Effect of neuromuscular electrical stimulation combined with effortful swallowing using electromyographic biofeedback on oropharyngeal swallowing function in stroke patients with dysphagia

A pilot study

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Abstract

Background: Electromyographic biofeedback (EMG-BF) is known to be an effective therapy for stroke rehabilitation. However, because few studies have investigated the therapy in patients with dysphagia, its effectiveness is not yet clear. This study aimed to investigate the effect of neuromuscular electrical stimulation (NMES) using EMG-BF on swallowing function in stroke patients with oropharyngeal dysphagia.

Methods: In this study, 10 patients with dysphagia were recruited. The 1-group, pre–post study design was adopted. All subjects received NMES combined with EMG-BF in the suprathyroid area. Electrical stimulation was provided as a reward when the electrical signal generated by effortful swallowing reached a preset threshold. The intervention was provided for 30 minutes a day, 5 times a week for 4 weeks. The videofluoroscopic dysphagia scale (VDS) and penetration–aspiration scale (PAS) based on the videofluoroscopic swallowing study were used to evaluate the swallowing function.

Results: Pre-intervention showed no significant differences in all items of VDS ($P > .05$). However, there was a statistically significant change in VDS from $13.36 \pm 5.94$ to $9.36 \pm 5.14$ ($P = .015$) in the oral phase, and from $38.36 \pm 7.42$ to $20.71 \pm 14.61$ ($P = .016$) in the pharyngeal phase. The PAS scores showed significant change from $5.14 \pm 2.27$ to $3.00 \pm 1.00$ ($P = .031$).

Conclusion: This study demonstrated that the use of NMES combined with EMG-BF had the potential to improve oropharyngeal swallowing in stroke patients with dysphagia.

Abbreviations: EMG-BF = electromyographic biofeedback, NMES = neuromuscular electrical stimulation, PAS = penetration–aspiration scale, VDS = videofluoroscopic dysphagia scale, VFSS = videofluoroscopic swallowing study.

Keywords: aspiration, biofeedback, dysphagia, neuromuscular electrical stimulation, stroke

1. Introduction

Neuromuscular electrical stimulation (NMES), a method for stimulating muscles with short electrical pulses, is widely used in the therapy of stroke patients with pharyngeal dysphagia. It enhances the strength of the muscles associated with swallowing and facilitates reflex swallowing by sensory stimulation. Clinically, NMES is used to depolarize nerve fibers at the point of attachment, inducing muscle contraction.\textsuperscript{[1]} Many clinicians use NMES in swallowing rehabilitation and its use appears to be growing; however, there is controversy regarding its efficacy for treating dysphagia.\textsuperscript{[2,3]} In addition, there have been clinical demands for practice and
learning movement that are novel and more effective therapeutic
approaches.

Recently, studies investigating NMES combined with electro-
myographic biofeedback (EMG-BF) in the rehabilitation of
stroke patients have been reported.\(^4,5\) EMG-BF is a scientific
tool that alerts a patient about their muscle activity by increasing
the myoelectric signals from the muscle and converting them to
visual and auditory signals. This allows the patient to control and
regulate the activity of the muscle. The use of therapy with
biofeedback increases the rate of motor learning and thus
improves the time efficiency of therapy.\(^6–8\) Applying EMG-BF
technology to conventional cyclic NMES adds the element of
patient effort and motivation to the therapy.

However, most previous studies using EMG-BF have investi-
gated improvement in upper or lower limb function in stroke
patients. Therefore, the effect of EMG-BF on patients with
dysphagia is still unclear. This study investigates the effect of
using NMES with EMG-BF during therapy for swallowing
function in patients with dysphagia after stroke.

2. Methods

2.1. Sample size calculation

A sample size of 10 was calculated based on the effect size of 0.9,
significance level (\(\alpha\)) of 0.05, and desired power (1 – \(\beta\)) of 0.80.

2.2. Participants

This study was designed as a 1-group, pre–post test design. Ten
patients diagnosed with dysphagia following a stroke admitted to
a rehabilitation department at tertiary hospitals in the Republic of
Korea who consented to participate were enrolled in the study.
The inclusion criteria were as follows: patients with dysphagia
following a stroke that was confirmed by a videofluoroscopic
swallowing study (VFSS), coughing after completion of a 3-oz
water swallow test, ability to initiate a voluntarily swallow not
necessarily in response to stimulation by a bolus, onset <6
months before the study, and no significant cognitive deficit (a
score of >20 points on the Mini-Mental Status Examination).
The exclusion criteria were: implanted cardiac pacemaker, severe
communication difficulties associated with dementia or aphasia,
history of seizure or epilepsy, unstable medical condition, and
skin problems associated with electrode placement.

We explained the objective and requirements of our study to all
participants, and they voluntarily signed informed consent forms.
Ethical approval was obtained from the Semyung University
Institutional Review Board before conducting the experiment.

2.3. Procedures

All patients received NMES combined with EMG-BF using
VitalStim Plus (Electrotherapy and sEMG Biofeedback System,
Chattanooga Group, Hixson, TN), which assists patients in
initiating swallow. In this study, the set threshold for providing
stimulation was the value obtained by 3 attempts at effortful
swallowing. Treatment parameters, such as phase duration,
frequency, and contraction and rest time, could be customized.
Patient were asked to focus on the swallowing experience by
looking at the EMG level displayed on the device’s screen and
other visual and auditory feedback while attempting to reach the
preset threshold during swallowing attempts\(^9\) (Fig. 1). The
electrical stimulation unit provided 2 channels of bipolar
electrical stimulation at a fixed 80-Hz pulse rate and a biphasic
pulse width of 700 \(\mu\)s; the intensity of the bipolar electrical
stimulation could be adjusted between 0 and 25 mA for each
channel. Two pairs of electrodes were placed horizontally on the
submental and thyroid cartilage regions (Fig. 2), with the


intensity set to a motor level defined as the “maximal tolerable.” The occupational therapist instructed the patients as follows: “From now on I will increase the electrical stimulation. Please say ‘stop’ when you feel a grabbing sensation in your neck but can tolerate the stimulation.” The intensity was increased gradually at an interval of 0.5 mA. The stimulation intensity was set differently for each participant, from 8.5 to 11.0 mA.

2.4. Outcome measures

To quantify the functional changes in swallowing, the video-fluoroscopic dysphagia scale (VDS) and penetration–aspiration scale (PAS) were assessed at baseline and after 4 weeks of intervention. VFSS was performed by experienced radiologists and rehabilitation physicians. VDS and PAS scores were interpreted by 1 occupational therapist.

The VDS is a functional assessment that comprehensively reflects the swallowing function of the mouth from the oral to pharyngeal phase based on the VFSS findings. It comprises 14 total items, 7 for the oral phase and 7 for the pharyngeal phase. The score ranges from 0 to 100, with a maximum score for oral function of 40 and a maximum score for pharyngeal function of 60. A higher score indicates greater dysphagia severity[10] (Table 1).

The PAS is an 8-points scale that measures selected aspects of airway penetration and aspiration. It is determined primarily by the depth to which a material passes in the airway and whether the material entering the airway is expelled. Higher scores indicate greater aspiration severity[11] (Table 2).

2.5. Data analysis

Participants’ characteristics were analyzed using IBM SPSS Statistics version 20 (IBM Corp., Armonk, NY). Descriptive statistics are presented as means with standard deviations. The Q–Q plots were used to test the normality of data distribution. The Wilcoxon signed-rank test was used to compare the differences in outcome measurements before and after the intervention. The significance level was set at \(P < .05\).

3. Results

3.1. General characteristics of the subject

This study included 10 patients with dysphagia after stroke with no dropouts until the intervention was completed (Fig. 3). Therefore, data from 10 subjects were analyzed (Table 3).

3.2. Oral phase of VDS

There were no significant differences in lip closure, bolus formation, mastication, tongue to palate contact, premature bolus loss, and oral transit time in the oral phase (\(P = .250, .500, .500, 1.000, .500, .063\), and \(.250\), respectively). However, there were significant differences in the total score in the oral phase (\(P = .015\)) (Table 4).

| Parameter                  | Findings | Parameter                  | Findings |
|----------------------------|----------|----------------------------|----------|
| Lip closure                | Intact   | 0                          | Normal   | 0 |
|                           | Inadequate| 2                          | Triggering of pharyngeal swallow | Delayed | 4.5 |
|                           | None     | 4                          |          |    |
| Bolus formation            | Intact   | 0                          | Vallecular residue | None | 0 |
|                           | Inadequate| 3                          | <10%     | 2 |
|                           | None     | 6                          | 10%–50%  | 4 |
|                           |          |                           | >50%     | 6 |
| Mastication                | Intact   | 0                          | Laryngeal elevation | Normal | 0 |
|                           | Inadequate| 4                          |          |    |
|                           | None     | 8                          |          |    |
| Apraxia                    | None     | 0                          | Pyriform sinus residue | None | 0 |
|                           | Mild     | 1.5                        | <10%     | 4.5 |
|                           | Moderate | 3                          | 10%–50%  | 9 |
|                           | Severe   | 4.5                        | >50%     | 13.5 |
| Tongue to palate contact   | Intact   | 0                          | Coating on the pharyngeal wall | No | 0 |
|                           | Inadequate| 5                          |          |    |
|                           | None     | 10                         |          |    |
| Premature bolus loss       | None     | 0                          | Pharyngeal transit time | <1.0 s | 0 |
|                           | <10%     | 1.5                        | >1.0 s   | 6 |
|                           | 10%–50%  | 3                          |          |    |
|                           | >50%     | 4.5                        |          |    |
| Oral transit time          | <1.5 s   | 0                          | Aspiration | None | 0 |
|                           | >1.5 s   | 3                          | Penetration | 6 |

| Score                      | Citation                                                                 |
|----------------------------|--------------------------------------------------------------------------|
| 1                          | Material does not enter the airway                                       |
| 2                          | Material enters the airway, remains above the vocal folds, and is ejected from the airway |
| 3                          | Material enters the airway, remains above the vocal folds, and is not ejected from the airway |
| 4                          | Material enters the airway, contacts the vocal folds, and is ejected from the airway |
| 5                          | Material enters the airway, contacts the vocal folds, and is not ejected from the airway |
| 6                          | Material enters the airway, passes below the vocal folds and is ejected into the larynx or out of the airway |
| 7                          | Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort |
| 8                          | Material enters the airway, passes below the vocal folds, and no effort is made to eject |
3.3. **Pharyngeal phase of VDS**

There were no significant differences in triggering of pharyngeal swallow, vallecular residue, laryngeal elevation, pyriform sinus residue, coating on the pharyngeal wall, pharyngeal transit time, and aspiration in the pharyngeal phase ($P = .025, .063, .125, .063, .500, .500, \text{and} .063$, respectively). However, there was a significant difference in the total score in the pharyngeal phase ($P = .016$) (Table 4).

**Table 3**

Demographic characteristics of the subjects.

| Subject | Gender | Age, y | Stroke type | Lesion site | Height, cm | Weight, kg | Poststroke, mo |
|---------|--------|--------|-------------|-------------|------------|------------|----------------|
| 1       | Man    | 79     | Hemorrhage  | MCA/Rt      | 170        | 65         | 5              |
| 2       | Man    | 62     | Infarction  | MCA/Lt      | 171        | 670        | 3              |
| 3       | Man    | 55     | Hemorrhage  | Pontine/Lt  | 162        | 54         | 3              |
| 4       | Man    | 56     | Infarction  | MCA/Rt      | 168        | 56         | 2              |
| 5       | Man    | 81     | Infarction  | MCA/Lt      | 159        | 58         | 4              |
| 6       | Woman  | 47     | Infarction  | MCA/Rt      | 169        | 60         | 5              |
| 7       | Woman  | 60     | Hemorrhage  | MCA/Rt      | 171        | 70         | 2              |
| 8       | Woman  | 60     | Infarction  | MCA/Rt      | 150        | 49         | 3              |
| 9       | Woman  | 53     | Infarction  | MCA/Lt      | 155        | 51         | 4              |
| 10      | Woman  | 48     | Hemorrhage  | MCA/Lt      | 163        | 55         | 2              |

MCA = middle cerebral artery, Lt = left, Rt = right.
Table 4
Changes in parameters before and after the treatment.

| Parameter                        | Before treatment (Mean ± SD) | After treatment (Mean ± SD) | Mean difference (Mean ± SD) | P-value |
|----------------------------------|------------------------------|-----------------------------|-----------------------------|---------|
| VDS (total score)                | 51.7 ± 9.95                  | 30.07 ± 15.80               | 21.64 ± 16.43               | .016*   |
| LC                               | 1.14 ± 0.17                  | 0.57 ± 0.98                 | 0.57 ± 0.97                 | .250    |
| BF                               | 2.57 ± 1.13                  | 2.14 ± 1.46                 | 0.43 ± 1.13                 | .500    |
| MAS                              | 1.71 ± 2.14                  | 1.14 ± 1.95                 | 0.57 ± 1.51                 | .500    |
| Apraxia                          | 0.00 ± 0.00                  | 0.00 ± 0.00                 | 0.00 ± 0.00                 | 1.000   |
| TPC                              | 4.29 ± 1.89                  | 3.57 ± 2.44                 | 0.71 ± 1.89                 | .500    |
| FBL                              | 1.93 ± 1.13                  | 1.07 ± 0.73                 | 0.86 ± 0.80                 | .063    |
| OTT                              | 1.71 ± 1.60                  | 0.86 ± 1.46                 | 0.86 ± 1.46                 | .250    |
| Oral phase (total)               | 13.36 ± 5.94                 | 9.36 ± 5.14                 | 4.00 ± 3.52                 | .015*   |
| TPS                              | 3.21 ± 2.20                  | 1.93 ± 2.41                 | 1.29 ± 2.20                 | .250    |
| VR                               | 3.43 ± 0.98                  | 1.43 ± 1.51                 | 2.00 ± 2.00                 | .063    |
| LE                               | 6.43 ± 4.39                  | 2.57 ± 4.39                 | 3.86 ± 4.81                 | .125    |
| PSR                              | 5.14 ± 3.11                  | 1.93 ± 2.41                 | 3.21 ± 3.40                 | .063    |
| CPW                              | 6.43 ± 4.39                  | 5.14 ± 4.81                 | 1.29 ± 3.40                 | .500    |
| FTT                              | 4.29 ± 2.93                  | 3.43 ± 3.21                 | 0.86 ± 2.27                 | .500    |
| ASP                              | 9.43 ± 3.21                  | 4.29 ± 2.93                 | 5.14 ± 5.04                 | .063    |
| Pharyngeal phase (total)         | 38.36 ± 7.42                 | 20.71 ± 14.61               | 17.64 ± 13.84               | .016*   |
| PAS                              | 5.14 ± 2.27                  | 3.00 ± 1.00                 | 2.14 ± 1.68                 | .031*   |

ASP = aspiration, BF = bolus formation, CPN = coating on the pharyngeal wall, LC = lip closure, LE = laryngeal elevation, MAS = mastication, OTT = oral transit time, PAS = penetration-aspiration scale, PBL = premature bolus loss, PSR = pyriform sinus residue, FTT = pharyngeal transit time, SD = standard deviation, TPC = tongue to palate contact, TPS = triggering of pharyngeal swallow, VR = vallecular residue, VDS = videofluoroscopic dysphagia scale.

* P < .05 by Wilcoxon test.

3.4. PAS assessment

There was a significant differences in the PAS score (P = .031) (Table 4).

4. Discussion

In this study, we evaluated the combined effects of NMES and EMG-BF during oropharyngeal swallowing therapy in dysphagic stroke patients. The results showed that this combination has the potential to positively influence and improve oropharyngeal swallowing function in stroke patients with dysphagia. NMES stimulates target muscles, which is effective for muscle activation, muscle atrophy prevention, and muscle re-education. It can also increase muscle strength with repeated application of the stimulation.[13] NMES was applied to the suprahypoid muscles located in the anterior cervical region of each patient. These are the muscles primarily responsible for the anterior-superior movement of the hyoid bone and contribute to the safety of normal swallowing by providing airway protection and upper esophageal sphincter opening.[13]

Unlike conventional cyclic NMES, the machine used in this study was equipped with an EMG-BF. This function requires electrical signals generated through muscle contraction to reach the set threshold value before releasing electrical stimulation. In our study, the patients performed effortful swallowing, which provided the NMES afferent stimulation. Release of the efferent NMES was triggered in the device when the muscle contraction force generated by effortful swallowing reached the threshold value. The EMG level displayed on the device’s screen provides immediate biofeedback on the swallowing effort, which prolongs the duration of the attempted swallow. In other words, the patient must exert more effort and concentration while performing effortful swallowing to receive the reward of NMES stimulation. Tang et al.[9] demonstrated the reduction of aspiration pneumonia with NMES combined with EMG-BF in Alzheimer patients with dysphagia, suggesting an improvement in pharyngeal swallowing function, including aspiration. This is in accordance with the results of this study. EMG-based biofeedback establishes a feedback path outside the body and makes each of the correct processes learnt gradually through repeated external signal such as visual or auditory cues, thus improving the regulation of the swallowing function of the motor area in the cerebral cortex. By activating the feedback loop, EMG-biofeedback helps improve normal reflex, promoting the central conduction pathway formation.[14] This theoretical background supports the results of this study.

Skeletal muscles, such as the muscles associated with swallowing, are a mixture of type 1 and type 2 fibers. Previous studies have shown that electrical stimulation is effective on type 1 fibers, and vasomotor activity is effective for stimulating type 2 fibers. Therefore, it may be more effective to use NMES and effortful swallowing together to stimulate both muscle fiber types.[15,16] The use of biofeedback in therapy increases the rate of motor learning and thus improves its time efficiency.[6-9] Crary et al.[17] reported that applying EMG-BF to a structured behavioral therapy, such as Mendelsohn maneuver, can facilitate functional oral intake in dysphagic patients after stroke or during treatment for head or neck cancer. The improvement in swallowing function found in our study shows that visual and auditory feedback from EMG-BF combined with NMES can enhance the effectiveness of effortful swallowing exercises.

This study has some limitations. First, the results of this study cannot be generalized because of the small number of subjects. Second, owing to absence of a control group in this study, we cannot compare the effects with those of other interventions. Third, the lesion locations of patients participating in this study were combined. Finally, the patients were in the subacute stage of stroke recovery, so the possibility of natural recovery cannot be ruled out. Therefore, these limitations need to be supplemented in further studies.
In order to propose the detail electrical stimulation, not only to identify the actual swallowing function, but also to understand the relationship between neural activities in the brain and muscle. For the further study, the brain monitoring technologies such as functional near infrared spectroscopy (fNIRS), functional magnetic resonance imaging (fMRI), and diffuse tensor imaging (DTI) should be employed to estimate brain function to evaluate the proposed method. In addition, it will also be important to select functional cortical ROIs on the brain, which can be done by employing the DTI-Derived Fiber shape model.[18]

5. Conclusion
This pilot study demonstrated that NMES combined with EMG-BF had the potential to improve oropharyngeal swallowing in stroke patients with dysphagia. Therefore, we propose NMES combined with EMG-BF to be considered as a therapeutic method for patients with dysphagia

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