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A Randomized Trial Comparing Two Tongue-Pressure Resistance Training Protocols for Post-Stroke Dysphagia

Catriona M. Steele, Ph.D.[1,2], **Mark T. Bayley, M.D., FRCPC**[1,2], **Melanie Peladeau-Pigeon, M.H.Sc.**[1], **Ahmed Nagy, MB, BCh, MSc, MD**[1,3], **Ashwini M. Namasivayam, M.H.Sc.**[1,2], **Shauna L. Stokely, M.H.Sc.**[1], and **Talia Wolkin, M.H.Sc.**[1]

[1] Toronto Rehabilitation Institute – University Health Network

[2] University of Toronto

[3] University of Fayoum

Abstract

The objective of this study was to compare the outcomes of two tongue resistance training protocols. One protocol ("Tongue-Pressure Profile Training") emphasized the pressure-timing patterns that are typically seen in healthy swallows by focusing on gradual pressure release and saliva swallowing tasks. The second protocol ("Tongue-Pressure Strength and Accuracy Training") emphasized strength and accuracy in tongue-palate pressure generation and did not include swallowing tasks. A prospective, randomized, parallel allocation trial was conducted. Of 26 participants who were screened for eligibility, 14 received up to 24 sessions of treatment. Outcome measures of posterior tongue strength, oral bolus control, penetration-aspiration and vallecular residue were made based on videofluoroscopy analysis by blinded raters. Complete data were available for 11 participants. Significant improvements were seen in tongue strength and post-swallow vallecular residue with thin liquids, regardless of treatment condition. Stage Transition Duration (a measure of the duration of bolus presence in the pharynx prior to swallow initiation, which had been chosen to capture impairments in oral bolus control) showed no significant differences. Similarly, significant improvements were not seen in median scores on the Penetration-Aspiration Scale. This trial suggests that tongue strength can be improved with resistance training for individuals with tongue weakness following stroke. We conclude that improved penetration-aspiration does not necessarily accompany improvements in tongue strength, however tongue-pressure resistance training does appear to be effective for reducing thin liquid vallecular residue.

Correspondence: Catriona M. Steele, Ph.D., Swallowing Rehabilitation Research Laboratory, Toronto Rehabilitation Institute – University Health Network, 550 University Avenue, 12th floor, Toronto, ON, Canada, M5G 2A2, Tel: +1 416 597 3422 X 7803, Fax: +1 416 597 7131, Catriona.steele@uhn.ca.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

Keywords

Deglutition; Deglutition disorders; Dysphagia; Rehabilitation; Tongue

The ability to swallow food and liquid is something that most people take for granted; however, studies show that approximately half of stroke survivors experience dysphagia (swallowing impairment)[1, 2]. Dysphagia involves two primary concerns: a) the ability to swallow *safely*, without aspirating material into the respiratory system; and b) the ability to swallow *efficiently*, without leaving residual material behind in the pockets of the pharynx (i.e., the valleculae and pyriform sinuses) [3]. The most common intervention for dysphagia is to eliminate problematic food or liquid items from the diet (those that are likely to be aspirated or leave residue) [4-6]. In addition to recommending diet texture, clinicians who work with dysphagia may prescribe exercises to address underlying weakness or discoordination in the swallowing musculature [7]. Among the muscles that can be targeted by exercise are those of the tongue, which plays a major role in bolus formation, control and propulsion in swallowing [8]. Several studies show that tongue strength declines in healthy aging [9-14] and reduced tongue strength, (i.e., maximum isometric pressures under 40 kPa), has been identified as a risk factor for aspiration [15, 16]. In 2005, Robbins and colleagues introduced tongue-pressure resistance training as an exercise based approach to improve tongue strength [17]. This treatment involves repeated compression of a pressure sensor between the tongue and palate; resistance varies depending on the effort used to squeeze the sensor against the stable hard palate. Robbins et al. successfully demonstrated increased tongue strength after 8 weeks of isometric tongue-palate pressure practice, performed on alternate days of the week, with goals set in the 60-80% of maximum range and 60 repetitions of the task on each day of exercise. Gains in tongue strength were achieved both by healthy seniors and in a case series of 10 individuals with dysphagia post stroke [17, 18]. The stroke cohort also demonstrated improved swallowing safety at the end of treatment [18].

When swallowing, healthy people are reported to use 50% or less of their maximum isometric pressure range [10-12]. Although maximum isometric pressures (MIPs) decline with age, swallowing pressures are preserved [19]. This begs the question whether increasing tongue strength is an optimal treatment goal for tongue-pressure resistance training programs? In the limb rehabilitation literature, it is argued that skill training can achieve similar or superior outcomes to strength training [20, 21]. On this basis, Steele et al. [22, 23] designed a tongue-pressure resistance training protocol known as *Tongue-Pressure Strength and Accuracy Training* (TPSAT), in which the treatment tasks were equally divided between strength targets (i.e., exceeding an 80% of MIP threshold) and accuracy targets (i.e., hitting specific pressure targets as closely as possible, with target pressures randomly chosen between 25 and 85% of the patient's MIP range). They argued that the ability to generate variable target pressures might more closely replicate the mealtime challenge of matching swallowing pressures to the flow properties of boluses with different viscosities [23, 24]. When used in a small case series of 6 patients with dysphagia following acquired brain injury [23], the TPSAT protocol achieved comparable strength gains to those reported for stroke patients in the strength-focused protocol developed by Robbins et al. [18]. These

patients also demonstrated improvements in penetration-aspiration at the post-treatment assessment.

Tongue strength is commonly assumed to be important both for oral bolus control and for effective bolus propulsion through the pharynx, without leaving residue behind in the valleculae [25]. Stage transition duration (also known as “swallow response time” [26] or “pharyngeal bolus dwell time” [27]) is a videofluoroscopic measure of the time interval between the bolus passing the shadow of the ramus of mandible and the onset of hyolaryngeal excursion for a swallow [28]. Expected values for stage transition duration in healthy swallowing typically fall under 350 ms across several studies [29-31]. It is not uncommon to see prolonged stage transition duration in healthy older adults [32] or in people with dysphagia [27, 33]; in these cases, the mechanism of impairment may involve either a sensory deficit (i.e., delayed initiation of the swallow), and/or a failure of oral bolus containment leading to premature spillage of liquids into the pharynx [16, 34]. In the latter case, it seems reasonable to propose that the ability to control a liquid bolus in the mouth might respond positively to lingual resistance training.

A previous study of healthy tongue-pressure generation patterns during swallowing has shown that the duration of tongue-pressure release is modulated when swallowing boluses of different consistency [24, 36]. Specifically, healthy adults display a significantly more gradual release of posterior tongue pressure with thin liquids compared to nectar-thick liquids. The authors of that study speculated that this gradual pressure release might reflect more active control of thin liquid flow during transfer to the pharynx. For the current study, we developed a novel tongue-pressure resistance training protocol, *Tongue-Pressure Profile Training* (TPPT), designed to emphasize a controlled release of posterior tongue pressure. Additionally, in contrast to the TPSAT protocol, the *Tongue-Pressure Profile Training* (TPPT) protocol was intended to optimize treatment specificity by including real swallows rather than pressure generation tasks in isolation. Half of the 60 tasks in each TPPT treatment session involve saliva swallows (either regular effort or effortful), and the session concludes with an additional generalization set of 5 bolus swallows with nectar-thick liquid. (The TPSAT protocol does not include any saliva swallows, but focuses exclusively on isometric tongue-palate pressures). All tasks in the TPPT protocol include instruction regarding the timing of pressure release. In the TPPT protocol, patients were instructed to perform either a tongue-pressure or swallowing task, and then to release tongue-palate pressure gradually, with the analogy that the pressure release should involve a slow, downward “hill” as opposed to a rapid, sheer “cliff”. This emphasis on pressure release also dictated that the bulb was located in a posterior position for all TPPT tasks. This placement will be described below in the methods section.

The current study was an exploratory randomized controlled trial comparing swallowing outcomes for stroke patients completing two contrasting tongue-pressure resistance training protocols (TPSAT and *Tongue Pressure Profile Training*). It should be emphasized that both of these protocols differ from the strength-training protocol previously described by Robbins et al. [17,18]. Additionally, it should be noted that the measures reported for this study focus on posterior tongue-palate pressures. In general, regardless of protocol, we hypothesized that tongue-pressure resistance training would lead to:

a) improved tongue strength on maximum isometric pressure generation tasks, consistent with previous studies [17, 18, 23];

b) improvements in bolus control, reflected by shorter stage transition duration with thin liquids;

c) improved swallowing safety, as measured by the Penetration-Aspiration Scale [35] and consistent with previous studies [18]; and

d) reduced post-swallow residue in the valleculae.

With respect to comparison of the two protocols, we hypothesized that the emphasis on controlled posterior tongue pressure release in the TPPT protocol would lead to superior improvements in measures capturing oral bolus control (i.e., stage transition duration) compared to the TPSAT approach.

Methods

Trial Design

The trial protocol has been previously published [37] and was approved by the local institutional research ethics board. The study involved prospective randomized parallel assignment of participants in an equal ratio to the experimental TPPT treatment arm or the comparison TPSAT treatment arm. A randomization scheme was generated for the first 20 participants at the outset of the study, with assignment printed and stored in sequentially numbered sealed envelopes until consent was obtained. The plan was to use the same assignment sequence for each block of 20 participants. Due to slow accrual, after completion of the first 9 participants, the randomization sequence was adjusted to ensure balanced assignment to the two treatment arms for each block of 6 consecutively enrolled participants. The new randomization schedule was generated and stored in a password-protected .pdf file that could be accessed only by the study coordinator to determine consecutive participant assignment after obtaining signed consent.

Sample Size

The study was originally designed to recruit a sample of 60 participants (30 per treatment arm). This sample size was powered to detect group differences in the frequency of improved stage transition duration using a binary categorization (i.e., above vs. below < 350 ms [29-31]). The previous study of TPSAT by Steele et al. [23] showed a 30% improvement rate for this binary classification of stage transition duration. This study was powered with the expectation that the TPPT protocol would yield greater improvement (66%) in this parameter.

Participants

The study was initiated at 3 stroke rehabilitation centers in Ontario, Canada. Ultimately, two of these sites were closed due to poor enrollment. As shown in the CONSORT flow chart in Figure 1, 26 adults consented to baseline testing to confirm eligibility to participate in the study. The inclusion criteria required:

- History of a recent stroke (4 to 20 weeks prior to enrollment) resulting in the new onset of swallowing difficulties;
- A one repetition maximum posterior maximum isometric tongue-palate pressure measure < 40 kPa at the intake appointment; and
- Stage transition duration of > 350 ms on at least one thin liquid barium swallow during the intake videofluoroscopy.

Individuals who displayed severe dysphagia with no functional opening of the upper esophageal sphincter were excluded. Additionally, individuals with pre-existing dysphagia or known diagnoses of head and neck cancer were excluded.

Instrumentation

The Iowa Oral Performance Instrument (IOPI) (www.iopimedical.com) was used both for tongue-pressure measurement and for monitoring tongue-pressure values during treatment sessions. The IOPI is a handheld manometry device, with a ½ teaspoon sized air-filled bulb, which is placed on the upper surface of the tongue [17]. Anterior placement means that the flat front end of the bulb is positioned just behind the teeth. Posterior placement involves aligning the flat front end of the bulb with the anterior edge of the first molar tooth [38]. When compressed, the amount of displaced air is registered in kilopascals on the device monitor. In order to provide visual biofeedback during treatment sessions for this study, the pressure signal was exported from the data out port on the device, and displayed as a waveform on a computer screen (see Figure 2). Visual biofeedback was provided to all participants in this manner, regardless of treatment arm.

Interventions

Participants were scheduled to receive 24 sessions of tongue-pressure resistance training (either the TPPT or TPSAT protocol), delivered 2 to 3 times weekly over 8 to 12 weeks. Each treatment session was conducted in the clinic under direct supervision by a licensed S-LP and involved 60 tongue-pressure tasks. There was no home practice involved between treatment sessions. Figure 3 illustrates the tasks involved in the two treatment protocols. Post-treatment tongue-strength measures were taken as the average of the first 3 posterior tongue-strength tasks measured during the final treatment session. A videofluoroscopy was then repeated using the same methods performed at baseline to derive the trial outcome measures.

Outcome Measures

The following outcome measures were monitored in this study:

a) Tongue Strength—Tongue strength was measured using a posterior maximum isometric tongue-palate pressure task. We chose to focus on the posterior tongue given previous evidence that MIP measures at this location tend to be lower than those collected in an anterior location, yet swallowing pressures at this location involve a greater percentage of MIP range [38]. This has been interpreted to suggest a greater role of posterior tongue-pressure generation in bolus propulsion. The highest pressure value obtained over the first 3

repetitions (also known as the 1-repetition maximum [17]) was recorded in kilopascals. This measure was taken at baseline and at the beginning of the final treatment session.

b) Swallowing Outcomes—Swallowing outcomes were measured at baseline and post-treatment using a standardized videofluoroscopic swallowing study involving 3 teaspoon-sized boluses of 20% w/v thin liquid barium. Additionally, 3 teaspoons of 20% w/v nectar-thick barium were included based on evidence that thicker consistencies are more likely to cause residue [39]. The thin stimulus was prepared using Bracco EZ-Paque™ powdered barium and water. The nectar-thick stimulus was prepared in the same way with the addition of a xanthan-gum thickening powder (Nestlé Resource® ThickenUp® Clear).

The videofluoroscopy recordings were spliced into short video clips, each containing the swallowing events for a single bolus. These recordings were relabelled with random numbers and assigned to blinded raters for analysis. All raters were licensed speech-language pathologists (S-LPs) previously trained to a high level of agreement on a set of training videofluoroscopies. For inter-rater reliability, 25% of the dataset was rated in duplicate. The following measures were extracted from the videofluoroscopy rating:

i. Stage Transition Duration on Thin Liquid Swallows: For each thin liquid bolus, the rater identified the first video frame where the head of the bolus was positioned below the shadow of the ramus of the mandible, and the first video frame of the hyoid burst movement associated with a swallow. The time difference between these two frames was calculated in milliseconds as the measure of stage transition duration. Inter-rater agreement for selection of the frames required to calculate stage transition duration was excellent, with an intra-class correlation (ICC) of 0.97 (95% CI: 0.96 to 0.98).

ii. Penetration-Aspiration: For each videofluoroscopy clip, the raters recorded the severity of airway invasion using the 8-point Penetration-Aspiration Scale [35]. Inter-rater agreement for penetration-aspiration scale scores was excellent (ICC: 0.89, 95% CI: 0.8 to 0.94).

iii. Vallecular Residue: In order to measure residue, raters first identified the frame of "swallow rest" corresponding to the end of the swallowing events for each bolus. This frame was then used for the measurement of residue in the valleculae using the Normalized Residue Rating Scale (NRRS) [40]. This method involves tracing the pixel-area of residue, as well as the area of the available space housing the residue. These measures are then entered into an equation, which incorporates an anatomical scaling factor to correct for differences in participant height, derived from a measurement of the length of the cervical spine. Intra-class correlations for NRRSv measures showed excellent inter-rater agreement (ICC: 0.98, 95% CI: 0.97 to 0.99).

Statistical Methods

All statistical analyses were run in SPSS 23.0 using an alpha-criterion of $p<0.05$. An intent-to-treat analysis approach was used for all tests, including baseline data for three participants who were lost to follow-up. Group differences in continuous parameters (tongue strength, stage transition duration and NRRSv scores) were analyzed using fully factorial linear mixed-model repeated measures ANOVAs with between-participant factors of protocol

(TPPT vs. TPSAT) and a repeated factor of time-point (pre- vs. post-treatment). An additional factor of age-group (under vs. over 80) was included in the analysis of tongue strength given previous literature reporting reduced MIPs for healthy adults over age 80 [9-14]. A compound symmetry covariance structure was used with Sidak tests for pairwise comparisons. For swallowing measures, the analyses were run separately for the thin and nectar-thick consistencies. Significant effects were further explored with post-hoc analyses of effect size using Cohen's *d*, which can be interpreted as showing a small effect size for values of <0.5, medium effect size for values of 0.5-0.8 and large effect size for values >0.8 [41, 42]. For the ordinal Penetration-Aspiration Scale score data, non-parametric Friedman's two-way ANOVAs for repeated samples by rank were performed, comparing pre and post-treatment scores for each treatment arm and for the entire pooled dataset.

Results

Participants

The trial ran from December, 2011 to July, 2015 and was then discontinued due to the end of funding. A consort flow chart describing participant flow through the study is shown in Figure 1. Of the 26 individuals who completed intake screening, 12 failed to meet the specified eligibility criteria. Of these, 10 individuals failed to meet the criterion of prolonged stage transition durations on thin liquid swallows. One individual was excluded due to history of tongue base cancer treated with radiation and one due to changes in cognition that hindered his ability to understand and follow study instructons. Fourteen individuals (9 male, 5 female) were accepted into the study and randomized to receive either the TPPT or TPSAT protocol. Table 1 provides demographic details regarding these participants, who had a mean age of 71 years (range 49-89) and were enrolled an average of 70 days following the stroke that resulted in the onset of dysphagia (range 18-150 days). The two treatment arms (each comprising 7 participants) did not differ significantly with respect to participant age or time-post-stroke ($p>0.05$). Three participants discontinued the study early without completing a post-treatment videofluoroscopy. Two were discharged from inpatient rehabilitation to the community and were unable to arrange transportation to attend further appointments. The third individual was withdrawn due to a further stroke. Therefore, at the end of the study, complete data (including pre- and post-treatment tongue-pressure measurements and videofluoroscopies) were available for 11 participants (4 female, 7 male). The number of treatment sessions completed by these participants ranged from 6-24 (mean: 16 sessions, 95% CI: 12-19). There were no statistically significant differences between the two treatment groups with respect to the number of treatment sessions completed ($p>0.05$).

Treatment Outcomes

1. Tongue Strength—For the 14 individuals enrolled in the study, baseline measures of maximum isometric posterior tongue-palate pressure (i.e., 1-repetition maximum taken over a sample of 3 repetitions) had a mean value of 21 kilopascals (95% confidence interval: 16-26 kPa). Post-treatment measures for the entire sample increased significantly to mean values of 41 kPa (95%CI: 35-46 kPa); [$F(1,9.01) = 53.09$, $p < 0.001$; Cohen's $d = 1.15$ (large)]. An overall significant main effect of protocol was also found [$F(1,11.33) = 10.4$, $p = 0.08$; Cohen's $d = 1.64$ (large)], reflecting the fact that pressures were lower for the

participants randomized to the TPPT group at both timepoints. Figure 4 illustrates this difference. In addition to these main effects, a significant protocol X age-group interaction was seen [$F(1,11.33) = 13.15$, $p = 0.04$], capturing the fact that participants over age 80 in the TPPT group had the lowest tongue-pressure measures. Post-hoc investigations of change in tongue-pressure showed average increases of 19 kPa in the TPSAT group (95% CI: 8-29) and 20 kPa in the TPPT group (95% CI: 12-28). There were no significant differences in the magnitude of change between treatment groups and no protocol X age-group interactions. When post-treatment tongue-pressure measures were expressed as a percent of baseline measures, the degree of increase averaged 119% (95% CI: 131-308%) and again did not differ significantly between treatment groups.

2. Stage Transition Duration on Thin Liquids—Overall, the 14 participants enrolled in this study had a mean stage transition duration of 2087 ms for 5 ml thin liquid swallows at baseline (95% confidence interval: 1014 ms to 3160 ms). For those who completed an outcome videofluoroscopy, stage transition duration dropped to a mean value of 854 ms (95% CI: −361 ms to 2070 ms). This reduction failed to achieve statistical significance (p=0.13) but did achieve a medium effect size (Cohen's $d = 0.67$). There were no significant differences between the two treatment groups. With respect to the number of participants who achieved post-treatment stage transition duration below the value of 350 ms (reported to be an upper threshold in healthy swallowing [29-31]), this was only true for 3 participants, with 2 in the TPSAT and 1 in the TPPT treatment arm.

3. Penetration-Aspiration—The median baseline score for penetration-aspiration of thin liquids for the 14 participants enrolled in the study was 3 on the 8-point Penetration-Aspiration Scale [35] (range: 1-8). Scores of 4 and 6 (i.e., penetration and aspiration with ejection) did not occur for any participant at any timepoint in this study. Post-treatment, mean PAS scores for thin liquids improved by 1 level (median: 2; range: 1 to 8). There were no significant differences post-treatment for either group, or across the entire pooled sample. For nectar-thick liquids, median baseline PAS scores for were 2 (range: 1 to 8). Post-treatment, median scores for nectar-thick liquids improved on average by one level on the PAS to 1 (range: 1-3). There were no significant differences for either group, or across the entire pooled sample.

4. Vallecular Residue (NRRSv)—Baseline scores for residue severity in the valleculae on thin liquids using the Normalized Residue Ratio Scale averaged 0.12 (95% CI: 0.05-0.20). Post-treatment, there was a reduction in NRRSv scores to an average of 0.06 (95% CI: 0.00 to 0.12) for thin liquids. This reduction was statistically significant [$F(1, 10.2 = 4.74$, $p = 0.05$; Cohen's $d = 0.58$ (medium)]. There were no significant differences between treatment groups. Pre-treatment measures of vallecular residue with nectar-thick liquids were worse than with thin liquids, with NRRSv scores averaging 0.34 (95% CI: 0.18-0.50). Post-treatment NRRSv scores for nectar-thick liquids declined to 0.22 (95% CI: 0.05-0.39). This reduction was not statistically significant, but had a medium effect size (Cohen's $d = 0.54$).

Discussion

This trial demonstrates that tongue-pressure resistance training can be used to improve tongue strength after stroke. This finding concurs with previous studies in healthy seniors, stroke patients and individuals with acquired brain injury [17, 18, 22, 23]. In this study, a similar magnitude of increased tongue strength was seen, regardless of the specific tasks included in the treatment protocol. Thus, the available evidence to date suggests that a variety of different tongue-pressure resistance training tasks can be used when there is a goal of building tongue strength. The average gain of 20 kPa seen for posterior tongue strength measures in this study was slightly smaller than the average increase of 24 kPa seen in the strength-focused study reported by Robbins [18]. Notably, the participants in our study began with posterior tongue strength measures that were markedly lower on average than those in the Robbins study [18] (i.e., 23 kPa vs 30 kPa).

This study failed to show significant improvements in stage transition duration after tongue-pressure resistance training. This finding suggests that stage transition duration is not sensitive to differences in tongue strength and challenges the idea that this parameter captures information about lingual bolus control. As previously mentioned, when stage transition duration exceeds 350 milliseconds, there are two plausible explanations: a) impaired sensation leading to delayed pharyngeal swallow initiation; and/or b) impaired lingual bolus control of the bolus, resulting in premature spill of the bolus into the pharynx. It is often challenging for clinicians to determine which of these mechanisms is occurring in a patient, and indeed, it is plausible that both can occur in the same patient. In this study, we found no systematic relationship between stage transition duration measures and tongue strength. Thus, it appears that in applying an inclusion criterion based on stage transition duration, we may have chosen to focus on a parameter that turns out not to be sensitive to the impact of tongue-pressure resistance training.

Unfortunately, in this study, improvements in tongue strength were not accompanied by significant improvements in swallowing safety with thin liquids or nectar-thick liquids, as measured by the 8-point Penetration Aspiration Scale [35]. This finding differs from that previously reported by Robbins et al. [18]. One difference, which may partially explain the difference in results, is the fact that the baseline swallowing safety of the participants in the Robbins study appears to have been more severe than in our study. Although descriptive statistics are not reported in their paper [18], a figure suggests a baseline mean of 6 on the PAS, with a wide confidence interval, compared to the median score of 3 in our study. In our study, the decision to base inclusion on thin liquid stage transition duration measures translated to fewer participants with PAS scores ≥ 3 at baseline. Of the 11 participants with complete pre- and post-treatment data, 5 displayed thin liquid PAS scores of concern at baseline; 2 of these individuals showed PAS scores in the normal range (i.e., scores of 1 or 2) post-treatment. For nectar-thick liquids 2 showed PAS scores ≥ 3 at baseline, and in both cases, PAS scores improved to 2 or 1 at the post-treatment videofluoroscopy. It must be noted that the small sample size in this study may also have been a reason for the lack of evidence regarding improved penetation-aspiration. It may be that with a larger sample size, differences in airway invasion related to changes in tongue strength would be observed. Nevertheless, the findings of our study point to two important conclusions: 1) not all stroke

patients with tongue weakness display aspiration of thin liquids during videofluoroscopy; and 2) improvements in tongue strength do not necessarily translate to improved penetration-aspiration. With respect to vallecular residue, previous studies have used 3- or 4-point ordinal measures for rating residue severity and have failed to demonstrate convincing improvements as an outcome of tongue-pressure resistance training [18, 23]. In this study, a new continuous measurement scale was used (the NRRSv) and a significant post-treatment reduction in thin liquid vallecular residue was demonstrated. It is particularly encouraging to note that average post-treatment scores for thin-liquid residue fell below the NRRSv threshold of 0.09, which has been reported to demarcate risk for subsequent aspiration of residue [43].

Limitations

There are several important limitations to note regarding this study. The first is the fact that the sample size was small, and fell substantially below the targeted sample size of 60. Barriers to recruitment included a smaller than expected cohort of stroke patients with dysphagia to draw from, and the fact that two of the original study sites did not have on-site access to videofluoroscopy in order to confirm eligibility. The lack of access to videofluoroscopy meant that the clinicians in these sites found the effort involved in arranging an intake assessment at another hospital to be prohibitive. Additionally, not all participants who were enrolled completed the full course of 24 treatment sessions, with 3 participants unable to attend the post-treatment data collection session. Our sample size calculation was based on expected frequencies of improved stage transition duration. The data failed to follow the hypothesized pattern for this parameter, and only 3 participants overall displayed post-treatment stage transition measures under 350 ms. These considerations suggest that the study may simply have been inadequately powered to reveal main effects of treatment, either overall or between the treatment groups. Given this caveat, the significant differences observed in the form of improved tongue strength and vallecular residue scores are particularly encouraging.

It must also be noted, that like previous studies of tongue-pressure resistance training, this study lacked a no-treatment control group. The participants in this study were at least 18 days post stroke at the time of enrollment, and might therefore reasonably be considered to be beyond the period of immediate post-stroke spontaneous recovery [44]. Nevertheless, we cannot rule out the possibility that the improvements seen in participants in this study were, to some extent, related to spontaneous recovery rather than the experimental interventions. A third limitation that must be pointed out has to do with the choice to use prolonged stage transition duration as an inclusion criterion. Not all of the participants enrolled had similar swallowing impairment profiles, despite being similar with respect to this inclusion criterion. Thus, a limited number of participants displayed unsafe swallows on thin liquids at baseline, and had opportunity to improve on this parameter. As discussed above, the data point to the possibility that prolonged stage transition duration in this study cohort may have been more indicative of sensory deficits than of poor lingual bolus control.

Conclusions

The results of this study have implications for future research on tongue-pressure resistance training as an intervention for dysphagia. Our results suggest that stage transition duration measures are not sensitive to the impact of improvements in tongue strength. Our study raises questions about the degree to which impaired lingual bolus control can be teased out as a factor contributing to prolonged stage transition duration, as opposed to delays in the initiation of the pharyngeal phase of the swallow. Our recommendation, based on the current study, is that future investigations of the effects of tongue-pressure resistance training should focus on individuals displaying the combination of reduced tongue strength and impaired swallowing safety.

Secondly, our study contributes evidence to a growing number of studies showing that improvements in tongue strength can be achieved using a variety of different tasks in therapy. Current evidence suggests that normative pressures in older adults on maximum isometric tasks are in the range of 40 kPa or higher [9, 12-16]. On this basis, we suggest that regardless of the specific treatment tasks used, future studies should begin by clearly articulating a treatment goal that will serve as an operational definition of improved tongue strength, such as surpassing a fixed threshold of 40 kPa or achieving a minimum magnitude of increase in tongue strength (e.g., doubling). It would be of great interest to measure changes in swallowing function at the point when the patient achieves this predefined tongue strength goal, rather than measuring swallowing function after a fixed number of treatment sessions..

The heterogeneity in swallowing impairment profiles seen in this study reflects a reality in dysphagia pathophysiology that poses a significant challenge for trials research. Although ideal from a conceptual perspective, it is unlikely to be feasible to recruit sufficient numbers of participants with reduced tongue strength who show either impaired swallowing safety or vallecular residue in isolation. One possible solution to this dilemma would be to focus on participants with impaired swallowing safety, involving penetration-aspiration before laryngeal vestibule closure. This group would presumably be different from those with late penetration-aspiration (i.e., after closure of the laryngeal vestibule closure) for whom post-swallow residue would be the most plausible pathophysiological mechanism contributing to impaired swallowing. Certainly, clarity regarding pathophysiology and the impact of tongue strength on these different mechanisms is something to strive for in future studies.

Finally, although underpowered, this study adds to a small existing body of literature demonstrating that reduced tongue strength is a concern in stroke survivors, which can be remedied with resistance exercise. This study suggests that in some (but not all) individuals, improvements in swallowing safety and/or efficiency are seen in conjunction with improved tongue strength. The lack of a no-treatment control group in this study, as well as in former studies of tongue-pressure resistance training, leaves doubt regarding the degree to which these improvements can be attributed to the effects of treatment versus spontaneous recovery. A strong recommendation arising from this research is the need for future studies to involve a proper no-treatment control group.

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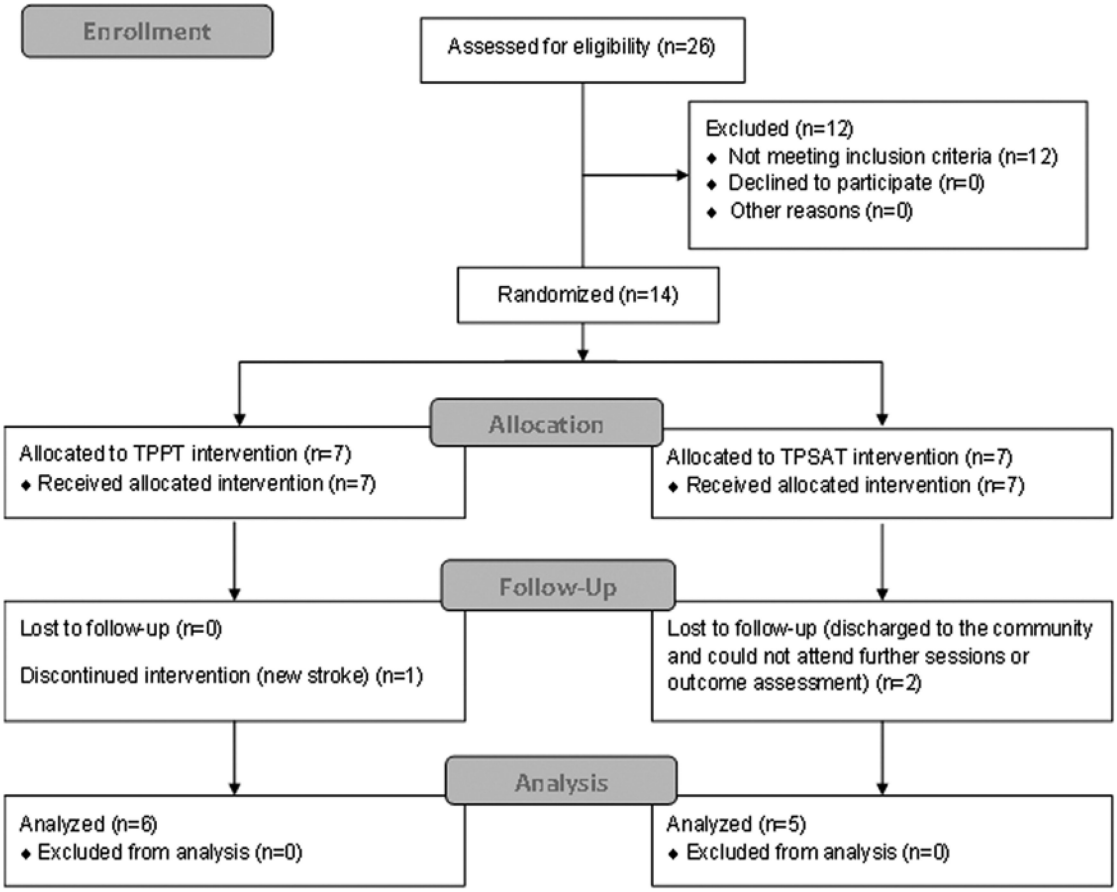

Figure 1.
CONSORT diagram of participant flow through the study.

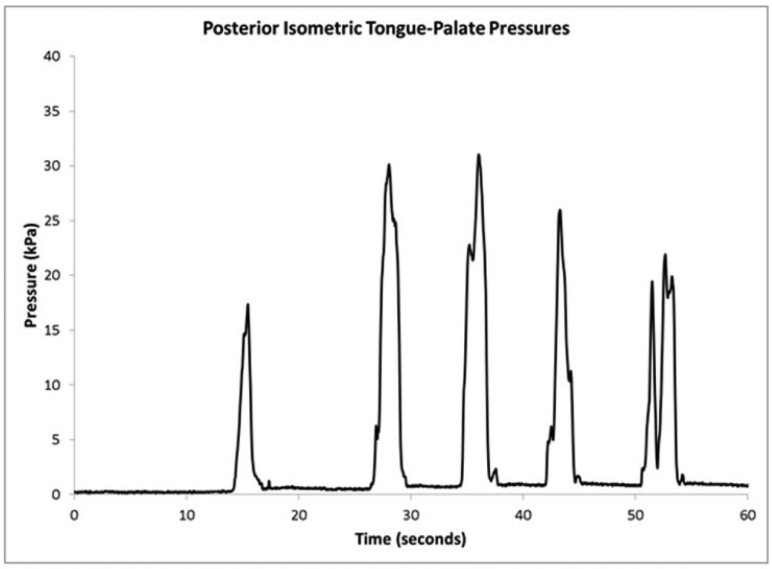

Figure 2.

An example of a tongue-pressure waveform collected by the Iowa Oral Performance Instrument during a series of 5 maximum isometric tongue-palate pressure tasks, with the bulb in the posterior position. In the study, participants were able to view waveforms like this on a computer screen for visual biofeedback.

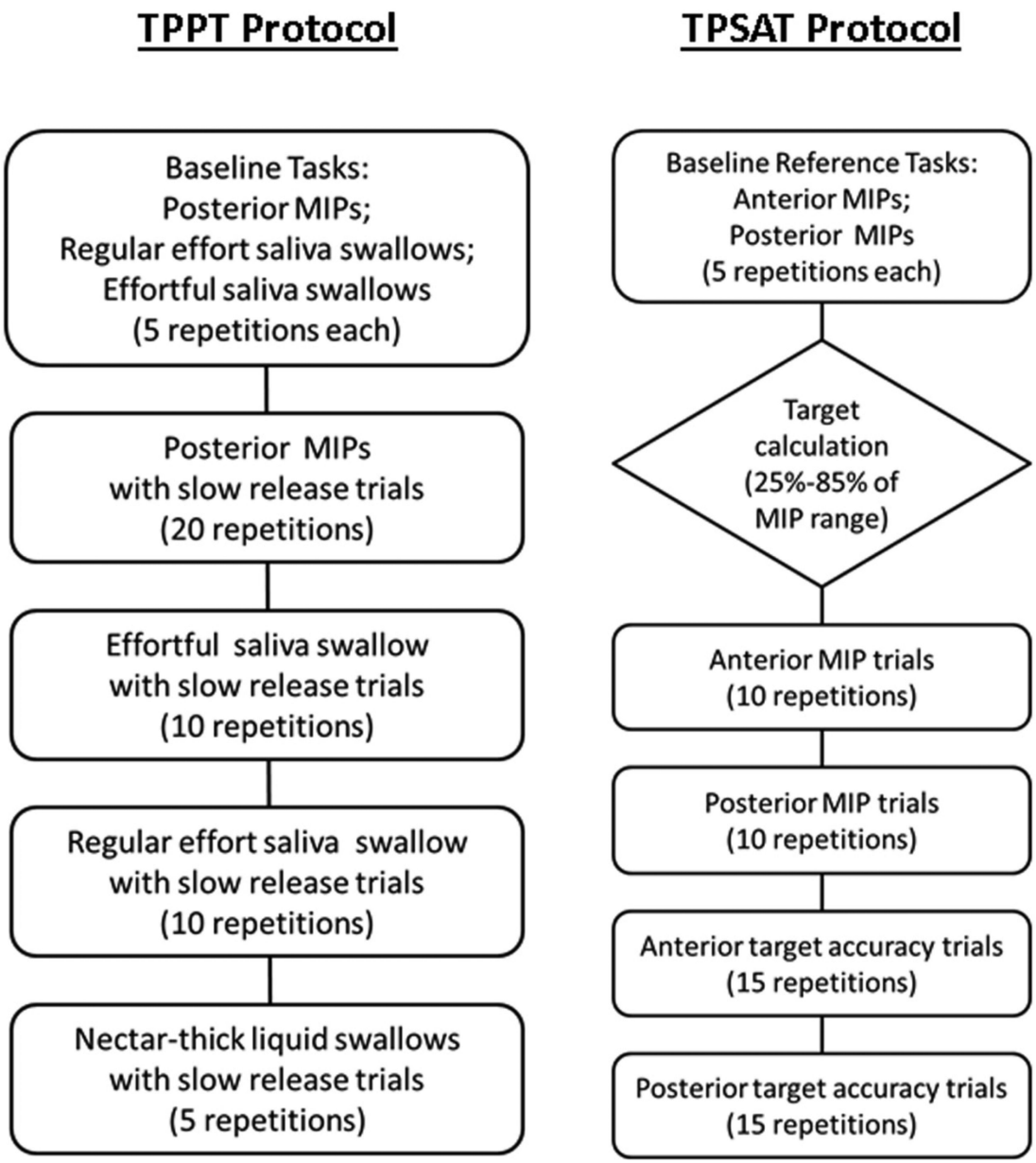

Figure 3.

Outline of the treatment protocols for the two arms in this study. TPPT = Tongue-Pressure Profile Training. TPSAT = Tongue-Pressure Strength and Accuracy Training. MIP = maximum isometric pressure.

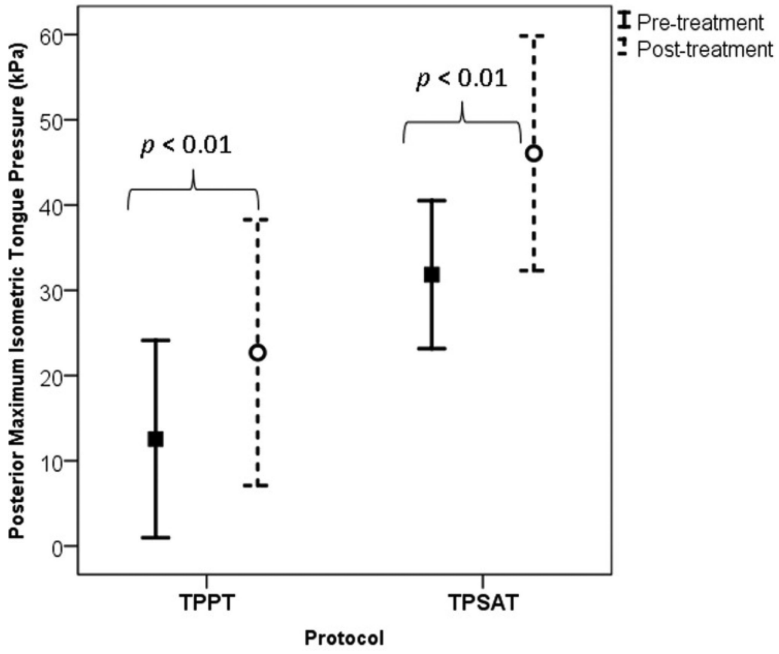

Figure 4.

Pre- and post-treatment measures of tongue strength (posterior maximum isometric tongue-pressures). A significant treatment effect was found in both conditions ($p < 0.01$). There were no significant differences between the treatment arms with respect to the increase in tongue-pressure seen post-treatment. TPPT = Tongue-Pressure Profile Training. TPSAT = Tongue-Pressure Strength and Accuracy Training.

Table 1

Demographic information regarding participants

Participant Number	Location of Stroke	Treatment Protocol	Sex	Age	Days post Onset
2	Right vertebral artery dissection; Right lateral medullary/ cerebellar CVA	TPSAT	F	49	45
5	Left basal ganglia ischemic CVA	TPPT	F	84	111
6	Right CVA	TPSAT	M	89	40
7	Right CVA	TPSAT	M	53	33
9	Left middle cerebral artery CVA; old cerebellar infarct with no residual dysphagia	TPPT	M	81	114
10	Left brainstem CVA	TPPT	M	82	126
11	Left brainstem CVA	TPPT	M	66	34
12	Right medullary CVA	TPSAT	M	55	97
13	Left frontal parietal ischemic CVA	TPPT	F	85	28
16	Left frontal parietal ischemic stroke; prior right frontal ischemic CVA with no residual dysphagia	TPPT	F	70	96
17	Right frontal-parietal-temporal ischemic CVA	TPSAT	M	78	18
20	Right thalamic CVA	TPSAT	F	62	150
22	Left cerebellar CVA	TPPT	M	56	29
24	Brainstem stroke as complication of heart surgery	TPSAT	M	84	63