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ORIGINAL RESEARCH

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Effect of respiratory muscle training on dysphagia in stroke patients—A retrospective pilot study

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Abstract

Background: Dysphagia is prevalent with cerebrovascular accidents and contributes to the burden of disease and mortality. Strengthening dysfunctional swallow muscles through respiratory muscle training (RMT) has proven effective in improving swallow effectiveness and safety. However, approaches to strengthen only the expiratory muscle groups (EMST) dominate the clinical study literature, with variable outcomes. This study investigated the effect of simultaneous inspiratory-expiratory muscle strengthening to improve swallowing function in stroke patients.

Methods: Recorded data of 20 patients receiving pro bono medical care for dysphagia following stroke were allocated to intervention (IG) or control group (CG) based upon whether they chose combined RMT (cRMT) or not while awaiting swallow therapy services. The intervention group was treated with three 5-minute sessions of resistive respiratory muscle training for 28 days, while the control group received no RMT or other exercise intervention. Respiratory and swallow outcomes were assessed pre- and post-intervention and included Mann Assessment of Swallowing Ability (MASA), fiberoptic endoscopic evaluation of swallowing (FEES) with penetration-aspiration scale (PAS), functional oral intake scale (FOIS), patient visual analogue scale (VAS), and peak expiratory flow (PEF).

Results: After 28 days, the intervention group demonstrated greater improvements (P value < 0.05) in PEF (IG: 168.03% vs CG: 17.47%), VAS (IG: 103.85% vs CG: 27.54%), MASA (IG: 37.28% vs CG: 6.92%), PAS (IG: 69.84% vs CG: 12.12%), and FOIS (IG: 93.75% vs CG: 21.21%).

Conclusion: cRMT is a feasible and effective method to improve signs and symptoms of dysphagia while improving airway protection.

Level of Evidence: 3

KEYWORDS

dysphagia, respiratory muscle training, stroke, pulmonary rehabilitation

This study was conducted at Southeastern Biocommunication Associates, LLC. This retrospective study was conducted under an IRB waiver granted from Western IRB.

1 | INTRODUCTION

Although dysphagia can occur across the lifespan from neonates to geriatrics, it is more prevalent in the elderly (over 65) due to age-mediated muscle degeneration, and in those with neurological disorders such as stroke, multiple sclerosis (MS) and Parkinson's disease (PD).[1,2] The reported incidence of dysphagia following CVA differs according to screening method, and ranges from 37% to 78%, with instrumental testing displaying the highest diagnostic sensitivity.[3,4] Consequences of dysphagia include malnutrition, dehydration, and weight loss, as well as increased risk of cardiac and respiratory conditions. Dysphagia is associated with a 13% increase in mortality, and causes 60 000 deaths per year in the US due to complications, especially aspiration pneumonia. Following a stroke, aspiration pneumonia increases the risk of mortality, the duration of hospitalization, as well as the average cost of hospitalization by $27 633.[4,5] Presence of dysphagia post stroke is an independent predictor for 90 day mortality.[6] In the majority of stroke patients with dysphagia (50.9%), this condition persisted beyond hospital discharge, and dysphagia was identified as an independent predictor of discharge destination.[7] Furthermore, dysphagia poses a significant burden on the healthcare system due to prolonged hospital stays, and the need for passive enteral feedings in affected patients. In the United States, the current annual economic burden is estimated at $547 million for prolonged hospitalization and $670 million for enteral feeding supplies, amounting to total annual costs well in excess of $1 billion, with an expected annual increase due to the aging population.[1,8] In addition, patients over 65 presenting with dysphagia, choking or globus represent 37.6% of all emergency department visits for food-mediated adverse events.[9]

The physiological process of deglutition comprises a complex set of events which begin when a given food, liquid, and/or medication bolus is introduced into the oral cavity via the lips and ends once the same bolus empties from the esophagus via the lower esophageal sphincter into the stomach.[10] The signs and symptoms of swallow dysfunction in persons with cerebrovascular accident (CVA) frequently include a delayed swallowing reflex, reduced pharyngeal peristalsis, reduced tongue control, and, less frequently, reduced laryngeal closure. Aspiration, most likely associated with the delayed triggering of the swallowing reflex, was observed in one third of patients.[11] Furthermore, lingual discoordination associated with impaired anterior-posterior tongue movement and dysfunctional bolus propulsion was evident in 19% of patients with CVA.[12] Some additional signs and symptoms of impaired swallow function following stroke may also include prolonged mastication, food/liquid/medication residuals in the oral cavity after the swallow, impaired labial containment of secretions as well as portions of a given food, liquid, and/or medication bolus, nasal regurgitation, a delay in the onset of the swallow, coughing, choking, regurgitation of bolus materials after a swallow, globus, and weight loss.[13] For the purpose of this article, dysphagia is defined as dysfunctional swallow physiology involving the oral cavity, velopharyngeal port, larynx, pharynx, esophagus, and/or the lower esophageal sphincter. This is consistent with the definition provided by the American Speech-Language-Hearing Association (ASHA).[14]

Treatment of dysphagia reflects the complexity of the disorder, and requires a multidisciplinary approach. Early intervention and therapy are associated with reduced risk of aspiration pneumonia and quicker recovery.[15,16] Both the muscles of inhalation as well as the muscles of exhalation are critical integrated components of the upper aerodigestive tract, whose function is necessary for swallow physiology.[17] Strengthening of either muscle group by inspiratory muscle strength training (IMST) or expiratory muscle strength training (EMST), respectively, has shown positive effects on respiration as well as on swallow physiology.[18-21] Some studies have also shown an exercise regimen which includes both IMST and EMST as separate components of the treatment plan to be beneficial in maximizing airway safety with swallowing in neurological patient populations.[22,23] The Breather was the first RMT device to receive a U.S. Patent and it incorporated resistive muscle training for both the muscles of inhalation and exhalation into a single therapeutic exercise device. However, its efficacy in the treatment of Dysphagia has not yet been reported. Therefore, the investigators elected to retrospectively analyze results from existing therapy records using this device (The Breather, PN Medical Inc., US Patent Number 4,739,987).[24] The Breather combines simultaneous strengthening of the inspiratory and the expiratory muscle groups.[25,26] This retrospective pilot study analyzes the effectiveness of a 4-week combined respiratory muscle training (cRMT) program on swallow function in stroke patients with diagnosed dysphagia following a single CVA. This research received an IRB exemption—HIPAA full waiver of authorization and regulatory opinion from the Western Institutional Review Board.

2 | METHODS

Data analyzed in this study is derived from persons who resided in the State of Alabama whose health had been compromised by a single acute CVA and who lacked a pay source to cover the cost of swallow therapy. Each subject had been referred to pro bono clinical speech-language pathology (SLP) services as needed through the Office of Hispanic Ministry at a Catholic Church in the Greater Birmingham Area of Alabama. Data was collected between 1998 and 2009.

Data from the medical records of subjects who met the inclusion criteria presenting with dysphagia after a CVA were included in this study. Inclusion criteria comprised of no prior neurological history, no history of swallow deficits prior to CVA, no pharmacological or surgical interventions, and no other therapy for swallowing during the study period. Exclusion criteria were failure to meet one or more of the inclusion criteria. In addition, there was no therapy of any other kind, including physiotherapy, occupational therapy, respiratory therapy, or speech therapy. Subjects were controlled for age, sex, race, hemisphere of CVA, presence of single CVA without extension. While all patients remained on the referral waiting list for treatment, each patient was offered a choice to be trained in the use of The Breather. Subjects who chose to use cRMT were considered as the intervention group (IG), while patients who chose to not use cRMT were treated as the control group (CG) for analysis.

2.1 | cRMT Intervention

Combined respiratory muscle training (cRMT) was performed using a resistive inspiratory and expiratory muscle training device. Patients using The Breather (intervention group) were trained on the device following the manufacturer's recommendations, which did not change during the time range of data collection. Patients were instructed to wear a nose clip, sit upright, and to forcefully inhale and exhale through the device using diaphragmatic breathing technique. Patients unable to maintain a tight lip seal with the mouthpiece of the Breather were trained to utilize a CPR (cardiopulmonary resuscitation) facemask in lieu of the standard Breather mouthpiece. Patients with upper limb weakness and inability to hold the device were supported by trained caregivers. The duration of intervention was 28 days (4 weeks), and included one skilled intervention and six homework sessions per week. During the skilled intervention, patients performed three sets of 5 minutes of cRMT under therapist supervision. Patients unable to perform a set of 5 minutes started on a shorter duration and worked up to a full set of three times 5 minutes. The home-based sessions were performed without supervision and consisted of three sets of a maximum of 5 minutes of cRMT per session, with three sessions per day. cRMT intensity was defined as the highest tolerated settings for both inhalation and exhalation. Importantly, these settings may be set independently from each other. Compliance and training adherence was monitored via patient communication during weekly skilled intervention sessions. Both groups received recommendations pertaining to the safest food consistencies, liquid consistencies, and medication consistencies, as well as positioning and compensatory strategies to optimize airway safety with swallowing while awaiting standard of care treatment.

2.2 | Assessments

Baseline and final assessments were identical. These included Mann Assessment of Swallowing Ability (MASA),[27] fiberoptic endoscopic evaluation of swallowing (FEES)[28] with penetration/aspiration scale (PAS) applied to thin consistency liquid,[29] functional oral intake scale (FOIS),[30] patient's visual analogue scale (VAS),[31] and peak expiratory flow (Spir-O-Flow Peak Flow Pocket Monitor, Spirometrics). Final assessment was done at the end of intervention (day 28).

2.3 | Data analysis

Data was analyzed using SPSS and StatPlus. Multivariate test for baseline scores was done using MANOVA. Student *t*-test with a mean difference of 0 between intervention and control group (null hypothesis) and a critical value of 5% was used to determine whether the means of the relevant data groups differed significantly. The between subjects independent variable was experimental group (interventions vs control group) and the within subjects independent variable was time (baseline vs final assessment). Evidence against the null hypothesis is represented by determination of *P* value.

3 | RESULTS

3.1 | Patient history and demographics

In total, after reviewing records from 203 patients, data from 20 subjects who either had or had not used the Breather fulfilled the inclusion criteria and were used for analysis in the study. Subject data were allocated to either intervention or control group. Based on the medical history and physicals reviewed for each subject, nine subjects had left hemisphere infarction, seven subjects had right hemisphere infarction, and four subjects had sustained brainstem infarction.

Demographics and baseline assessment data are outlined in Table 1.

The baseline scores for all variables were compared in terms of experimental condition, and gender, using MANOVA. The multivariate test was not significant for experimental group, $F(5, 9) = 2.15$; $P = .151$, or for gender, $F(5, 9)=1.12$, $P = .415$. Therefore, no covariates were included in the main analysis.

Baseline data were collected before the initiation of the cRMT intervention and are outlined in Table 2.

Analysis of baseline data shows that there are no significant differences between the intervention group and the control group (*P* value between groups).

Posttest final assessment was performed after 4 weeks of cRMT intervention, and is summarized in Table 3.

Average peak flow increased significantly by 168.03% in the intervention group (IG), compared to 17.47% in the control group (CG). The visual analog scale (VAS) improved by 103.85% in the intervention group, and 27.54% in the control group. Likewise, scores in the assessment of swallowing ability (MASA) also significantly improved by 37.28% in the intervention group, compared to a 6.92% increase in the control group. The PAS was reduced by 69.84% in the intervention group, and by 12.12% in the control group. A reduction in PAS numerical value signifies an improvement in swallowing safety by indicating a reduction in airway invasion. The FOIS improved by 93.75% in the intervention group, and by 21.21% in the control group, indicating improvement in the functional level of intake of food and liquid. Comparison of baseline and final evaluation data within the groups revealed significant improvements over time in all assessments in the intervention, but not the control group. Between group analysis showed either

TABLE 1 Patient demographics

	Intervention group	Control group
n	10	10
Sex male	2	6
Sex female	8	4
Mean age	70.50	66.10

TABLE 2 Data collected before cRMT intervention at baseline

Baseline data	Intervention group	Control group	*p* between groups
PEF	94	88	.73142
VAS	44.10	37.40	.56885
MASA	133.30	127.10	.60229
PAS	6.30	6.60	.70254
FOIS	3.20	3.30	.91152

Abbreviations: FOIS, functional oral intake scale; MASA, Mann assessment of swallowing ability; p, *P*-value (*T*-test, two-tailed); PEF, peak expiratory flow; PAS, penetration aspiration scale; VAS, visual analog scale.

TABLE 3 Baseline data and data collected at the end of the 4 week intervention

Assessment	Group	Baseline		Final		Percent change	*p* pre < post	*p* between groups
		Mean	*SD*	Mean	*SD*			
PEF	IG	94	44.02	258.00	54.12	168.03%	<.001	<.001***
	CG	88	41.85	107	31.29	17.47%	.02240	
VAS	IG	44.10	24.84	89.90	12.01	103.85%	<.001	.00127**
	CG	37.40	27.60	47.70	23.35	27.54%	.04355	
MASA	IG	133.3	23.35	183.00	11.09	37.28%	<.001	<.001***
	CG	127.1	25.90	135.90	21.75	6.92%	.00762	
PAS	IG	6.30	2.21	1.90	1.37	69.84%	<.001	.00158**
	CG	6.60	1.90	5.80	1.87	12.12%	.08684	
FOIS	IG	3.20	2.20	6.20	0.92	93.75%	<.001	.01153**
	CG	3.30	2.16	4.00	1.89	21.21%	.11076	

Abbreviations: CG, control group; FOIS, functional oral intake scale; IG, intervention group; MASA, Mann assessment of swallowing ability; p, p-Value (T-Test, two tailed); PAS, penetration aspiration scale; PEF, peak expiratory flow; VAS, visual analog scale. Asterisks (*) indicate level of statistical significance.

two-star (**, *P* value < .05) or three-star (***, *P* value < .001) significance in all evaluated parameters, indicating the effectiveness of the intervention in improving swallowing-related symptoms.

4 | DISCUSSION

The data analysis presented reveals the benefits of the utilization of cRMT as an effective therapy in the treatment of neurogenic dysphagia following CVA. Four weeks of using a combined resistive RMT therapy device significantly improved airway safety with swallow function, compared to no direct treatment. Clinical parameters that improved included both objective measures such as PEF, FEES and FOIS, as well as subjective evaluations such as the VAS and MASA. These findings underline the effectiveness of the applied RMT method in the setting of dysphagia following stroke.

Subjects evaluated in this study had employed a resistive combined inspiratory and expiratory muscle trainer that provides training resistance by breathing through different sized apertures covered by a silicone membrane. This method differs from the also widely distributed threshold devices. In contrast to previously reported different outcomes related to the type of device, recent research has revealed no significant differences in treatment outcomes when controlling for threshold dependent RMT devices and non-threshold dependent RMT devices. Some of the evidence highlighted increased cost-effectiveness and simpler instructions for usage of non-threshold RMT devices compared to threshold dependent RMT devices.[32-34] This study analyzes the use of a resistive device which trains both inspiratory as well as expiratory muscle strength, while comparable later studies may have employed devices that add workload to only one part of the breath cycle, or that provide insufficient workloads to elicit respiratory muscle hypertrophy. These approaches may be insufficient, as evidence reveals that functionality of both aspects of the breath cycle is required for effective cough and pulmonary hygiene.[35] As the application of cRMT is likely to be more comprehensive than using IMST and/or EMST separately or sequentially, it may therefore be less cumbersome and more cost effective to use cRMT in lieu of IMST and/or EMST alone.

Respiratory muscle weakness (RMW) and associated swallow dysfunction are prevalent in stroke patients, with a reduction in respiratory muscle strength by approximately 50%, compared to matched controls. These deficiencies may contribute to tracheobronchitis and pneumonia due to aspiration, decreased cough effectiveness and poor pulmonary hygiene. On average, post-stroke pneumonia affects 10% of all patients, on average, and is associated with higher mortality, hospitalization rates, worse outcomes, and higher care needs.[36,37]

Respiratory muscle training is an evidence-based strategy targeting RMW. It follows the principle that respiratory muscles respond to exercise and training stimuli in the same manner as skeletal muscles do, a notion that was originally observed by the Greek physician Claudius Galen,[38] and that has inspired the development of systematic training of the respiratory muscles.[39] Regular workload by training against resistance triggers respiratory muscle hypertrophy, fiber formation, and improved function. This improves the adaptability of respiratory muscles to increased ventilatory demand, and/or the functionality of laryngeal and pharyngeal muscles used for speech and swallow.

This study showed that respiratory muscle strengthening of both the inspiratory and expiratory muscles significantly improves peak flow and swallowing function, as assessed by swallowing ability, food intake and penetration/aspiration, in patients with CVA. Fourweeks of cRMT improved peak flow by 168%, penetration/aspiration by 70%, food oral intake by 94%, and swallowing ability by 37% (Table 2).

Improvements in peak expiratory flow may correlate with more efficient clearance of supraglottic and tracheal secretions or aspirated material, which is also reflected by improved PAS scores. Associated improvements in deglutition can be expected to reduce pneumonia and malnutrition. Furthermore, improved peak expiratory flow may contribute to reduced risk of mortality, as peak flow has recently been identified as an independent predictor of mortality in the aging population.[40]

The overall findings are in agreement with Pitts et al,[41] in that RMT of the expiratory muscles improved swallowing and cough function in patients with PD, including cough acceleration for improved airway clearance and increased penetration/aspiration scores, indicating improved efficacy during swallowing. A 4 week intervention of EMST improved the penetration/aspiration scores by 41%, and cough acceleration volume by 103%.[41] In contrast, other studies have not found EMST to be beneficial in post-stroke patients.[37] Differences in outcomes may be attributed to different training regimes and adherence during the study period, and may also be device dependent. Furthermore, unilateral exercise limited to strengthening of the expiratory muscle group may limit effectiveness of this approach as an adjunctive approach for neurogenic swallow physiology rehabilitation. Further research is warranted.

4.1 | Limitations

There are some limitations inherently involved in this study. First amongst the limitations is the lack of randomization and the inability to have a placebo control group. This first limitation is associated with an inability to rule out skewing of the data towards positive results as motivation may have been higher in the intervention group. In addition, as the level of cognitive communication competence was not controlled, it may be the persons in the intervention group had a greater capability to process, attend, and implement the cRMT protocol. Furthermore, it is possible that persons who chose to participate in the intervention group were more active physically and had a higher level of cognitive communication competence than those who chose not to, thereby causing a difference in levels of exercise performed between the groups. As general exercise alone can improve symptoms of respiratory muscle weakness, the positive outcomes of this study may have been enhanced by this imbalance. Also, acute stroke can be followed by rapid improvement, which was not otherwise assessed in the subject population, and may have influenced individual results. While baseline differences in the outcome parameters between control and intervention group were found to not be significant, overall functional differences between the groups were not evaluated. In addition, the adherence to cRMT was not monitored throughout the intervention period, so it is unclear whether individual results may have been influenced by level of compliance. The records also did not contain specific site of lesion of each person's CVA. Next, the positive results of the study were derived from a small population, possibly limiting its general conclusiveness. Therefore, conducting a double-blinded randomized prospective sham-controlled trial with a larger sample population and an extended follow-up period to assess therapeutic retention of the approach is recommended to confirm the results of this analysis. Future investigations evaluating the effect of cRMT on dysphagia following a single CVA may benefit from diversification of biophysical measurements by including the Yale Pharyngeal Residue Severity Rating Scale, as well as manometric measurements of respiratory muscle strength (maximum inspiratory and expiratory pressure, respectively).[42]

5 | CONCLUSION

This study confirms feasibility, usefulness, and effectiveness of combined inspiratory and expiratory muscle training (cRMT) for improving airway protection in people with dysphagia. Further investigations evaluating the effect of cRMT on dysphagia are warranted to verify the findings of the studies in larger and more diverse populations. Future studies should be controlled, randomized, and include follow-up evaluations to investigate the long-term effectiveness of cRMT-mediated benefits in people with dysphagia following stroke.

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CONFLICT OF INTEREST

N. B. serves as independent Chief Scientist for PN Medical. R. J. A. declares no conflict of interest.

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