Lingual Endurance Exercise in Treating Post-Stroke Dysphagia

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Last Institutional Review Board Approval Date: 2/18/25

Study Protocol

All procedures and study team members were approved by University of Cincinnati Institutional Review Board (IRB# 2022-0218). A convenience sample of participants were recruited from word-of-mouth referrals (e.g. UC stroke team) and information flyers that were distributed locally throughout the community and at other institutions in the area. Participants were eligible to participate if they had a history of ischemic stroke, were 21 years of age or older, at least 3 months since initial ischemic stroke, and able to follow 2 step directions. Exclusion included any history of dysphagia prior to the ischemic stroke, if participant was pregnant, or had a history of temporomandibular joint disorders. Final eligibility for full protocol enrollment included at least one impaired oral component score according to the MBSImP (Modified Barium Swallow Impairment Profile). This was judged at time of initial visit in the fluoroscopy suite by an MBSImP trained speech language pathologist (SLP).

Study Visits

This study used a prospective quasi-experimental design, with pre-test and post-test measures. Study visits included an initial in-person baseline visit with patient reported outcome measures (Swallowing Quality of Life Questionnaire, SWAL-QoL, and Eating Assessment Tool, EAT-10) and a modified barium swallow study (MBSS) followed by 8-10 weeks of at home lingual exercise with use of the Tongueometer™ device. Weekly virtual visits completed with a license speech language pathologist. At the end of the 8-10 weeks participants came for an in person visit for post-treatment data collection. Participants were asked to complete lingual presses based on 75% repetitions at 50% of their maximum isotonic press. Participants were assigned to complete this task 3 times per day. Half of the participants were instructed to complete this task 2 times a day and once a day to do 10 effortful swallows with feedback from the device. Post-treatment data were collected at a final study visit where the same PROs were administered (SWAL-QoL, EAT-10) along with a post-treatment MBSS. Procedural details for study visits and exercises described below:

Modified Barium Swallow Study

A standard MBSImP protocol was utilized under videofluoroscopy using Varibar Barium products (Varibar® E-Z-EM, Inc. 40% w/v ratio. This includes 12 bolus trials including: thin (International Dysphagia Diet Standardization Initiative, IDDSI 0), mildly thick (IDDSI 2), moderately thick (IDDSI 3), and Varibar pudding (IDDSI 4+), and a solid (cookie) with 5ml Varibar pudding.

Lingual Pressure Measures

Two lingual manometers were used for data collection at the pretreatment and post treatment visits. Collected with the Iowa Oral Performance Instrument (IOPI), the following measures were recorded (in repetitions, time, or kP) in the anterior position: swallow pressure x3 (saliva swallow), effortful swallow x3 (swallow with focus on muscle contraction and tongue pressing to the roof of the mouth), maximum isotonic pressure (MIP) x3 (press as hard as able and release), isometric endurance (ISO-M) x1 (press and hold at 50% of the highest MIP). Posterior lingual measures with IOPI were measured: MIP x3, ISOM, isotonic endurance maximum (ISO-T) (press and release as many times until fatigued to reach 50% of posterior MIP) . The Tongueometer™ device, was sent home with the participants for their at home exercise. To determine lingual exercise, baseline Tongueometer™ measurement included anterior ISO-T. Participant were prescribed 75% anterior lingual presses at 50% of

their max MIP. For example: if patients' max MIP was 50 kPa and max ISO-T was 100 presses. Participant would be asked to complete 75 presses with force at least 25 kPa.

Adherence Monitoring

Tongueometer™ device allows for virtual reports of adherence data and exercise parameters (pressure settings) to be sent securely to study team. Participants met with SLP virtually every week. Every two weeks participants Max MIP x3 and new ISO-T was measured updated number or repetitions, and max press was provided.

MBSS Data Analysis

Each pre and post MBS was rated by two license speech language pathologist for MBSImP, , and pixel based and timing measures following the Analysis of Swallowing Events, Physiology, and Timing (ASPEKT) method. If discrepancies were noted, they were resolved during consensus meetings.

Statistical analysis

Descriptive statistics were calculated on all variables. Frequencies and percentages are reported for categorical variables. The normality of continuous variable distributions were assessed using histograms and box plots. For normally distributed continuous variables, means and standard deviations are reported, while . medians and interquartile ranges are provided for non-normally distributed continuous variables.

To examine treatment effects, differences in baseline measures from pre-treatment to post treatment were calculated, including EAT-10 scores; IOPI measures: average swallow pressure (kPa) over 3 trials, maximum effortful pressure (kPa) over 3 trials, maximum anterior max strength (kPa) over 3 trials, anterior isometric endurance max (seconds), and maximum anterior isotonic endurance (reps); maximum posterior strength (kPa) over 3 trials, posterior isometric endurance max (seconds), posterior isotonic endurance max (reps); MBSImP Oral Total scores, MBSImP Pharyngeal Total scores; and Swallowing Quality of Life questionnaire scores (SWAL-QOL), including overall total score, eating duration, food selection, fear, and fatigue; and ASPEKT measures, including Swallow reaction time, Pharyngeal swallow duration, UES opening, Laryngeal vestibular closure reaction time, Laryngeal vestibular closure duration, Pre-swallow residue, Vallecular residue, Pyriform sinus residue, Other residue, Pharyngeal area at max constriction, Maximum opening of UES, and Peak hyoid movement.

Linear regression models were used to examine differences in baseline measures from pre-treatment to post treatment. Treatment group (Endurance only vs Endurance plus transference) and baseline measures were included as covariates. Models were evaluated for parsimony. Treatment group effects that were not statistically significant were eliminated from the model and re-evaluated. Residuals were examined to assess model fit. Bowker's test of symmetry was used to test for differences in PAS score category and FOIS from pre- to post-treatment. Cohen's d was used to calculate effect sizes. Statistical significance was determined at p-values less than 0.05. All analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).