Shirley Ryan AbilityLab

Improving swallowing outcomes in hospitalized post-stroke patients with dysphagia:

A novel skill-based intervention program using Mobili-T®

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A. INTRODUCTION

Stroke is the leading cause of swallowing disorders (i.e., dysphagia), accounting for more than 420,000 cases[1]. It is estimated that up to 80% of acute post-stroke patients have dysphagia[2]. Additionally, post-stroke dysphagia is associated with significant clinical complications, including aspiration pneumonia, malnutrition, and dehydration. Swallowing disorders and aspiration pneumonia contribute to an increased mortality rate and disability in this population[3,4]. Approaches to dysphagia rehabilitation that focus on muscle strengthening strategies are limited because they do not consider causes of swallowing deficits other than weakness. Timing and coordination of oral and pharyngeal structures also play a critical role in the swallowing process, including motor planning and execution of swallowing events. Better understanding of swallowing neural control has shifted the swallowing rehabilitation paradigm and introduced a new direction for dysphagia management, *skill-based training*[5]. Preliminary studies using skill-based swallowing treatments have shown improvements in swallowing physiology and function. <u>However, there is a paucity of protocols for skill-based swallowing treatment.</u>

At Shirley Ryan AbilityLab (SRAlab), the Dysphagia Committee frequently discusses clinical cases where patients present with swallowing impairments other than weakness, thus, showing poor outcomes following therapy. Moreover, SRAlab speech-language pathologists (SLPs) recently implemented the use a mobile surface electromyographic (sEMG) device (Mobili-T®) as an adjuvant to swallowing therapy to track swallowing performance (Figure 1). Using this device, they observed altered swallowing patterns in patients, such as delay in swallow initiation and discoordination of swallows. While SRAlab SLPs have attempted to incorporate motor learning approaches using this new device (e.g., by providing visual feedback of swallows), neither the device nor the swallowing treatment literature specifies training parameters (e.g., number of swallows, timing) to address these skill-based impairments. <u>Therefore, there is a critical need to develop swallowing interventions targeting timing and coordination of the swallow while incorporating clinicians' daily experiences into practice changes.</u>

Skill-based swallowing training interventions seek to modulate movement patterns, timing, and force during swallowing tasks by refining performance[5], consequently improving overall swallowing outcomes. Proponents of skill-based training in dysphagia literature have highlighted several parameters for necessary inclusion in future studies, such as (i) task specificity (e.g., swallowing varied bolus sizes and consistencies), (ii) task challenge (e.g., changing the time of swallow initiation and the force of swallow), and (iii) feedback of performance (e.g., the use of sEMG as a visual biofeedback tool)[6]. The effortful swallow (EFS) strategy is the most recommended dysphagia intervention[7-9]. It improves multiple swallowing components such as increasing tongue and pharyngeal pressures, hyoid bone and laryngeal movements, and suprahyoid muscle (muscles under the chin) strength[10-16]. Furthermore, the EFS is a swallowing-specific task involving swallowing hard while squeezing the tongue or throat muscles, it can be performed at different effort levels and times to challenge patient's performance, and its learning and execution are facilitated by sEMG[17,18]. Thus, the EFS is a good strategy for use in a skill-based intervention program, potentially improving coordination and timing of biomechanical swallowing events, pressure generation for swallowing efficiency, and muscle strength. This **quality study aims** to develop and implement a novel skill-based intervention program for post-stroke patients with swallowing disorders, expanding the use of a recently acquired device (Mobili-T®) in a new way, to improve patient care at SRAlab and analyze data to establish scientific evidence of the effectiveness of this intervention program.

Aim 1: Develop a skill-based intervention program using the EFS for hospitalized post-stroke patients with dysphagia. We will (i) develop a skill-based program using the EFS for hospital use, including the three essential components recommended by the literature (task specificity, task challenge, and feedback), and with specific goals to be achieved each session.

Aim 2: Implement the skill-based intervention program using the EFS in post-stroke patients with dysphagia. We will (i) implement the developed skill-based program using the EFS in post-stroke patients with dysphagia and (ii) compare swallowing outcomes between the new skill-based intervention and usual swallowing care.

B. Significance and Innovation

Although weakness is a crucial component of swallowing disorders, it is not always the cause of dysphagia. Swallowing deficits include altered movement of swallowing structures (e.g., tongue, hyoid bone, and larynx), timing and coordination of swallowing events, pressure generation during swallowing (e.g., mouth and pharynx), and muscle strength (e.g., oral and pharyngeal muscles)[5,19]. Usually, these impairments co-occur and impact swallowing efficiency and safety. The proposed quality project of a novel skill-based intervention program for dysphagia is significant and innovative, representing an advancement for dysphagia rehabilitation. This project uniquely draws on the clinical experience of SRAlab SLPs and their challenges with managing skill-based dysphagia impairments in neurologic populations. Furthermore, it will use an established sEMG device, the Mobili-T® that was recently acquired by SRAlab in a novel way to train parameters associated with timing and coordination in post-stroke patients. In 2022, SRAlab admitted 543 adult inpatients with stroke, and almost 70% of these patients were treated for swallowing disorders. Although many post-stroke survivors with swallowing disorders recover their swallowing function in the first few weeks, around 50% still have swallowing deficits after 6 months[20].

Persistent dysphagia is associated with long-term disability, institutionalization, and poor quality of life[20-22]. Our proposed quality study addresses physiological, functional, and perceived-functional outcomes in post-stroke dysphagia as currently used by the SLPs at SRAlab. Additionally, it will incorporate the Mobili-T® device for visual biofeedback to help measure task accuracy and performance during the intervention (Figure 1). During the implementation process of Mobili-T® at SRAlab, SLPs participated in training sessions about biofeedback and sEMG, and a group of five core clinicians was trained to initiate the use of Mobili-T® in therapy. Therefore, our skill-based intervention program will incorporate this new device and adapt and refine the use of Mobili-T® for skill-based training.

Figure 1: Mobili-T® system. (A) sEMG device and (B) biofeedback screen.
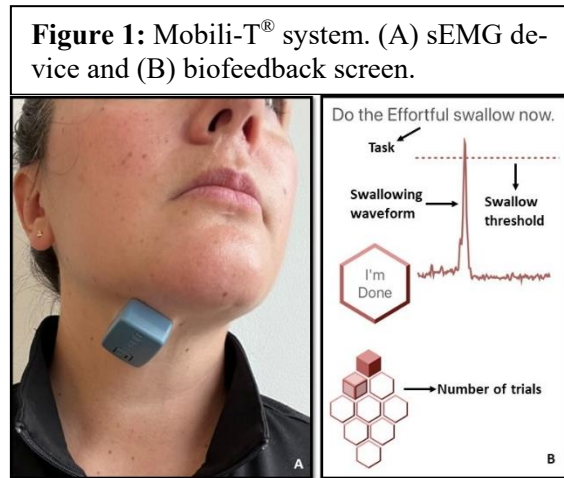
C. Methods

Plan: We will follow Steps 1-4 during the planning process. ***Step 1 – Development:*** The development phase will include (i) a critical review and analysis of the swallowing literature for existing skill-based programs and (ii) the design of the skill-based intervention program using the EFS ensuring task specificity, task challenge, and biofeedback, specific goals for each swallowing session (8 sessions total), and therapy materials. ***Step 2 – Feedback and Adaptation I:*** This phase will include (i) a presentation of the intervention program to the Dysphagia Committee at SRAlab for feedback and suggestions, (ii) adjustments to the intervention program, specific goals, and therapy materials, and (iii) discussion of potential candidates for using the intervention program (inclusion and exclusion criteria) considering patients characteristics such as swallowing impairments and cognitive abilities. ***Step 3 – Pre-implementation and Adaptation II:*** In this phase, we will (i) conduct a pilot test to assess the feasibility of the intervention program in post-stroke participants with dysphagia (n=2) and collect clinician's feedback, (ii) use single subject design to evaluate outcomes, including the Mann Assessment of Swallowing Ability (MASA)[23], the Functional Oral Intake Scale (FOIS)[24], the Modified Barium Swallowing Impairment Profile (MBSImP)[25], the Penetration-Aspiration Scale (PAS)[26], a visual analog scale (VAS), and the Eating Assessment Tool (EAT-10)[27]. Moreover, (iii) adaptations to the intervention program, specific goals, and therapy materials will be performed as needed. ***Step 4 – Implementation:*** This phase will be divided into two steps: (i) the investigators will develop the intervention program flowchart, including eligibility criteria, and (ii) the intervention program will be applied to 10 post-stroke patients with dysphagia. Additionally, 10 post-stroke patients with dysphagia receiving usual swallowing care will be a comparison group. Patients' SLPs at SRAlab will recommend the usual swallowing care appropriate for each patient. The final analysis will include pre- to post-intervention assessment using the same measurements in Step 3. Furthermore, we will compare the group receiving the new skill-based intervention program and the group receiving usual swallowing care.

Outcome measures: (i) swallowing physiology and function (MASA, FOIS, MBSImP, and PAS), (ii) patient-reported outcomes (VAS), and (iii) swallowing-related quality of life (EAT-10).

Anticipated Project Timeline

Tasks	0-3	3-6	6-9	9-12	12-18
IRB submission (exemption review)	x				
Steps 1 and 2	x	x			
Steps 3 and 4a		x	x		
Step 4b			x	x	
Data analysis				x	x
Dissemination of findings				x	x

Planned Deliverables

(1) Presentation to the Dysphagia Committee at SRAlab during their monthly meeting describing the expanded and novel use of the recently acquired device (Mobili-T®); (2) Training of all SLPs across levels of care in the use of this skill-based protocol; (3) Abstract submission for the Dysphagia Research Society Annual Meeting and the American Speech-Language-Hearing Association Convention; (4) Manuscript submission.

D. References

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