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Article

Innovative Swallowing Rehabilitation Balloon and Its Impact on Swallowing Outcomes in Home-Based Stroke Cases in Taiwan: Study Protocol for Randomized Controlled Trial

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Abstract: We outlined a randomized controlled trial assessing the effect of a novel swallowing rehabilitation balloon on post-stroke dysphagia in home-based care. Stroke often causes dysphagia, and standard rehabilitation methods have limitations, prompting the need for innovative interventions. Stroke-induced dysphagia is challenging as it requires improved interventions beyond current limitations. The effect of the swallowing balloon's impact on aspiration efficiency was assessed in and risk of the trial with stroke patients. Patient satisfaction, compliance, and cost-effectiveness were also evaluated. The outcome showed better swallowing and reduced risk of aspiration were achieved. This indicated the effectiveness of home-based balloon therapy. This novel approach enhances post-stroke dysphagia rehab, improves patients' health, and reduces healthcare costs.

Keywords: Stroke, Dysphagia, Swallowing rehabilitation balloon, Randomized controlled trial, Home-based care, Innovative intervention, Swallowing outcomes, Taiwan

1. Introduction

Dysphagia is linked to stroke, Parkinson's disease, motor neuron disease, and developmental disabilities [1]. The global prevalence of dysphagia is around 8% with a higher occurrence in elderly people [2]. Among the elderly in local communities, the prevalence of dysphagia is approximately 15%, whereas in hospitalized patients, it increases to about 30%. This condition is most frequently observed in elderly patients with neurological disorders and dementia, with respective prevalence rates of 64% and 80% [3].

Dysphagia, a prevalent clinical condition, manifests difficulties in swallowing. It is categorized into subtypes: oropharyngeal dysphagia. It occurs with the oral cavity and pharynx, and esophageal dysphagia, which encompasses impediments related to the esophageal body and the esophagogastric junction [2]. Oropharyngeal dysphagia hinders a swallowing motion or the movement of food through the oral cavity and throat. Esophageal dysphagia accompanies structural or inflammatory irregularities, as well as motility disorders [4,5]. As the severity of dysphagia intensifies, it has a significant adverse impact on well-being and overall quality of life [6]. Failing to accurately assess and promptly address dysphagia exacerbates its consequences and causes complications including dehydration, malnutrition, and aspiration pneumonia. It is necessary to promptly identify oropharyngeal dysphagia to prevent the associated risk of aspiration [7]. After a stroke, water inhalation may cause choking and coughing. A nasogastric tube can lead to reflux or aspiration pneumonia. Frequent replacements can harm the nasal passage and pharynx, impacting physical and mental well-being, as well as quality of life. Failing to remove the tube with proper swallowing training increases the risk of pneumonia and mortality [8].

Adjustments to food textures, modifications in positioning, and the implementation of rehabilitative and compensatory strategies have been developed to enhance swallowing efficiency and diminish the likelihood of complications in individuals with dysphagia [9]. Research results indicated that hyoid and laryngeal movements significantly contribute to swallowing function. A decrease in their range of motion increases the chance of aspiration and food retention in the pharynx. Swallowing training aids and rehabilitation exercises such as the Shaker exercise or Chin tuck against resistance (CTAR) have been proven effective for enhancing swallowing. In the Shaker exercise, patients lay on their backs and raise their heads to gaze at their feet. On the other hand, the

CTAR exercise involves sitting and gently tucking the chin against a compressible rubber ball during swallowing. These exercises are performed in rehabilitation [10–12].

Research has indicated the effectiveness of Sheck's or CTAR exercises enhances the strength of supraglottic and thyroglossal muscles in healthy adults and individuals with swallowing disorders [13,14]. Nevertheless, there is a dearth of localized research focused on stroke-related swallowing disorders primarily for cases in the ward. The auxiliary rubber ball's diameter for the CTAR exercise intervention measures approximately 12 cm [12]. Regrettably, the present study result lacked statistical data for depth pressure, which is essential to show the comparative advantages of pressure measurement.

2. Materials and Methods

A clinical trial with a randomized and prospective design, wherein eligible participants were randomly assigned to either the experimental group receiving the intervention using a swallowing rehabilitation balloon or the control group receiving standard dysphagia care. Employing double-blind conditions for both patients and evaluators.

2.1. Participants

Participants were recruited from home-based stroke patients residing in different regions of Taiwan. Inclusion and exclusion criteria were meticulously applied to ensure the homogeneity of the subject population. Inclusion criteria included confirmed stroke diagnosis, presence of swallowing difficulties, and willingness to participate. Exclusion criteria included severe cognitive impairment and inability to comply with the intervention protocol. Patients who met the inclusion criteria and none of the exclusion criteria were invited to participate in the research. They were delivered for information orally and in written form. They were informed about the random allocation in different study groups, each receiving distinct techniques suitable for their condition. The study's objective, to ascertain the most effective technique, was communicated. Patients did not provide their information to their assigned group. Participants were requested to consent to the experiment in a written form. The initial assessment was carried out by the same physiotherapist responsible for recruitment.

2.2. Sample Size Calculation

The necessary sample size was calculated for each outcome variable using a web-based tool (Granmo v7.12) provided by the Mar Institute of Medical Research Foundation (https://www.imim.es/ofertadeserveis/software-public/granmo/) for a two-tailed test. Considering that 95% of CTAR exercise participants in the control group reported brain injury with dysphagia at follow-up, compared to 70% in the intervention group, a sample of 35 participants per group was calculated at 80% power and 5% significance level. Therefore, we included 45 patients in each group as they were expected to discontinue during the 6-week study period. To understand the differences between the pre and post-test results, a one-way covariate analysis for two independent samples was conducted to know if there were differences among the participants, and their pressure was measured when swallowing the ball to monitor the changes in the average pressure.

2.3. Randomization Process

A list of numbers (ranging from 1 to 45) was generated before participant recruitment. Each of these numbers was allocated randomly to one of the two study groups using a computer program (www.random.org). Without any foreknowledge of the generated list, initial assessments were conducted on each enrolled by physiotherapists. The physiotherapist conducted the therapy for randomly selected patients. Given the manual nature of the techniques employed, this physiotherapist was unblinded and aware of the subject's group allocation by the assigned number but they remained unaware of the subject's assigned group.

2.4. Intervention

The CTAR exercise included static and dynamic methods. In the static method, continuous chin clenching of the ball was conducted by sitting up straight with shoulders tucked back, putting the swallowing ball under the chin, and clenching it in hands. The force inward on the chin (close to mouth) was exerted on the ball for 60 seconds without interruption and in the next 60 seconds, it was released. This was repeated three times. In the dynamic method, the chin clenching and releasing of the ball was repeated by sitting up straight with shoulders backed, putting the digital swallowing ball under the chin, and clenching in The chin was contracted inward close to the mouth to press the ball and release it. This motion was repeated 90 times. In this study, the pressure parameter of 1 psi was used as the ball pressure setting of the swallowing ball. The changes in pressure were recorded by 3 healthy adults after the introduction of CTAR exercise as shown in Table 1.

Table 1. Innovative digital swallowing ball pressure test (mmHg).

Testers	Pre-Test Pressure	During Test Pressure[1]	Post-Test Pressure
A	250	300	400
B	200	287	320
C	300	380	490

Note 1: One week after the continuous implementation of the CTAR exercise.

The swallowing balloon, a rubber device with an adjustable diameter and pressure, was developed for this study. The experimental group used the swallowing ball for exercise. The control group used ordinary swallowing balls (excluding isometric swallowing exercises). The intervention was conducted in three sessions per week for six weeks. Participants were guided through prescribed exercises using the balloon under the supervision of a trained therapist. The balloon was inflated to a predetermined pressure and gradually adjusted based on the participant's tolerance.

2.5. Innovative Digital Swallowing Ball Design For Pressure Measurement

We developed a digital swallowing pressure ball for the exercise. It had a flexible body, a pressure sensing unit, and a processing unit (Figs. 1 and 2). The body had a flexible shell, a vent, and a holding space. The flexible shell contained holding space and the vent on the periphery. The pressure sensor unit comprised a sensing body and a connecting tube. The connecting tube was connected to the sensing unit at one end and the vent at the other end. The user was trained for swallowing, which deformed the flexible body, and the pressure sensing unit detected and transmitted the pressure of the capacitated space to the processing unit. The processing unit processed the measured pressure. An LED was used to warn the user of abnormal pressures (Figs. 3 and 4). In addition to the Schott's hardness tester to confirm the original ball pressure of the swallowing test ball, the internal pressure of the swallowing was used to confirm that the swallowing ball maintained the same elasticity, softness, and hardness for consistent testing, and the measured pressure value was displayed on the electronic panel meter and stored in the training data (Fig. 5). We measured the ball pressure using the commercially available elastic ball and the developed swallowing ball by using Schott's hardness tester to confirm the accurate measurement. The pressure of the commercially available elastic ball at Schott's hardness of 18 was 1 psi. The pressure parameter was used for setting the pressure of the developed swallowing ball in this study.

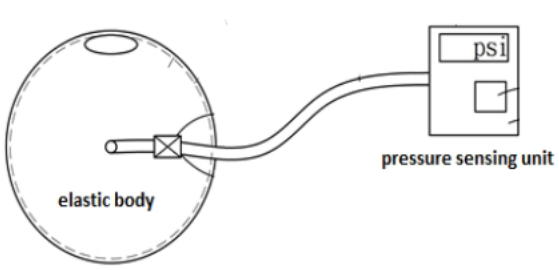

Fig. 1. Measuring pressure using developed ball.

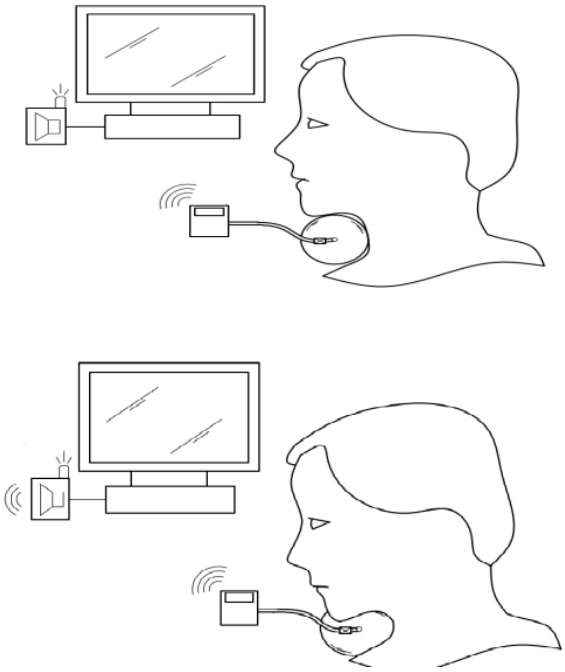

Fig. 2. Pressure ball measurement.

Fig. 3. CTAR exercise at normal pressure with blue LED light.

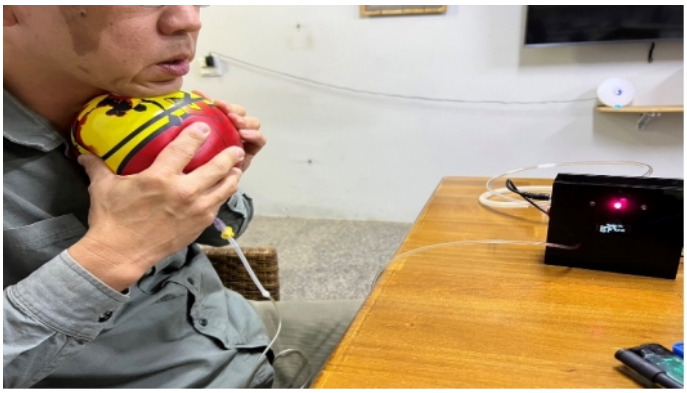

Fig. 4. CTAR exercise with excessive pressure with red LED light.

Fig. 5. Schott's hardness tester and electronic panel meter.

2.6. Study Tools

This study anticipated the collection and analysis of pre- and post-intervention data. The sEMG amplitude analysis was adopted for food intake/inhalation assessment with a related structured questionnaire. The questionnaire included personal information (including body weight), sEMG amplitude analysis results, food intake/inhalation assessment, swallowing quality of life questionnaire assessment, adherence and satisfaction, adherence to the intervention, and participant satisfaction. Follow-up interviews were conducted after a self-reported satisfaction questionnaire.

2.7. Statistical Analysis

Data were collected before the intervention for the baseline determination and after the six-week intervention. Descriptive statistics were obtained to summarize the demographic property. Upon completion of data collection for the entire sample, statistical analysis was executed with the SPSS Statistics® version 26.0 software package. The significance level was 0.05, and a confidence interval of 95% was established. The quantitative variables were assessed using the Kolmogorov-Smirnov test, augmented with Lilliefors corrections, to determine adherence to a normal distribution. Additionally, the preliminary homogeneity across groups was assessed using either two-way ANOVA or Kruskal-Wallis, contingent upon the normality of data distribution. Based on the outcomes of the homogeneity and normality assessments, parametric or non-parametric statistical methods were employed for within-group and between-group analysis. For within-group analysis, two-way ANOVA was utilized when initial homogeneity and normality were confirmed. When the data showed homogeneity but not normality, the Friedman test was employed. Alternatively, when initial homogeneity was lacking, a linear mixed model adjusted for baseline values was employed. Between-group results were examined using the two-way ANOVA with Bonferroni's post hoc analysis with homogeneity and normality. If homogeneity was present but not

normality, the Kruskal-Wallis test was employed. When initial homogeneity was lacking, a linear mixed model adjusted for baseline values was implemented. Paired t-tests or Wilcoxon signed-rank tests were employed to assess changes in swallowing function and quality of life scores. Qualitative data from adherence and satisfaction assessments were analyzed thematically. Furthermore, the intention-to-treat analysis was performed, too. In instances of follow-up attrition, any unrecorded outcome variables were imputed with the last recorded data for each respective variable by using the Last-Observation-Carried-Forward Analysis.

3. Result and Discussion

Stroke, a prevalent neurological disorder, often results in compromised swallowing function, thereby affecting patients' quality of life and nutritional intake. Executing the exercise with a swallowing rehabilitation ball is necessary but challenging. Thus, we developed a swallowing function by introducing a novel swallowing rehabilitation balloon. We used a randomized controlled trial design to ensure the reliability and efficacy. By randomizing stroke patients into the treatment and control groups, we compared the extent of swallowing function improvement. This approach mitigated selection bias and enabled a more precise assessment of the actual effects of the swallowing rehabilitation balloon. The experiment was conducted at patients' homes to reflect real-life situations. Undertaking swallowing rehabilitation was challenging when patients lived far from medical facilities, which brought the potential absence of professional medical oversight. In this case, patients were required to train autonomously. To evaluate the impact of the developed swallowing balloon, quantitative and qualitative data were collected. The data was analyzed to assess the balloon's efficacy in enhancing swallowing function and gauge patients' subjective experiences with the ball. The result assists healthcare professionals in better understanding the potential value of this innovative therapeutic approach. The exercise using the developed ball approach enhanced the swallowing function of stroke patients. Its effectiveness was proven by using a scientific methodology. By conducting a randomized controlled trial, the result offers more rehabilitation options for stroke patients to enhance their quality of life and rehabilitation journey.

4. Conclusions

By developing a swallowing rehabilitation balloon and assessing its efficacy for stroke patients, a randomized controlled trial was designed and the result was analyzed. The result provides an effective rehabilitation strategy and insights into how to improve the efficacy of the intervention. The experiment was conducted at the homes of the participants, which allowed a more holistic assessment of the intervention's viability in real-life scenarios and increased the applicability of the results in actual rehabilitation practices. Combining quantitative and qualitative methods, the effectiveness of the developed swallowing rehabilitation balloon's impact was validated. This multifaceted approach ensured a nuanced evaluation of functional improvements and patient experiences, providing well-defined results for healthcare practitioners and decision-makers. The result of this study reshapes the landscape of rehabilitation strategies for stroke patients and can be used to enhance their quality of life in their recovery process. By addressing a critical aspect of post-stroke challenges, a new way of neurorehabilitation for stroke patients was proposed for the elderly in general. The proven efficacy and practicality of the developed swallowing rehabilitation balloon fosters advancements in stroke care and rehabilitation practices. The study result contributes to stroke rehabilitation and the mitigation of dysphagia management. To enhance the quality of life for home-based stroke patients, more advanced ways of innovative interventions can be developed based on the study results.

5. Patent

Innovative Swallowing Rehabilitation Balloon was registered as a Invention Patent (Invention No. I823714) by the Intellectual Property Bureau of the Ministry of Economic Affairs. Date of approval: November 21, 2023. Main Inventors: Nai Ching Chen.

Author Contributions: Conceptualization, N.-C. Chen and Y.-R. Lin; methodology, N.-C. Chen; software, J.-Y. Weng; validation, J.-Y. Weng and Y.-L. Lee; formal analysis, Y. Chou; investigation, H.-Y. Chen; data curation, N.-C. Chen and Y.-R. Lin; writing—original draft preparation, N.-C. Chen; writing—review and editing, J.-R. Kuo. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data of this study are available from the corresponding author upon reasonable request.

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Conflicts of Interest: The authors declare no conflict of interest. We have no conflict of interest with the Toby Design & Development Co., Ltd.

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