Critical Review:
Evidence for the Use of Non-Swallowing Oral Motor Exercises*

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This critical review examined literature on the effects of non-swallowing oral motor exercises on swallowing for head and neck cancer (HNC) patients who have received radiation therapy (RT). Seven experimental studies and one critical review were included in this investigation. Overall, these studies provided suggestive evidence to support the use of non-swallowing exercises as part of dysphagia rehabilitation for post-RT HNC patients. Recommendations for clinical practice and further research are discussed.

Introduction

According to the specificity principle of exercise physiology, exercises should resemble the goal/task (Burkhead, Sapienza, & Rosenbek, 2007). Using this principle, ideal swallowing exercise would be swallowing. Several oral-motor swallowing exercises exist, that incorporate functional swallow practice into the exercise (ex. 'hard swallows', trial swallows of water or saliva). However, there are also oral-motor exercises that target the underlying muscles involved in swallowing. These exercises do not incorporate functional swallowing practice, and are thus deemed to be non-swallow oral motor exercises (ex. tongue strengthening exercises, jaw range of motion exercises).

Patients with head and neck cancer (HNC) often receive radiotherapy (RT) with or without chemotherapy as a part of their treatments (Pauloski, Rademaker, Logemann, & Colangelo, 1998). RT has shown to have negative effects on swallowing, including mucositis, xerostomia, fibrosis, and dysphagia (Murphy & Gilbert, 2009; Langmore & Krisciunas, 2010). Features of post-radiation dysphagia include reduced muscle strength and range of motion, resulting in decreased pharyngeal contraction, decreased hyoid bone elevation, and abnormal upper esophageal sphincter (UES) function (Langmore & Krisciunas, 2010).

While both swallowing and non-swallowing oral motor exercises are used in clinical settings, it is of interest to know what evidence exists to support the use of non-swallow oral motor exercises in HNC patients who have received RT as part of their treatment. This is of interest because clinicians reported using non-swallow oral motor exercises, and felt that they were effective based primarily upon their anecdotal experiences (Krisciunas et al, 2012). Furthermore, knowing the impact of non-swallowing oral motor exercises on swallowing function may help to streamline the selection of swallowing intervention program tasks.

Objectives

The primary objective of this paper is to critically evaluate the existing literature examining the effect of non-swallow oral motor exercises on dysphagia outcomes in head and neck cancer patients compared to functional swallow oral motor exercises. The secondary objective is to provide evidence-based recommendations for future research.

Methods

**This paper was created as a required assignment for the CSD9639 Evidence Based Practice for Clinicians course at Western. While it has been evaluated by course instructors for elements of accuracy and style, it has not undergone formal peer-review.*

Search Strategy

A literature search was conducted through the PubMed computerized database using the search terms: ((oral cancer) AND (radiation) AND (swallowing) AND (exercise*)).

A literature search of the Scopus online database was conducted using the terms: ((dysphag*) AND (exercise*) AND (treatment)). Searches were limited to articles written in English.

Additionally, several articles were suggested through consultation and correspondence with Dr. Ruth Martin.

Selection Criteria

Studies included in this review were required to use HNC patients who had received RT as participants, and use non-swallowing oral motor exercises as part of dysphagia intervention.

Data Collection

The search criteria yielded eight articles: three randomized clinical trials, three case-controlled studies, one randomized block design study, and one critical review.

Results

In their 2012 mixed, randomized controlled trial, Carnaby-Mann et al. measured swallowing function and muscle preservation in patients with oropharyngeal cancer scheduled for (chemo)radiotherapy. Participants (n=58) were randomly assigned to 3 groups (traditional therapy, sham therapy, pharyngocize therapy). Participants in the traditional therapy group received neither swallowing or non-swallowing exercises (ex. diet or posture modifications). The sham therapy group performed non-swallowing exercises as well as received diet modifications. Participants in the experimental 'pharyngocize' group performed both swallow and non-swallow exercises as well as received diet modifications. Data were analyzed using appropriate statistical measures. Exercising during (C)RT resulted in greater maintenance of swallowing musculature and improved swallowing indexes. Greatest effects were seen for the pharyngocize group, but small effects were also noted for the sham exercise group, suggesting that the pharyngocize (mixed swallow and non-swallow) therapy was the most effective of the three.

Statistically, the authors of this study employed accurate analyses, accounting for possible Type 1 Errors with the use of Dunnett's and Bonferroni's corrections. However, effect sizes, as calculated in Drulia & Ludlow (2013), between pharyngocize and sham therapy as well as between pharyngocize and usual care were found to be small. Blinding of both researchers and assessors as well as group assignment lends strength to these findings. The use of a control group as well as a sham therapy group adds credibility to the use of the experimental exercise protocol. Exercises for all groups were clearly described for future replication. While most outcome measurements are clearly linked to functional swallowing ability (for example, the Functional Oral Intake Scale (FOIS), videofluoroscopic swallowing studies, and the Mann Assessment of Swallowing Ability (MASA) (Crary, Mann, & Groher, 2005; Mann, 2002), the use of T2-weighted MRI measuring change in muscle size and composition may not reflect direct functional changes in swallowing ability. Overall, this level 1 study provided compelling evidence for the inclusion of 'pharyngocize' exercises as a part of dysphagia intervention for HNC patients.

Drulia and Ludlow (2013) examined the trends and efficacy of several approaches to dysphagia therapy in their critical review. This review examined 27 studies, comparing the efficacy of non-swallowing (indirect) and swallowing (direct) methods in the rehabilitation of swallowing disorders. Four of the studies examined in this review included HNC patients as participants. However, several other studies (Striezel et al, 2011) examined

treatment in non-neurologically-based dysphagia patients, which may have some clinical applicability to HNC patients. The authors calculated effect sizes (Cohen's D, repeated effect size dz) from the presented data with the use of statistical software, which then were used to compare the efficacy of each intervention.

The review was well-organized, grouping studies into ones that used swallowing exercises (direct therapy) and interventions that targeted underlying disease (non-swallowing, indirect therapy). Articles reviewed were then grouped further by research design. While only a portion of the articles reviewed used HNC participants, the critical review reported small effect sizes between groups in these select studies. As a whole, the four studies using HNC patients provide suggestive evidence to support the use of non-swallowing exercises. However, the authors acknowledge that little research exists regarding optimal session duration, number of sessions, and time period of therapy necessary. Additionally, they noted that the strongest effect sizes for swallowing exercise regimens are within the post-stroke population using cortical stimulation and direct therapy concluded that dysphagia therapy as a whole has small-to-moderate effects. The dearth of articles regarding dysphagia therapy in the HNC population is believed to reflect the lack of research into different therapy approaches for this population, and suggests more research into this population is necessary.

A randomized control trial by Lazarus et al examined the functional swallowing outcomes for stage 2-4 oral and oropharyngeal cancer patients treated with (C)RT (n=23) (2014). The control group performed a mix of both swallow and non-swallow exercises. Subjects in the experimental group performed primarily non-swallow exercises (the same exercises as the control group, with additional non-swallow exercises). Appropriate non-parametric statistical methods were used. No difference in lingual strength, oropharyngeal swallow efficiency, or global quality of life (QOL) was noted pre/post treatment between the groups. The experimental group scored higher on attitudinal/functional QOL scales, but lower for social disruption QOL scales. Overall, the data strongly reject the use of tongue-strengthening exercises to increase tongue strength.

Strengths of this study included the selection of appropriate measures. Measures included the Iowa Oral Performance Instrument (IOPI), and the Head and Neck Cancer Inventory (HNCI) (IOPI Medical, 2013; Funk et al, 2003). The objective method for measuring xerostomia had been previously validated (Kohler & Winter, 1985). Poor compliance with the exercise programs in both groups could account for the null findings. Other factors that may have influenced the data included pre-treatment participant depression and the timing of treatment delivery (1 month post-radiotherapy). Tissue fibrosis, which is a significant contributor to post-radiotherapy dysphagia, typically develops further than 1 month post-RT (National Cancer Institute, 2014). The authors postulate that introducing this protocol 6 months post-(C)RT may tease out differences between the two exercise programs and more accurately address difficulties arising as a result of fibrosis. This study provides suggestive evidence against the use of non-swallowing exercises.

Lin et al (2011) explored the functional changes in swallowing following electrical stimulation (VitalStim) compared to an exercise regimen consisting of swallowing and non-swallowing tasks in a mixed, case-controlled study. Participants (n=20) had been diagnosed with nasopharyngeal cancer, were at least 12 months post-radiotherapy, and demonstrated swallowing difficulties evidenced by a score less than 6 on the *Dysphagia Outcome and* Severity *Scale* (DOSS) (O'Neil et al, 1999). The experimental group performed primarily swallow exercises. The control group

performed mostly non-swallow exercises. Outcome measures selected consisted of a Chinese translation of the MDADI (Chen et al, 2001) and a variety of videofluoroscopic measurements. Appropriate statistical analyses were used (paired *t*-tests). Results of the study showed significant differences in hyoid elevation and Penetration-Aspiration Scale scores between the groups, with the experimental (swallow exercises) group showing greater improvements (Rosenbek et al, 1996). Although both groups showed some decline in swallowing ability, this study suggests that functional swallowing exercises combined with non-swallowing electrical stimulation (VitalStim) may help reduce aspiration and increase hyoid movement and speed.

Strengths of this level 2b design study included the objective measurement of many indicators of swallowing ability. The measurement of such fine details may reveal small differences between groups. However, with the use multiple comparisons, there was no mention of Bonferroni's correction to account for the possibility of family-wise errors. Other strengths included the control of potential clinical confounds (sex and DOSS score). The evidence provided by this study is suggestive. Authors recommended further research on the use of electrical stimulation for HNC patients with dysphagia, as well as continued research into tissue fibrosis and individual variation.

Logemann et al compared the functional swallowing and aspiration reduction outcomes of two exercise treatment programs in a randomized clinical trial (2009). Particpants (n=19) were randomly assigned to the Shaker exercise program and the 'traditional therapy' control group. Participants in the Shaker group performed solely non-swallowing exercises. Participants in the control group performed primarily swallowing exercises. Outcome measures consisted of a VFSS modified barium study, observation of residue, and Performance Status Scale for Diet (PSS-D) (List et al, 1990). Appropriate statistical measures were used. Results indicated that the Shaker exercise group displayed greater reduction in post-swallow aspiration than the control group. However, the control group showed significant improvements in biomechanical swallowing measures (such as superior laryngeal and hyoid movement). No difference in score on the PSS-D or oral residue was noted between groups.

Strengths of this study included the use of blinding of analysts and researchers as well as stringent participant selection criteria. These strict criteria controlled for many confounding variables (such as other neuromuscular disorders, cognitive difficulties). Although 19 participants received treatment, only 11 patients had their data fully analyzed, due to participant attrition and unavailability of videofluoroscopic assessment. Additionally, the protocol for the traditional exercise group was not described in enough detail to replicate the study: exercise dosage is not provided. Overall, this study provided suggestive evidence for the use of non-swallow Shaker exercises for patients with post-swallow aspiration.

Van der Molen et al's prospective, randomized controlled trial examined the functional swallowing outcomes for two treatment programs (2011). Participants with advanced squamous cell carcinoma (n=49) were randomly assigned to groups. The experimental group performed primarily non-swallow exercises. The control group performed a mix of swallow and non-swallow exercises. Appropriate statistical methods were used. Short term functional differences between the groups were roughly equivalent, with the experimental TheraBite group showing less pharyngeal residue during imaging studies on cake consistencies, suggesting greater muscle strength in the pharynx for the experimental treatment group. Ultimately, measurements indicated that both the standard and experimental treatments were equally effective in rehabilitating short-term (up to

10 weeks post-therapy) functional swallowing outcomes

Van der Molen et al followed participants (n=29) from the 2011 study comparing two swallowing treatment programs up to two years out (2014). Maximum interincisor mouth opening, weight changes, body mass index, FOIS, and videofluoroscopic measurements were taken at 10 weeks, 1 year, and 2 years post-CRT. Appropriate statistical analyses were used. Participants who received the experimental swallowing treatment program showed greater weight gain 2 years post-treatment, suggesting that the use of the TheraBite exercise program results in improved functional outcomes for patients over standard exercise protocol. Additionally, it was noted that use of these exercises in patients with primary tumour location below the hyoid bone resulted in greater functional outcomes.

Although there was no mention of blinding in these studies, treatment protocols were clearly outlined for replication. Additionally, outcome measurements were multidimensional. Measures included videofluoroscopic study of swallowing, maximum interincisor mouth opening, weight changes, body mass index, and FOIS (Crary, Mann, & Groher, 2005). Feasibility of this treatment protocol was also assessed through the evaluation of participant compliance and familiarity with the exercises. Interestingly, in the 2011 study, although the experimental (non-swallow) group was less compliant, functional outcomes were not significantly different. The authors also compared functional outcome measures of this study with the current literature, providing some context and guidance to the selection of exercises for patients. Authors noted several factors that may have impacted the results of the studies (likelihood of trismus development, compliance with exercises), while also acknowledging the lack of research in these areas. Interestingly, patients in the experimental (non-swallow) group reported significantly greater familiarity with the exercises 2-years post-treatment than the control (swallow) group. Although not assessed, this suggests that the experimental group may be more compliant with exercises long-term. Overall, results of these study are compelling, suggesting that non-swallow exercises facilitate dysphagia rehabilitation post-RT.

In a randomized control trial, Virani et al compared the functional swallowing outcomes of two swallowing exercise regimens (2015). FOIS (Crary, Mann, & Groher, 2005) scores and percutaneous endoscopic gastrostomy (PEG) tube dependence were measured pre-, during, and post-treatment to reflect functional swallow abilities. Participants (n=50) were divided into two regimens, one consisting of swallow tasks only. Participants in the control group performed only swallow exercises. The experimental group performed a mixture of swallow and non-swallow exercises. Appropriate statistical measures were used. Although there was no difference in PEG tube dependence immediately following treatment, the addition of oral-motor exercises to the rehabilitation regimen was found to significantly reduce PEG tube dependence 3-months post treatment, compared to the use of only swallow exercises.

Strengths of this article include clearly defined and replicable exercise regimens. Descriptions of exercises and dosage are given. Granting that no control conditions were used, the authors justified their use of two experimental groups based on previous evidence for better swallowing outcomes when using prophylactic exercises and the ethical dilemma in denying patients effective prophylactic treatment. Additionally, exercises selected for the oral motor exercise protocol addressed both oropharyngeal and pharyngoesophageal events of swallowing. Authors did acknowledge several possible confounds, including diminishing compliance, small number of participants, and heterogeneity among participants with respect to tumour site, tumour stage, and concomitant cancer treatments. Overall,

results of this study provide compelling evidence for the use of non-swallowing exercises.

Discussion

Research into optimal exercise programs for the treatment of dysphagia in HNC patients is still in the early stages. Although the studies present compelling evidence, there is still not enough information available to make a strong recommendation for changing clinical best practices. In the context of dysphagia intervention, the sum of the articles reviewed present early suggestive evidence for improved swallowing outcomes following non-swallowing oral motor exercises. This supports clinician experiences that non-swallow exercises are beneficial in dysphagia rehabilitation (Krisciunas et al, 2012).

It is difficult to determine the effectiveness of non-swallowing oral-motor exercises in swallowing rehabilitation due to the nature of research with cancer populations. Participant attrition rates are notable, as patients undergo lifesaving procedures that disqualify them from participant eligibility. Considerable variety between subjects both within and between studies exist, due to the heterogeneity of cancers (Langendijk et al, 2009; Hutcheson et al, 2012). It is possible that non-swallowing oral motor exercises are optimal for a sub-set of HNC patients, but this difference has not yet been teased apart, as further research into this population is needed.

With the exception of Drulia and Ludlow (2013), there was no mention of power or effect sizes in any of the studies provided. It is difficult to compare the strength of relationships between studies without the use of such statistics. (Howell, 2010). Additionally, it is also difficult to compare these articles as there were considerable differences between control groups in these studies in terms of the treatment/exercises selected. This is consistent with Krisciunas et al's 2012 study, demonstrating large variability in dysphagia management practices between clinicians.
In 6 of 7 experimental studies, no explanation was given for the selection of exercises as part of the treatment protocol for either the experimental or control groups. Virani et al (2015) justified their selection of exercises based upon evidence in the existing literature. The remaining 6 studies used no clear method in selection of an exercise protocol. However, with greater research into the effects of oral-motor exercises, the selection process may become increasingly evidence-based and streamlined (Krisciunas et al, 2012).

Furthermore, the purpose of this investigation was to determine the effects of oral-motor exercises for post-RT HNC patients, but there were sizeable differences in the amount of radiation administered to patients. Varying amounts of radiation may impact the likelihood of developing or severity of dysphagia post-RT (National Cancer Institute, 2014; Hutcheson et al, 2012). This potentially confounds the evaluation of efficacy of oral-motor exercises. Carnaby-Mann et al were the only researchers to control for this variable (2012).

Additionally, there was considerable variety between studies with regards to the amount and frequency of oral-motor exercises. The American College of Sports Medicine Position Stand suggests that resistance training should take place at least 2-3 days each week for average healthy adults (Garber et al, 2014). Several studies (Virani et al, 2015, Krisciunas et al, 2012) recognized the need for further research into the optimal dosage for exercise programmes. As well, further research into the time of intervention administration (ex. prophylactic exercises, or exercises concurrent with RT) is necessary to evaluate optimal usage of oral-motor exercises (Hutcheson et al, 2012; Krisciunas et al, 2012).

Clinical Implications

There is growing evidence to support the use of exercise regimens for HNC patients. As the use of exercises becomes a routine part of care for patients receiving (C)RT, it is critical to select tasks that will have the maximum benefit. Further research into multiple exercises is warranted in order to streamline the design of exercise programs. Additional research will clarify best practice in incorporating oral-motor exercises into dysphagia rehabilitation.

Early suggestive evidence for the use of non-swallowing oral-motor suggests that these exercises may be better suited for use with a sub-set of HNC patients (Van der Molen, 2014). Research shows beginning evidence for the use of non-swallow tasks for patients who exhibit post-swallow aspiration (Logemann, 2009). For patients who are unable to safely swallow without aspirating, non-swallowing oral-motor exercises may be a safe place to start in the rehabilitation process.

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