enhance swallowing behavior[9].

Sensory treatment, motor treatment, and neuromuscular stimulation have been used to treat patients with dysphagia following stroke. The purpose of this study was to compare the effects of these three treatments combined when with conventional swallowing therapy on the patients' swallowing-related quality of life following a stroke.

Material and Methods

Study design and sampling

The study was conducted on a hospital-based, cross-sectional method. One hundred forty-nine stroke patients with dysphasia were randomly selected from the Department of Neurology, the Department of Rehabilitation and the Department of Stroke of the Affiliated Hospital of Inner Mongolian University for the Nationalities between July 2018 and April 2019.

The inclusion criteria were as follows: (1) a primary diagnosis of medullary infarction with brain computed tomography or magnetic resonance imaging; (2) disease onset <1 month previously; (3) presence of oropharyngeal dysphagia confirmed by videofluoroscopic swallowing study, including different levels of water choke to cough, choking, prolonged eating time, difficulty with swallowing, and nasal regurgitation after swallowing, (4) age within the range of 40 to 80 years; (5) no severe cognitive degeneration that could restrict cooperation with the checks and treatment, with a mini-mental state examination (MMSE) score 21; and (6) 30-mL water swallow test (WST) level of 3, 4, or 5.

The exclusion criteria were as follows: (1) unstable vital signs caused by a highly inflammatory state, severe cardiopulmonary disease or carotid sinus syndrome (i.e., temperature >38.5□C or <35.5□C, systolic blood pressure >180 or <90mmHg, diastolic blood pressure >110 or <60mmHg, heart rate >100 or <60 times per min, respiratory rate >25 or <12 times per min); (2) a cardiac pacemaker or other electrically sensitive implanted stimulator; (3) dysphagia caused by structural lesions (e.g., radiotherapy, extensive surgery of the head and neck region); (4) skin lesions of the area to be treated or implants containing metal parts within the area of treatment; (5) a history of epilepsy, malignancies, or other neurologic disease; (6) pregnancy; or (7) spastic paralysis.

Swallowing function was assessed using Swallowing-Related Quality of Life (SWL-QOL) Scale, which includes 11 types of 44 checklists. This scale checks burden, feeding duration, desire, symptom frequency, food selection, communication, fear, mental health, social function, sleep, fatigue. Each scale is evaluated using the Likert method with a range of 0 to 100 points. A score of 0 points indicating an extremely impaired quality of life while 100 points indicating no impairment experienced by the individual[10].

Participants were randomized into one of three intervention groups: Group A received sensory treatment approach combined with conventional swallowing therapy, Group B received motor treatment approach combined with conventional swallowing therapy, and Group C received neuromuscular stimulation combined with conventional swallowing therapy.

Conventional swallowing therapy

Traditional swallowing therapy includes exercising, adaptation, drug treatment, and dietary modifications. Also, it involves compensation strategies to augment the impaired aspects of oropharyngeal swallowing, such as postural adjustment, increasing the sensory input through thermal-tactile stimulation, strengthening weak oropharyngeal musculature through oral exercise, and swallowing maneuvers.

Sensory treatment

This approach used a German vocaSTIM-Master machine (vocaSTIM-Master PH00088, PHYSIOMED, Elektromedizin AG, Germany) to perform neural electrical stimulation. The electrical stimulation was performed 30 minutes per session, once a day,

six days per week. One course of treatment continued for four weeks. The cathode was placed on the submental region, and the anode was placed on the occipital region while the patient was sitting. The intensity of the electrode stimulation was 0 to 15mA and was increased gradually up to point initiation of swallowing. This treatment was combined with conventional swallowing therapy in patients in Group A.

Motor treatment

This approach used a two electrode Vitalism machine (Vitalstim plus, Chattanooga group, USA) to perform electrical muscular stimulation. The cathode and anode were placed in parallel on the skin of the anterior belly of the digastric muscle in the submental region. The current intensity was started at 2mA and increased by 1mA intervals until the target muscle contracted, and the electrode stimulation ranged from 0 to 60mA. This treatment was combined with conventional swallowing therapy in patients in Group B.

Neuromuscular stimulation treatment

Neuromuscular stimulation treatment is a treatment for dysphagia that involves sensory and motor treatment. The intensity and duration of sensory and motor treatment were identical with Group A and Group B. This treatment was combined with conventional swallowing therapy in patients in Group C.

Statistical analysis

Before statistical analysis, the data were tested for normality using the Shapiro–Wilk test and parametric tests were used when data were normally distributed. Descriptive data were reported as mean ± SD when normally distributed variables for baseline characteristics. One-way ANOVA with Bonferroni multiple post-hoc comparisons were used to assess differences between the three groups in age, and SWAL-QOL score. Paired t-tests were used to evaluate the pre and post-treatment outcomes. Differences were considered to be statistically significant when $p \leq .05$. All statistical analyses were performed SPSS 22.0 (IBM, New York, USA).

Ethical statement

The study was conducted after obtaining the approval of the Bioethical Research and Ethical subcommittee of the Mongolian National University of Medical Sciences on September 21, 2018. Each patient signed a consent form before participating in the study.

Result

Baseline characteristics

A total of 149 patients were 34 - 77 years of age (59.70 ± 9.55) participated in our study. By age group, 8 (5.4%) people were 31 - 40 years of age, 21 (14.1%) people were 41 - 50 years, 46 (30.9%) were 51 - 60, 59 (39.6%) were 61 - 70, and 15 (10.1%) were above age 71 (Table 1). Compared the treatment groups, the average age of the study population was 60.73 ± 10.04 years in Group A, 59.35 ± 9.06 in Group B and 59.00 ± 9.62 in Group C. There were no statistically significant differences between the ages of the patients in the three groups ($p = .609$) (Figure 1).

Table 1. Patient characteristics in 3 treatment groups.

	Treatment			Total	p-value
	Group A	Group B	Group C		
n	51	49	49	149	-
Male (n)	37 (24.83%)	41 (27.51%)	38 (25.50%)	116 (77.85%)	.561
Female (n)	14 (9.39%)	9 (6.04%)	10 (6.71%)	33 (22.15%)	-
Mean age (y)	60.73 ± 10.04	59.35 ± 9.06	59.00 ± 9.62	59.70 ± 9.55	
31-40	3 (5.9%)	3 (6.1%)	2 (4.1%)	8 (5.4%)	
41-50	5 (9.8%)	6 (12.2%)	2 (4.1%)	21 (14.1%)	.635
51-60	16 (31.4%)	17 (34.7%)	13 (26.5%)	46 (30.9%)	
61-70	21 (41.2%)	19 (38.8%)	19 (38.8%)	59 (39.6%)	
Over71	6 (11.8%)	4 (8.2%)	5 (10.2%)	15 (10.1%)	

Descriptive statistics, One-Way ANOVA test; Group A - Sensory approach combined with conventional swallowing therapy; Group B - Motor approach combined with conventional swallowing therapy; Group C - neuromuscular stimulation combined with conventional swallowing therapy.

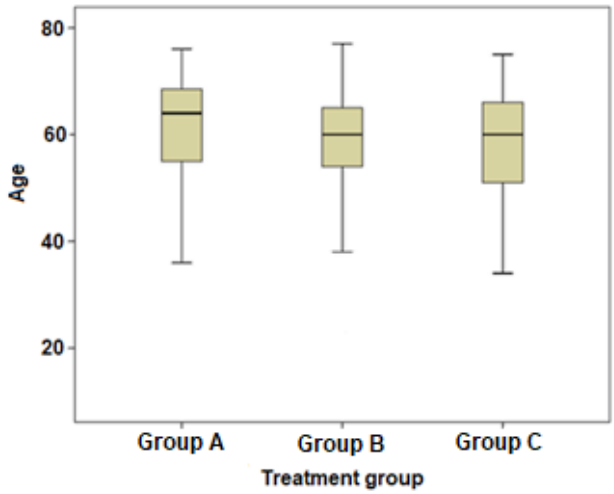

Figure 1. Age of study participants.

Swallowing-Related Quality of Life (SWAL-QOL)

We measured the swallowing-related quality of life using 11 types of valuations consisting of 44 parameters, and compared pre-treatment and post-treatment conditions with a score 0 - 100 (Table 2).

The average score of before treatment in Group A was 26.76 ± 3.12, and it increased following treatment to 39.25 ± 3.50 (p=.0001). In Group B the pre-treatment average score was 27.12 ± 3.45 and increased significantly to 39.10 ± 3.54 (p=.0001) after treatment. In Group C, the score increased from 26.82 ± 4.06 before treatment to 42.12 ± 4.55 after treatment (p=.0001).

Regardless of the treatment used, the post-treatment SWAL-QOL scores were significantly higher than pretreatment, indicating improvement of quality of life with treatment.

The pretreatment SWAL-QOL scores for Groups A, B, and C were not statistically significantly different from each other (p=.777) (Table 3, 4). However, post-treatment SWAL-QOL scores of Groups A, B, and C were significantly different using ANOVA (p=.0001) (Figure 2, Table 3). Post-hoc multiple comparisons showed that Group C post-treatment scores were significantly

Table 2. Swallowing-Related Quality of Life measurements.

	Group A		Group B		Group C	
	Mean	± SD	Mean	± SD	Mean	± SD
Pretreatment	26.76	3.12	27.12	3.45	26.82	4.06
Posttreatment	39.25	3.50	39.10	3.54	42.12	4.55
p-value	.0001		.0001		.0001	

Paired t-test; Group A- Sensory approach combined with conventional swallowing therapy; Group B - Motor approach combined with conventional swallowing therapy; Group C- neuromuscular stimulation combined with conventional swallowing therapy

Table 3. Comparison of SWAL-QOL score between pretreatment and post-treatment state.

	Group A		Group B		Group C		p-value
Test score	N	± SD	N	± SD	N	± SD	
Pretreatment SWAL-QOL	26.76	3.12	27.12	3.45	26.82	4.06	.777
Post-treatment SWAL-QOL	39.25	3.50	39.10	3.54	42.12	4.55	.0001

One-way ANOVA test; Group A - Sensory approach combined with conventional swallowing therapy; Group B - Motor approach combined with conventional swallowing therapy; Group C - neuromuscular stimulation combined with conventional swallowing therapy

Table 4. Comparison of pretreatment SWAL-QOL scores between groups

Comparison between groups		p-value
Group A (26.76 ± 3.12)	Group B (27.12 ± 3.45)	.667
Group A (26.76 ± 3.12)	Group C (26.82 ± 4.06)	.779
Group B (27.12 ± 3.45)	Group C (26.82 ± 4.06)	.481

Group A - Sensory approach combined with conventional swallowing therapy; Group B - Motor approach combined with conventional swallowing therapy; Group C - neuromuscular stimulation combined with conventional swallowing therapy

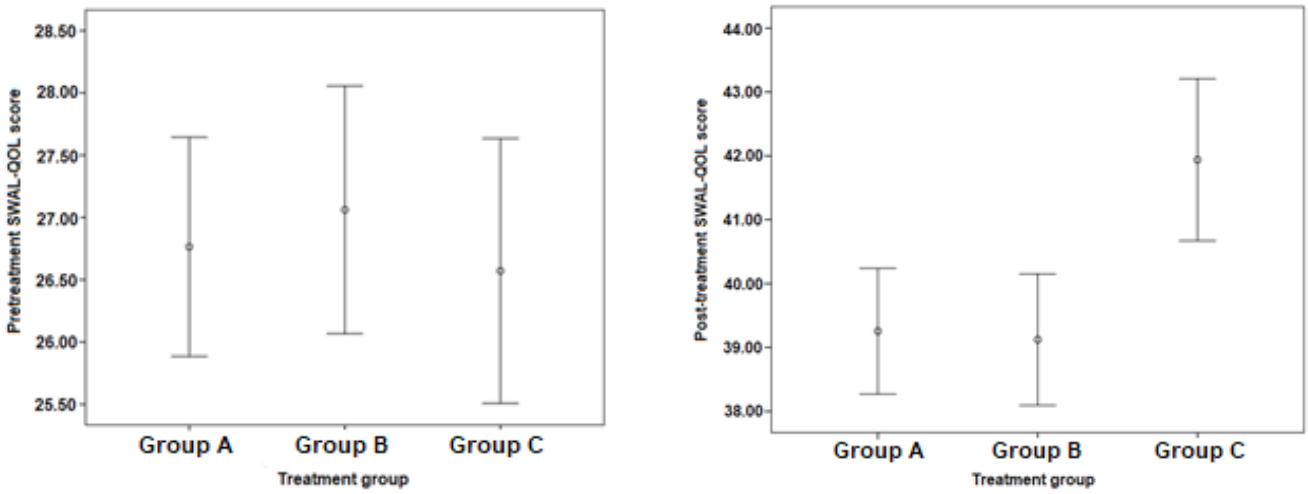

Figure 2. Pretreatment and post-treatment SWAL-QOL.

Table 5. Comparison of SWAL-QOL score between post-treatment state within groups

Comparison between groups		*p-value
Group A (39.25 ± 3.50)	Group B (39.10 ± 3.54)	.864
Group A (39.25 ± 3.50)	Group C (42.12 ± 4.55)	.01
Group B (39.10 ± 3.54)	Group C (42.12 ± 4.55)	.001

*Post hoc test (Bonferroni); Group A - Sensory approach combined with conventional swallowing therapy; Group B - Motor approach combined with conventional swallowing therapy; Group C - neuromuscular stimulation combined with conventional swallowing therapy

higher than Group A or B (Table 5).

These results demonstrate that combining with conventional swallowing therapy with neuromuscular stimulation (Group C) resulted in higher quality of life scores compared to conventional-neural electrical stimulation (Group A), and conventional-electrical muscular stimulation (Group B).

Discussion

Swallowing is a complex function that is regulated by the central nervous system. The nucleus solitarius and nucleus ambiguus of XI cranial nerve in the medulla oblongata are responsible for swallowing function[14]. Neural and muscle stimulation therapies are non-surgical treatments for swallowing impairment[15]. Neurostimulators stimulate nerve fibers, which activate the swallowing function of central nervous system[12]. Muscle stimulation therapy is effective because it prevents atrophy of stimulating muscles, when swallowing function is impaired[10]. These therapies are advocated to be an effective and safe treatment for patients with dysphagia caused by stroke, therefore, are commonly used in clinical setting recently[12-16].

According to Kushner et al. combining traditional swallowing therapy with electric stimulation is more effective than using each of them separately, and reduces the feeding tube dependent dysphagia in patients with an acute stroke[13]. Our study also identified that the combination of conventional swallowing and neuromuscular stimulation therapies positively affected swallowing function and increased the quality of life. According to Zhang et al. showed that the quality of life scale based on swallowing function (SWAL-QOL) after neural electrical stimulation therapy increased from 43.6 ± 8.1 to 77.4 ± 26.5 ($p<.01$), and after electrical muscle stimulation therapy it increased from 42.8 ± 9.1 to 63.5 ± 23.9 ($p<.01$)[8]. In our study, the SWAL-QOL score after a combination of traditional swallowing and neural electrical stimulation therapies increased from 26.76 ± 3.12 to 39.25 ± 3.50, and the combination of conventional swallowing and muscular stimulation therapies the score increased the score a similar amount from 27.12 ± 3.45 to

39.10 ± 3.54 (p=.0001). However, after using the combination of neuromuscular stimulation therapy and conventional therapy, the SWAL-QOL score increased from 26.82 ± 4.06 to 42.12 ± 4.55, which was significantly higher than the other two treatment methods.

Comparing our study to other research results of foreign countries, the combination of neuromuscular stimulation with conventional swallowing therapies has more efficacy. According to Zhang et al. the minimum post-treatment SWAL-QOL score was 63.5 ± 23.9, which is higher than our results suggesting better post-treatment care in Zhang's research. This result might also be related to participants in our study, who had lower SWAL-QOL score compared to others.

According to Heijnen et al. after separate treatments using conventional swallowing or neural stimulation, the SWAL-QOL score increased significantly compared to pretreatment scores[17-19]. In Heijnen's study, the effects of traditional swallowing and muscular stimulation groups were similar, similar to our study where the SWAL-QOL score of conventional therapy-neural stimulation treatment group and conventional therapy-muscular stimulation therapy groups increased similarly. The electrical neural stimulation therapy group in other studies has shown higher improvement, but in our research, there was a significant improvement when neuromuscular stimulation was combined with traditional swallowing therapy[19].

Our study was limited by the small number of patients and ethical concern associated with withholding treatment we did not have an untreated the control group. So, we could not compare the treatments to the natural history of the dysphagia following stoke. Studies involving a larger number of participants are needed, and the long-term beneficial treatment effects warrant further investigation. However, our study provides an excellent basis to support the use of neuromotor electrical stimulation as an adjunctive to conventional therapy in post-stroke dysphagia. The present data, upon which current guidelines are based, may have many flaws, and there appears to be a great need for further well-designed studies to accurately determine to safety and efficacy of this technique, the populations in whom it is most efficacious, and the optimal treatment regime to produce and maintain results.

Our study suggests that neuromotor electrical stimulation added to conventional therapy is more effective than single therapy. However, using a sensory approach may increase the local sensory input to the central nervous system, therefore, eliciting both sensory and motor effects and the sensory stimulation may have a long-term beneficial effect on the reorganization of the human cortex, resulting in the enhancement swallowing control following stroke[20-22]. It is known that even a few days without normative daily swallowing can result in disuse atrophy of the oropharyngeal muscles; the motor approach may enhance local muscle contractions, which may improve laryngeal elevation and protect the muscles from atrophy[23-24].

Combining traditional swallowing therapy with neuromuscular electrical stimulation treatment to improve swallowing following stroke is more effective than using neuromuscular electrical stimulation therapy alone. Moreover, it is non-invasive evidence-based therapy.

Conflict of Interest

The authors state no conflict of interest.

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