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Rehabilitation Treatment Outcomes among Stroke Patients with Dysphagia

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Objectives: Dysphagia is a major complaint following stroke and occurs 37-78% of the time. It is associated with poor clinical outcome and high mortality rates. There are approximately 220-290 new stroke cases per 100.000 person-years in Mongolia and 178-260 in China. Rapidly changing lifestyles, socioeconomic status, stress, and increasing cardiovascular diseases are leading causes of stroke in the world and its diagnosis and treatment are one of the challenges of health care. Therefore, we aimed to characterize the swallow status and treatment outcome among dysphagic patients. **Methods:** The study was conducted in a hospital-based, cross-sectional method. Study participants were obtained 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. 149 patients with dysphagia were evaluated by video fluoroscopic assessment (VFSS) before and after the treatment. **Results:** In total, 149 participants (mean age = 59.70 ± 9.55 years) aged between 34-77 were obtained in this study. There were no statistically significant differences between the three groups in age ($p = 0.583$). The data showed a statistically significant positive treatment effect for all three groups ($p = 0.000$). The VFSS score was 7.94 ± 1.04 in the A group, 7.52 ± 1.12 in the B group, and 8.36 ± 0.98 in the C group after the treatment. The VFSS score shows a statistically significant difference, after the treatment ($p = 0.000$). **Conclusion:** Rehabilitation treatment combined with neuromuscular electrical simulation shows a better outcome than rehabilitation treatment without combined neuromuscular stimulation among stroke patients with dysphagia. The assessment of swallowing function should include both clinical and video fluoroscopic evaluation. Video fluoroscopic features are important predictors of swallowing abnormalities and complications.

Keywords: Nerve Stimulation, Muscular Stimulation, Videofluoroscopy

Introduction

The global burden of stroke is increasing [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 a hemorrhagic stroke) [1]. The occurrence of stroke is more serious in Asian countries because more than 60% of the world population reside in Asia Pacific regions. Stroke epidemiology study in South, East, and South-East Asian countries revealed that stroke mortality in Asia is higher than North America and Europe. Moreover, stroke related mortality exceeds the ischemic heart disease burden in China, Mongolia, and Thailand [2]. China Stroke Statistics of 2019 showed that the age-standardized incidence of stroke was 246.8 per 100,000 person-years [3]. A prospective cohort study conducted by Hu et al. also demonstrated that ischemic stroke incidence in the Inner Mongolian population is 326 per 100,000 person-years. The authors concluded that smoking is an independent risk factor for ischemic stroke [4].

Post stroke neuromuscular impairment affects the majority of stroke patients. Especially, post-stroke dysphagia occurs in 37 - 78% of patients and increases the risk of pneumonia ≥ 3-fold and increases the risk 11-fold in patients with confirmed aspiration [5 - 8]. Also, numerous studies demonstrated that dysphagia occurs in 51-100% of brainstem stroke patients, and it could be an independent factor to predict mortality.

An analysis of California and New York inpatient databases showed that in the stroke group, the adjusted odds ratio (OR) for dysphagia was significantly higher for Asians than whites in California and New York after adjusting for age, sex, presence of hemiplegia and aphasia, number of comorbidities, and stroke type [9]. Moreover, Davis et al. demonstrated increased deep infarct volume in Shanghai Chinese subjects compared with the American and European population, due to the high prevalence of hypertensive vasculopathy in Chinese subjects. Hypertensive vasculopathy has been sited to be associated with brainstem infarction, which is commonly associated with dysphagia [10].

Dysphagia not only increases morbidity and mortality after stroke but also significantly affects the quality of life. As a result of that, as dysphagia increases, it becomes one of the pressing issues of health care. It results in malnutrition and prolonged hospital stays [4]. Unfortunately, its diagnosis and treatment are still not clearly defined. Bakhtiyari et al. recommended early interventions for dysphagia in stroke in order to promote rapid recovery from dysphagia and prevention of complications such as aspiration pneumonia. In this study, the group of patients who were allocated to early treatment using outcome measures such as the North-western Dysphagia Patient Check Sheet, functional oral intake scale, and video fluoroscopy resulted in decreased frequency of pneumonia and more effective swallowing recovery [5]. There are several research reports that have compared separate results of traditional swallowing therapies and electric stimulation in dysphagia patients. As reported in systematic review and meta-analysis by Chen et al. there was a significant standardized mean difference (SMD) of 1.27 (95% confidence interval (CI) = 0.51 - 2.02, $p = 0.001$) between "swallow treatment with neuromuscular electrical stimulation vs. swallow treatment without neuromuscular electrical stimulation" [6]. Further, Zhang et al. compared traditional swallowing therapy and neuromuscular electrical stimulation (NMES) in 2 different modes, acting on the sensory input and the motor muscle, separately. Both the sensory approach combined with traditional swallowing therapy and motor approach combined with traditional swallowing therapy showed significant improvement compared to a traditional swallowing therapy only group ($p < 0.05$) [7]. In a randomized controlled trial conducted by Li et al. 4-week VitalStim therapy (neuromuscular electrical stimulation group) combined with traditional swallowing therapy significantly improved post-stroke dysphagia ($p < 0.001$) [8]. Also, Vasant et al. demonstrated that two-weeks post-active pharyngeal electrical stimulation (PES) with 5Hz frequency on stroke patients resulted in accelerated swallowing recovery [11]. However, another study by Power et al. also applied stimulation at different frequencies (0.2 and 5 Hz) and found that stimulation at 0.2 Hz did not enhance swallowing behavior [9].

Normal oropharyngeal function such as swallowing is significantly complicated, and it depends on both sensory and motor functions involving a large number of muscle groups. Therefore, management of stroke, especially with dysphagia rehabilitation is crucial in stroke patients. There are various paramedical treatments generally carried out in order to improve swallowing functions. Beside the use of traditional swallowing therapy, numerous studies have introduced neuromuscular electrical stimulation (NMES) of the swallowing muscles. Consequently, there are variety of protocols and techniques for performing and all these protocols have their own pros and cons.

Especially, output of these techniques are largely dependent on the placement of electrodes and the intensity of the stimulation. To our knowledge, there are only 2 meta-analyses regarding NMES, however, both of these studies concluded that the effectiveness of the NMES on dysphagia is still not superior to traditional post-stroke rehabilitation alone [6, 11]. Even though, the above mentioned several studies suggested that electrical stimulation therapy coupled with traditional swallowing therapy may be beneficial for post-stroke dysphagia, it is obvious that it has not sufficiently resolved the problem of proving the effectiveness of combined traditional swallowing techniques and NMES. In this study, therefore, by using video fluoroscopic assessment (VFSS), we aimed to study treatment outcomes among stroke patients with dysphagia by evaluating the electrical stimulation therapy (neural and muscular) and traditional swallowing therapy outcome among dysphagia patients in order to understand the benefits of the combined therapeutic approach.

Materials and Methods

Study design and sampling

This is a hospital-based repeated measurement study design. A total of 149 participants 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 participants were divided into three groups (Group A -nerve stimulation combined with rehabilitation; Group B- muscular stimulation combined with rehabilitation; Group C-neuromuscular combined with rehabilitation).

Video fluoroscopic assessment

Video fluoroscopic assessment involves anteroposterior and lateral view of the oral-pharyngeal phase, with slow motion features to allow characterization of the swallow mechanism and severity of dysfunction. Lateral view allows assessment of oral-pharyngeal transit time, delay, and physiological problems. Anterior views delineate residue asymmetries in the valleculae and pyriform sinuses, and visualize abduction of the vocal chords.

We tested for non-swallowing on an X-ray using a contrast agent (barium). The test was divided into three phases: oral, pharyngeal, and esophageal. Stage 3 assessments were not performed in cases of complete loss of swallowing in stage 1 or 2.

Video fluoroscopic assessment was done using X-ray (Pantoshkop, Siemens, Erlangen, Germany). The assessment was divided into three phases: oral, pharyngeal, and esophageal. Depending on the amount of residual material in the valleculae or piriform sinuses, pharyngeal retention was graded in three stage 1 - 3. Stage 3 assessments were not performed in cases of complete loss of swallowing in stage 1 or 2. 1st and 2nd stage is evaluated by 0 to 3 points. 3rd stage is evaluated by 0-4 points. 0 point indicating extremely impaired quality of life while 3 points indicating no impairment experienced by the individual.

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 video fluoroscopic 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 as 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 highly inflammatory, severe cardiopulmonary disease or carotid sinus syndrome (e.g. temperature > 38.5 ^{0}C or < 35.5 ^{0}C, systolic blood pressure >180 or < 90mmHg, diastolic blood pressure >110 or < 60 mmHg, 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 (eg, 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 diseases; (6) pregnancy; or (7) spastic paralysis.

Traditional 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.

Neural electrical stimulation

This approach used a German vocaSTIM-Master machine (vocaSTIM-Master PH00088, PHYSIOMED, Elektromedizin AG, Germany). The electrical stimulations were 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 15 mA and the intensity was gradually increased till the swallowing process starts.

Electrical muscular stimulation

This approach used a two electrode Vitalism machine (Vitalstim plus, Chattanooga Group, USA). 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 2 mA and increased by 1-mA intervals until the target muscle contracted, while the electrode stimulation ranged from 0 to 60 mA.

Statistical analysis

Prior to statistical analysis, the data were tested for normality using the Shapiro-Wilk test and parametric tests were used when data were normally distributed. The main effects of time, treatment type and their interaction were determined using a mixed two-way ANOVA with a multiple comparison test (Tukey HSD test). A critical p-value of < 0.05 was used. SPSS version 24 software (SPSS Inc., Chicago, IL, USA) was used for statistical analyses.

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 (No. 2018/3-13). Each patient signed a consent form before participating in the study.

Results

Baseline characteristics

Participants were randomized over 3 intervention groups: Group A (nerve stimulation combined with rehabilitation treatment) or a sensory approach combined with traditional swallowing therapy,

Table 1. Patient characteristics in 3 groups.

Variables	Treatments Group A (n = 51)	Group B (n = 49)	Group C (n = 49)	Total (n = 149)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Age, years	60.73 ± 10.04	59.35 ± 9.06	59.00 ± 9.62	59.70 ± 9.55	0.089
Age groups	N (%)	N (%)	N (%)	N (%)	
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)	
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)	
> 71	6 (11.8)	4 (8.2)	5 (10.2)	15 (10.1)	
Gender					
Male	37 (72.5)	41 (80.3)	38 (74.5)	116 (77.9)	0.561
Female	14 (27.5)	9 (19.7)	10 (15.5)	33 (22.1)	
Diagnosis					
Ischemic stroke	15 (32.2)	18 (36.7)	15 (30.6)	48 (32.2)	0.705
Hemorrhagic stroke	36 (70.6)	31 (63.2)	34 (69.3)	101 (67.7)	

Note: Group A- nerve stimulation combined with rehabilitation; Group B-muscular stimulation combined with rehabilitation; Group C- neuromuscular stimulation combined with rehabilitation.

Group B (muscular stimulation combined with rehabilitation treatment) or a motor approach combined with traditional swallowing therapy, and Group C (neuromuscular stimulation combined with rehabilitation treatment) or a neuromuscular stimulation combined with traditional swallowing therapy.

In total, 149 people aged between 34 - 77 years (mean age of 59.70 ± 9.55) participated in our study. According to the age group, 8 (5.4%) people in the age group 31-40, 21 (14.1%) people in the age group 41 - 50, 46 (30.9%) people in the age group 51 - 60, 59 (39.6%) people in the age group 61 - 70, 15 (10.1%) people in the age group above 71, were patients (Table 1). Compared to the treatment group, the average age of the study population was 60.73 ± 10.04 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 = 0.609).

Video fluoroscopic assessment (VFSS)

The average score before treatment in the A group was 4.78 ± 1.22, and it changed after treatment to 7.94 ± 1.04, which shows a statistically significant difference (p = 0.000). Accordingly, the B group pre-treatment average score was 4.49 ± 1.24, and the post-treatment score was 7.52 ± 1.12, which also shows a statistically significant difference (p = 0.000). In the C group, the pre-treatment score was increased from 4.47 ± 1.54 to 8.36 ± 0.98, and a statistically significant difference was shown (p = 0.000) (Table 2). Post-treatment VFSS score rose statistically significantly and it revealed improvement of quality of life post-treatment.

Pretreatment VFSS scores of Groups A, B and C showed no statistically significant difference with each other (p = 0.583) (Table 3, 4). However, post-treatment VFSS scores of Groups A, B and C were statistically different using ANOVA (p = 0.001) (Table 3, 5). Post-hoc multiple comparisons showed that Group C post-treatment scores were significantly higher than Group A

Table 2. Vide of fluoroscopic assessment (VFSS) values at pre and post treatments.

Variable	Treatments				p-value
	Group A[a] (n = 51)	Group B[b] (n = 49)	Group C[c] (n = 49)	Total (n = 149)	
VFSS	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	
Pretreatment [d]	4.78 ± 1.22	4.49 ± 1.24	4.47 ± 1.54	4.58 ± 1.33	0.000
Post-treatment [e]	7.94 ± 1.04	7.52 ± 1.12	8.36 ± 0.98	7.94 ± 1.04	0.000

Note: Group A- nerve stimulation combined with rehabilitation; Group B-muscular stimulation combined with rehabilitation; Group C- neuromuscular stimulation combined with rehabilitation. Two-way mixed ANOVA results: Interaction of time and treatment F (1.819, 337.59) = 23.195, p < 0.005; Main effect of time F (1.917, 336.58) = 345.31, p < 0.002; Main effect of treatment F(1,176) = 0.676, p = 0.451; Pairwise comparisons: [a]pretreatment vs. posttreatment, p = 0.009; [b]pretreatment vs. posttreatment, p = 0.014; [c]pretreatment vs. posttreatment, p = 0.000; Multiple comparisons: [d]group A vs. group C, p = 0.000; [e]group A vs. group C, p = 0.000.

Table 3. National Institutes of Health Stroke Scale (NIHSS) values at pre and post-treatment.

Variable	Treatments				p-value
	Group A[a] (n = 51)	Group B[b] (n = 49)	Group C[c] (n = 49)	Total (n = 149)	
NIHSS	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	
Pretreatment [d]	13.61 ± 3.77	13.08 ± 3.78	11.10 ± 3.03	12. 61 ± 3.69	0.003
Post-treatment [e]	8.43 ± 2.94	7.97 ± 2.61	6.94 ± 2.08	7.79 ± 2.63	0.057

Note: Group A- nerve stimulation combined with rehabilitation; Group B-muscular stimulation combined with rehabilitation; Group C- neuromuscular stimulation combined with rehabilitation. Two-way mixed ANOVA results: Interaction of time and treatment F (1.917, 337.59) = 21.124, p < 0.051; Main effect of time F (1.967, 337.48) = 332.35, p < 0.020; Main effect of treatment F (1,196) = 0.676, p = 0.652; Pairwise comparisons: [a]pretreatment vs. posttreatment, p = 0.0519; [b]pretreatment vs. posttreatment, p = 0.032; Multiple comparisons: [c]group A vs. group C, p = 0.000.

Table 4. Water swallowing test (WST) scores.

Variable	Treatments				p-value
	Group A[a] (n = 51)	Group B (n = 49)	Group C[b] (n = 49)	Total (n = 149)	
WST	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	
Pretreatment	3.84 ± 0.46	3.87 ± 0.56	3.98 ± 0.52	3.87 ± 0.52	0.593
Post-treatment	1.98 ± 0.32	2.22 ± 0.68	1.71 ± 0.54	1.97 ± 0.57	0.840

Note: Group A- nerve stimulation combined with rehabilitation; Group B-muscular stimulation combined with rehabilitation; Group C- neuromuscular stimulation combined with rehabilitation. Two-way mixed ANOVA results: Interaction of time and treatment F (1.917, 337.59) = 21.124, p < 0.051; Main effect of time F (1.967, 337.48) = 332.35, p < 0.020; Main effect of treatment F (1,196) = 0.676, p = 0.652; Pairwise comparisons: [a]pretreatment vs. posttreatment, p = 0.0431; [b]pretreatment vs. posttreatment, p = 0.047.

or B (Table 5).

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

Discussion

Neurostimulator stimulates neuro fibers, which activate the swallowing function by affecting the central nervous system [12-14]. Muscle stimulation therapy is effective in the way it prevents atrophy by stimulating muscles when swallowing function is impaired. Swallowing is a complex function that is regulated by the central nervous system. The nucleus solitarius and nucleus ambiguus of cranial nerve XI on the medulla oblongata are responsible for swallowing function [15]. Further, video fluoroscopic studies are the gold standard for evaluating the pharyngeal phase of swallowing. It allows precise assessment of the dynamic aspects of swallowing, especially of the pharyngeal stage of deglutition. The protocol described by Logemann et al. in 1993 continues to be followed in most clinical settings.

Neural and muscle stimulation therapy are non-surgical treatments for swallowing impairment. This therapy is announced to be an effective and safe treatment for patients with dysphagia caused by stroke, therefore it is commonly used in clinical settings recently [10-14]. According to Kushner's research, combined therapy of traditional swallowing and electric stimulation is more effective than using each of them separately, besides, it reduces feeding tube dependent dysphagia in patients with an acute stroke [16].

According to Zhang's research, the VFSS scale after neural electrical stimulation therapy increased, significantly [17-19]. These changes had statistically significant differences (p < 0.01). In other words, neural electrical stimulation therapy is more beneficial than using electrical muscular stimulation therapy.

We presented in the current study that a combination of traditional swallowing and neuromuscular stimulation therapies positively affects swallowing function and increases the quality of life of a patient.

The data showed a statistically significant positive treatment effect for all three groups (p = 0.000). The VFSS score was 7.94 ± 1.04 in the A group (i.e. sensory approach combined with traditional swallowing therapy), 7.52 ± 1.12 in the B group (i.e. motor approach combined with traditional swallowing therapy), 8.36±0.98 in the C group (i.e. neuromuscular stimulation combined with traditional swallowing therapy) after the treatment. The VFSS score shows a statistically significant difference after the treatment (p = 0.000). The rehabilitation treatment combined with neuromuscular electrical simulation shows better outcomes than nerve or muscular stimulation combined with rehabilitation among stroke patients with dysphagia. 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 post-treatment VFSS score was 5.67 ± 0.88 in the treatment group of Vitalstim electric stimulation, which is lower than our results. When Vitalstim electric stimulation and acupuncture combined therapy was held, the VFSS score was improved (7.97 ± 1.05) [20]. Another study of electric stimulation for swallowing disorders in stroke patients conducted by Freed et al. showed that electric stimulation which was administered with a modified hand-held battery-powered electrical stimulator connected to a pair of electrodes positioned on the neck with 1hour daily treatment, resulted in a VFSS score of 5.5. On the other hand, thermal-tactile stimulation, consisted of touching the base of the anterior faucial arch with a metal probe chilled by immersion in ice, resulted in a VFSS score of 6.0 [21 - 24].

Further, our study suggests that NMES added to traditional therapy is more effective than single therapy among patients. The 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 effect in a reorganization of the human cortex, resulting in the enhancement of brain recovery in swallowing control [18 - 20]. 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 [25 - 27].

Despite the small number of patients and ethical concern associated with withholding treatment in the control group, our study provides an excellent basis to support the use of neuromotor electrical stimulation as an adjunctive to traditional 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 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 has some limitations. First, study size of the present study was small. 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. Second, various studies revealed that there could be different outcomes depending on the early or late stage of dysphagia rehabilitation. Early dysphagia rehabilitation often results in significantly good progress toward recovery. Consequently, for further investigation, we need to include criteria of rehabilitation starting stage in order to determine whether early rehabilitation could be a significant factor in dysphagia patients. Third, in the present study, we did not include dental as well as nutritional issues. Thus, the next step of our research is describing the effects of neuromuscular stimulation combined with traditional swallowing therapies of dysphagia by the evaluation from multiple professional perspectives such as dentists and nutritionists.

Conclusions

Combining traditional swallowing therapy with neuromuscular electric stimulation treatment to improve the ability to swallow for stroke patients is more effective than using neuromuscular electric stimulation therapy alone. In the present study, we have confirmed that rehabilitation treatment combined with neuromuscular electrical simulation shows better outcomes than only nerve or muscular stimulation combined with rehabilitation among stroke patients with dysphagia. The assessment of swallowing function should be clinical and video fluoroscopic. The video fluoroscopic features are important predictors of swallowing abnormalities and complications.

Conflict of Interest

The authors state no conflict of interest.

Acknowledgements

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