Prophylactic Swallowing Exercises in Patients With Head and Neck Cancer Undergoing Chemoradiation

A Randomized Trial

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Objective: To assess the efficacy of prophylactic swallowing exercises on swallowing function in patients undergoing chemoradiation therapy (CRT) for head and neck cancer.

Design: Randomized controlled trial.

Setting: Tertiary care, academic medical center.

Patients: Twenty-six patients with head and neck cancer receiving CRT.

Intervention: Patients performed 5 targeted swallowing exercises throughout their CRT and participated in weekly swallowing therapy sessions to promote adherence and accurate technique. Controls had no prophylactic exercises and were referred for swallowing treatment after completion of CRT if indicated.

Main Outcome Measures: Swallowing function was assessed with the Functional Oral Intake Scale (FOIS) and the Performance Status Scale for Head and Neck Cancer Patients (PSS-H&N) at baseline, immediately after CRT, and at 3, 6, 9, and 12 months after CRT.

Results: There were no statistically significant differences in FOIS scores between intervention and control patients immediately after CRT (immediately after CRT: intervention group median score, 3 [range, 1-7], vs median control score, 4 [range, 1-6] \( P = .88 \)). However, intervention patients had significantly better scores at months 3 and 6 (median 3-month intervention score, 5 [range, 3-7] \( P = .03 \); median 6-month intervention score, 7 [range, 6-7], vs median control score, 6 [range, 3-7] \( P = .009 \)). There was no significant difference in scores at months 9 and 12 (\( P = .24 \) and \( P = .93 \), respectively). The same pattern between intervention and control patients was observed for scores on the PSS-H&N.

Conclusions: Patients who performed prophylactic swallowing exercises had improved swallowing function at 3 and 6 months after CRT but not immediately after CRT or at 9 and 12 months after CRT. The small sample size may have limited our ability to detect significant differences beyond 6 months of observation as well as additional significant differences in our study.


To avoid the significant ablative effects of traditional surgical resection as well as the need for extensive free flap reconstructions, patients with head and neck cancer (HNC) are increasingly undergoing radiotherapy with concurrent chemotherapy (CRT) as the primary treatment approach for their disease.\(^6\)\(^7\) The advantage of preserving the structures necessary for safe and efficient swallowing function has encouraged the increased use of this treatment regimen. However, it is now evident that simply sparing these organs from surgical resection does not ensure the preservation of their function. Moreover, the toxic effects of CRT themselves result in significant swallowing dysfunction.\(^6\)\(^7\)

Serious and persistent dysphagia is now recognized as a common complication for patients who have undergone CRT both acutely\(^8\) and long after the treatment is completed.\(^9\)\(^10\) Patients experience considerable changes in their swallowing ability with restricted diets and in some cases the need for persistent reliance on percutaneous endoscopic gastrostomy (PEG) tube feedings for adequate nutrition,\(^11\) with clinically significant negative effects on the quality of life (QOL).\(^12\)\(^13\)

The specific changes in patients’ swallowing mechanism after CRT have been identified using objective videofluorographic assessment.\(^14\)\(^17\) These swallowing changes include decreased base of tongue retraction resulting in reduced propulsion of the bolus into the pharynx, as well as reduced laryngeal elevation with...
residue in the valleculae and the pyriform sinus after the swallow. In addition, decreased pharyngeal contraction has been shown to result in bolus residue in the pharynx after the swallow and to further reduce the effectiveness of bolus propulsion into the esophagus.

Swallowing exercises directed toward these specific post-CRT swallowing impairments have been used to improve the mobility and motility of these critical swallowing structures after treatment is completed.\(^{18-20}\) Patients have learned to improve tongue and jaw range of motion, and well base of tongue to posterior wall contact, laryngeal elevation, and pharyngeal contraction, resulting in resumption of oral feeding and discontinuation of feeding via PEG tubes.

With improvements in swallowing function from post-treatment exercises, interest in the use of prophylactic swallowing exercises to prevent or minimize post-CRT swallowing dysfunctions has grown. Indeed, some cancer treatment centers recommend prophylactic swallowing exercises for all their patients undergoing CRT.\(^{21-23}\) However, despite the promise of this approach, the research data on its impact on swallowing function are limited.

We conducted a randomized controlled trial to determine if intensive swallowing exercise initiated at the start of CRT and before the onset of dysphagic symptoms improves swallowing outcomes for patients with HNC.

**METHODS**

**PATIENTS**

From July 2007 through January 2010, we recruited consecutive patients scheduled for CRT for newly diagnosed HNC in the clinical practice of the Department of Otolaryngology–Head and Neck Surgery at The Mount Sinai Medical Center in New York, New York. We excluded patients with a history of head and neck surgery, including tracheostomy, those who had previously undergone radiation treatment, and those with a history of neurological diseases that could affect swallowing function. In addition, all patients were required to have adequate mental and cognitive ability to follow multiple-step commands and understand how to answer specific questions on a questionnaire. The study was approved by the institutional review board of The Mount Sinai Medical Center.

**TREATMENT**

Patients were randomized to receive the intervention or control treatments. The intervention was prophylactic swallowing exercises initiated prior to the start of radiation, and patients were instructed to continue these specific swallowing exercises for the duration of their CRT. The control treatment was standard of care, which involved referral to a head and neck speech pathologist (T.K.) for swallowing assessment and treatment if dysphagic symptoms were present after the completion of cancer treatment.

There were 5 intervention swallowing exercises, chosen because each has been shown to improve swallowing function for patients experiencing dysphagia after CRT.\(^{24}\) They included the Effortful Swallow,\(^{25}\) 2 tongue base retraction exercises,\(^{26,27}\) the Super Supraglottic Swallow technique,\(^{19}\) and the Mendelssohn maneuver.\(^{28}\)

**Figure 1.** Prophylactic swallowing exercises.

The Effortful Swallow increases tongue base retraction and pharyngeal pressure during the swallow to improve bolus clearance from the valleculae. The tongue base retraction exercises improve tongue base to posterior pharyngeal wall contact and therefore improve pharyngeal propulsion of the bolus. The Super Supraglottic Swallow technique facilitates closure of the airway entrance before and during the swallow and also increases tongue base motion and speed and extent of laryngeal elevation. Finally, the Mendelssohn maneuver increases the extent and duration of laryngeal elevation. Among treated patients with HNC, use of this maneuver has been shown to produce higher tongue base pressure amplitudes, longer pressure durations, and less pharyngeal residue.

Because patients undergoing CRT mostly present with dysphagia characterized by difficulty transporting food or liquid over the tongue base and through the pharynx and into the esophagus, all of the study exercises used different techniques to promote bolus transport and decrease postswallow pharyngeal residue. The overlap of the benefits of the exercises allowed for different approaches to work together toward the same functional goal. This is particularly important because some patients may have difficulty with some, but not all, of the exercises. Patients were instructed to vary the order of the exercises because they may exert more effort with the initial exercise.

Intervention patients were asked to perform 3 sets of 10 repetitions of each exercise on a daily basis. Because there are no available research data on swallowing exercise dosage, this regimen was chosen to provide an intensive exercise experience without being overwhelmingly onerous for the patients. In addition, it was thought that by using a 3-times-a-day paradigm, an individual could coordinate the exercises with either breakfast, lunch, and dinner or morning, noon, and night to promote better recall. Patients were instructed to keep a log of their daily performance to further encourage adherence to the swallowing exercise protocol and to provide a record of individuals who were unable to complete them. Each patient was given written instructions on how to perform the individual swallowing exercises (**Figure 1**).

Intervention patients participated in weekly face-to-face swallowing therapy sessions with the same head and neck speech pathologist (T.K.), who ascertained the patients’ compliance with the swallowing exercises and reinforced learning to ensure proper technique.
SWALLOWING ASSESSMENT

Functional swallowing assessments were performed using 2 separate swallowing-specific scales that also addressed some swallowing-related QOL issues. These included the Performance Status Scale for Head and Neck Cancer patients (PSS-H&N) and the Functional Oral Intake Scale (FOIS).

A clinician specifically trained in the use these scales and blinded to the intervention assignment assessed all study patients prior to the initiation of CRT within 1 week after completion of CRT and at 3 months, 6 months, 9 months, and 12 months after CRT.

The PSS-H&N is a brief, clinician-rated instrument consisting of 3 discrete subscales: Eating in Public, Understandability of Speech, and Normalcy of Diet (Figure 2). Each subscale ranges from 0 to 100, with the higher score indicating better function. The Eating in Public subscale addresses swallowing-related QOL issues by documenting the patient’s ability to share a meal with others and in what type of environment. The Understandability of Speech subscale rates the degree to which the interviewer is able to understand the patient’s speech. The Normalcy of Diet subscale assesses the extent to which the patient is able to tolerate a regular diet. This subscale includes a ranking of 10 food categories with easy-to-eat options at the low end and more difficult-to-eat options at the high end. This scale has been proven reliable across raters and is sensitive to functional differences across a broad spectrum of patients with HNC. We did not analyze the Understandability of Speech subscale of the PSS-H&N because difficulty with speech is not generally reported as an adverse effect of CRT.

The FOIS is a 7-point scale of oral dietary tolerance (Figure 3). It ranges from complete PEG dependence (1) to tolerance of an oral diet with no restrictions (7). It provides important information about what types of special preparations or limitations patients must make in their oral diet as well as the need for nutritional supplementation via a PEG tube. Status of parenteral feedings via PEG tubes was also documented at each time interval.

STATISTICAL ANALYSIS

We examined differences in treatment assignment by patient characteristics using the Wilcoxon rank sum test for continuous variables and Fisher exact test for discrete variables. Scores on the PSS-H&N and the FOIS were handled as continuous variables.

Outcomes for intervention and control patients were examined in intention-to-treat analyses. We reported the difference in scores at each time point subsequent to baseline (immediately after CRT and 3, 6, 9, and 12 months after CRT) and calculated differences between the scores using the Wilcoxon rank sum test. Significance was set at the level of \( P < 0.05 \) (2-tailed). We also compared differences between the intervention and control arms using change scores (the difference between baseline score and each follow-up score) for the 5 assessments and calculated \( P \) values using the Kruskal-Wallis test. We found the results of the change score analysis to be qualitatively similar to the comparison of raw scores at each time point. For ease of interpretation, we report only the former herein. Results of the change score analysis are available on request.

Twenty-six patients agreed to participate. The mean age of study participants was 59 years; 77% were men, and 77% had stage IV disease. There were no significant differences between characteristics of the intervention and control groups in terms of age, sex, primary tumor site, cancer stage, cancer treatment regimen, and pre-CRT swallowing function or swallowing-related QOL (see Table 1 for \( P \) values). All patients completed 7 weeks of radiation treatment. Baseline scores on all assessments were the same for most patients in the intervention and control arms. All patients completed the 12 months of follow-up.

SWALLOWING FUNCTION AND SWALLOWING-RELATED QOL

As expected, swallowing-related QOL and normalcy of diet scores as measured by the Eating in Public and Normalcy of Diet subscales of the PSS-H&N declined from baseline to the post-CRT period for patients in both the intervention and control groups. These scores, however, improved through post-CRT months 3 and 6. There were no statistically significant differences in Eating in Public subscale scores between patients receiving prophylactic exercises and the control group immediately after CRT (median intervention score, 50 [range, 0-100], vs median control score, 50 [range, 0-100]; \( P = 0.35 \), but were significantly better among intervention patients at months 3 and 6 (median intervention score, 100 [range,
There was no significant difference in Eating in Public subscale scores between intervention and control patients at months 9 and 12 (9-month intervention: median intervention score, 100 [range, 75-100], vs median control score, 100 [range, 75-100]; 
P = .17; 12-month intervention: median intervention score, 100 [range, 75-100], vs median control score, 100 [range, 75-100]; 
P = .82) (Table 2).

Likewise, there were no statistically significant differences in the Normalcy of Diet subscale of the PSS-H&N scores between the patients receiving prophylactic swallowing exercises and the controls immediately after CRT (median intervention score, 100 [range, 50-100], vs median control score, 100 [range, 50-100]; 
P = .90). However, scores improved for intervention patients relative to controls at months 3 and 6 (median intervention score, 20 [range, 0-100], vs median control score, 20 [range, 0-80]; 
P = .03); and 6-month (median intervention score, 100 [range, 50-100], vs median control score, 50 [range, 30-100]; 
P = .006). There was no significant difference in Normalcy of Diet scores between intervention and control patients at months 9 and 12 (median 9-month intervention score, 100 [range, 50-100], vs median control score, 80 [range, 30-100]; 
P = .82; and median 12-month intervention score, 100 [range, 50-100], vs median control score, 80 [range, 30-100]; 
P = .12) (Table 2).

### Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Sample</th>
<th>Intervention</th>
<th>Control</th>
<th>P Value</th>
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<tr>
<td>Age, mean (SD), year</td>
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<td>57 (10)</td>
<td>62 (11)</td>
<td>.12</td>
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<td>Male sex</td>
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<td>10 (77)</td>
<td>10 (77)</td>
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<tr>
<td>Base of tongue</td>
<td>11 (42)</td>
<td>6 (46)</td>
<td>5 (38)</td>
<td></td>
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<td>Tonsil</td>
<td>11 (42)</td>
<td>4 (31)</td>
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<tr>
<td>Glottic larynx</td>
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<td>Nasopharynx</td>
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<td>1 (8)</td>
<td>0</td>
<td></td>
</tr>
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<td>Oropharyngeal wall</td>
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<td>1 (8)</td>
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<td>3</td>
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<td>3 (23)</td>
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<td>4</td>
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<td>Chemoradiation therapy regimen</td>
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<td>0</td>
<td>1 (8)</td>
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</tr>
<tr>
<td>RT + cisplatin</td>
<td>14 (54)</td>
<td>8 (62)</td>
<td>6 (46)</td>
<td></td>
</tr>
<tr>
<td>RT + fluorouracil, hydroxyurea, cetuximab</td>
<td>11 (42)</td>
<td>5 (28)</td>
<td>6 (46)</td>
<td></td>
</tr>
<tr>
<td>Radiation dosage, cGy, median (range)</td>
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<td>7000 (6300-7200)</td>
<td>7200 (6200-7350)</td>
<td>.27</td>
</tr>
<tr>
<td>FOIS Score, baseline, median (range)</td>
<td>7 (6-7)</td>
<td>7 (6-7)</td>
<td>7 (7)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>PSS-H&amp;N—eating in public subscale, median (range)</td>
<td>100 (100)</td>
<td>100 (100)</td>
<td>100 (100)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>PSS-H&amp;N—normalcy of diet subscale, median (range)</td>
<td>100 (50-100)</td>
<td>100 (50-100)</td>
<td>100 (100)</td>
<td>&gt;.99</td>
</tr>
</tbody>
</table>

Abbreviations: FOIS, Functional Oral Intake Scale; PSS-H&N, Performance Status Scale for Head and Neck Cancer Patients; RT, radiation therapy.

Values in columns may not sum to 100% due to rounding errors.

### Table 2. Comparison of Intervention and Control Arms by Functional Assessment Scores

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Median (range)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Pre-CRT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Eating in public</td>
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</tr>
<tr>
<td>Intervention</td>
<td>100</td>
</tr>
<tr>
<td>Control</td>
<td>100</td>
</tr>
<tr>
<td>Normalcy of diet</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>100 (50-100)</td>
</tr>
<tr>
<td>Control</td>
<td>100</td>
</tr>
<tr>
<td>FOIS</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>7 (6-7)</td>
</tr>
<tr>
<td>Control</td>
<td>7 (6-7)</td>
</tr>
</tbody>
</table>

Abbreviations: CRT, chemoradiation treatment; FOIS, Functional Oral Intake Scale.

P < .05 in cross-sectional analysis for the given time point by Wilcoxon rank sum test.

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Oral dietary tolerance (FOIS score) followed a similar pattern among intervention and control patients with a decline from baseline in both groups immediately after CRT. There were no statistically significant differences in FOIS scores between individuals receiving prophylactic swallowing exercises and the controls immediately after CRT (median intervention score, 3 [range, 1-7]; vs median control score, 4 [range, 1-6]; P = .88). However, patients in the intervention arm did have significantly improved FOIS scores at months 3 and 6 (median 3-month intervention score, 7 [range, 5-7], vs median control score, 5 [range, 3-7]; P = .03; and median 6-month intervention score, 7 [range, 6-7], vs median control score, 6 [range, 3-7]; P = .009). There was no significant difference in FOIS scores between intervention and control patients at months 9 and 12 (median 9-month intervention score, 7 [range, 6-7], vs median control score, 6 [range, 5-7]; P = .24; median 12-month intervention score, 6 [range, 5-7], vs median control score, 6 [range, 5-7]; P = .93) (Table 2).

Finally, there were no differences in the incidence of PEG insertion between intervention and control patients (46% vs 46%, respectively; P > .99). Among those who had PEG insertion (12 patients), the median time to removal of the PEG from the completion of therapy was 3 months, regardless of the treatment assignment (P = .15).

STUDY FOLLOW-UP AND ADVERSE EVENTS

Sixty-nine percent of patients (9 of 13) assigned to the intervention were unable to perform the swallowing exercises throughout the entire course of their CRT. Four patients discontinued the swallowing exercises after week 4 of their radiation treatment, and 5 additional patients discontinued the exercises after week 5 of their radiation treatment. As reported by the participants, this was due to the considerable CRT-associated oral pain, throat discomfort, and overall fatigue and was not an adverse effect of the prophylactic exercises themselves.

COMMENT

In this study of patients with HNC undergoing CRT, we found that patients randomized to perform prophylactic swallowing exercises before and during their CRT had functional swallowing and swallowing-related QOL outcomes that were significantly better than those of patients who were referred for swallowing assessment and treatment on an as-needed basis after completing their treatment.

These improvements were observed at 3 and 6 months after completion of CRT but not immediately following CRT or at 9 and 12 months after CRT. These differences were observed despite the finding that 69% of patients assigned to the intervention arm had discontinued the swallowing exercises by week 5 of the radiation therapy, indicating that even without adherence to the swallowing exercise regimen to the completion of the CRT, clinically and statistically meaningful improvements in swallowing function were seen.

We acknowledge that the small sample size of our study may make the detection of differences more difficult and that true differences may be only partially reflected. Consequently, the fact that at 9 and 12 months after CRT our patients no longer showed any statistically significant difference in swallowing function may be the result of a lack of statistical power. Further study of the effect of prophylactic swallowing exercises over time may help to more definitively address this lack of difference. The question remains whether the control patients may have caught up to the intervention patients in terms of improved swallowing performance. Additional research with a greater number of patients is needed to determine if the control patients with persistent dysphagic symptoms who received swallowing evaluation and treatment after completion of CRT were able to improve their swallowing function to the level seen by the patients who had performed the prophylactic swallowing exercise intervention by the 9-month mark.

Although we did not see a difference in PEG insertion rates between those patients who performed the prophylactic swallowing exercises and those who did not, this is likely unrelated to the presence or absence of swallowing exercise performance but rather is an expected result of the acute sequelae of the CRT, including mucositis and odynophagia, which the swallowing exercises would not be expected to influence. In addition, the numbers of patients in the PEG group was too small to assess whether prophylactic exercise could have an impact on hastening PEG removal.

Our findings are important for several reasons. By performing a prospective randomized controlled trial of the effect of prophylactic swallowing exercises on swallowing outcomes in patients undergoing CRT, we were able to corroborate the findings of prior research that has been subject to some criticism because of methodologic issues.

Kulbresh et al assessed the effect of pretreatment swallowing exercises on patient responses to the M. D. Anderson Dysphagia Inventory (MDADI), a self-administered survey that specifically evaluates the impact of swallowing dysfunction on the QOL of patients who have been treated for HNC. They found higher scores among the patients who had performed pretreatment swallowing exercises. However, this study was not randomized, and the MDADI surveys were administered to the control group several years before it was administered to the group receiving pretreatment swallowing therapy, a difference in time over which treatment of HNC may have improved at that institution.

Another frequently cited study, by Carroll, et al, evaluated the effect of pretreatment swallowing exercises on posttreatment swallowing physiologic mechanisms as measured by videofluoroscopic swallowing evaluation. This was a retrospective, case-controlled study that compared 9 patients undergoing CRT who had performed pretreatment swallowing exercises with 9 patients undergoing CRT who had not. At 3 months after treatment, they found that patients who had performed the pretreatment swallowing exercises had improved tongue base to posterior pharyngeal wall approximation and better maintained epiglottic inversion than patients who did not perform swallowing exercises. No differences were observed between the 2 groups on other swallowing outcomes, including laryngeal elevation, presence of aspi-
ration, cricopharyngeal opening, and PEG removal rates. Without the benefit of randomization, it is impossible to know if the patients in this study who performed the prophylactic swallowing exercise program are a fair representation of all patients undergoing CRT or characterize a subset of patients who experienced fewer adverse effects from treatment and consequently were able to participate in swallowing exercises while undergoing CRT.

The mechanism behind improvement in swallowing function with exercise is not entirely clear. Patients with HNC treated with CRT can present with progressive onset of fibrosis, whereby the edematous tissue caused by the radiation is replaced with stiffer fibrotic tissue.\textsuperscript{33} For other patients, the fibrosis can occur years after the cancer treatment is completed. Either way, this fibrosis impairs the movement and coordination of the swallowing structures and results in the disruption of the efficient and effective bolus transport necessary for swallowing function.\textsuperscript{22} A recent study of the effect of exercise on wound healing and reduction in inflammation in mice suggests that exercise may work to decrease some of the factors implicated in postradiation fibrosis.\textsuperscript{25} In addition, exercise of the swallowing structures may help to strengthen the nonfibrotic tissue to compensate for the lack of mobility of the fibrotic structures.

It is also interesting to note an abstract presented by Carnaby-Mann et al\textsuperscript{36} at the Dysphagia Research Society Meeting in 2007 looking at the effectiveness of a behavioral program of swallowing exercises on maintenance of swallowing-related muscle composition. They found greater preservation of swallowing muscle size for patients who underwent behavioral swallowing treatment during CRT compared with controls.

Our study has a number of notable strengths. The intervention involved established swallowing exercises and the combination of exercises were selected to enhance bolus transport, which is well recognized as the primary dysphagic complication of patients with HNC after CRT. We also used 2 validated, clinician-administered measures of swallowing function, which provided a detailed description of the patients’ oral tolerance and intake and the need for complete or partial PEG use, and addressed the swallowing-related QOL issues of being able to eat with other people and outside the home.

Nonetheless, some limitations of our study deserve mention. We did not use videofluoroscopic evaluations that might have provided a more sensitive measure of the effect of the exercises on swallowing function. Future study may benefit from including videofluoroscopic swallowing evaluations at these same time points. Also, a larger sample size may have enabled us to predict which patients would have been more likely to benefit from prophylactic swallowing exercises and would also be needed to answer the important question of how much and how often do the exercises need to be performed to produce a swallowing benefit. In addition, as noted, the small sample size may have limited our ability to detect statistically significant differences is swallowing function as well as accurately identify the magnitude of the differences that were observed. Finally, the sample size was inadequate to provide an analysis of the effect of prophylactic swallowing exercises on earlier PEG removal.

Despite the encouraging results of this study, we must still remain cognizant of the significant toll that undergoing CRT for the treatment of HNC takes on our patients. While implementing a rigorous prophylactic swallowing program clearly shows some benefit in terms of swallowing outcomes after treatment, we must not lose sight of the additional demand this places on the individual patient and remain sensitive to how much some patients can or cannot endure.

In conclusion, in our study, patients who performed prophylactic swallowing exercises designed to address the specific swallowing dysfunctions associated with CRT had significantly better swallowing outcomes than patients who did not receive this intervention at 3 and 6 months after cancer treatment. At 9 and 12 months after CRT this difference was no longer significant. Continued study with a larger sample size is needed to expand on these findings and provide a more powerful analysis of the effect of prophylactic swallowing exercises on patients with HNC treated with CRT.

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Author Contributions: Ms Kotz and Drs Federman and Kao had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Kotz, Kao, Milman, and Genden. Acquisition of data: Kotz, Kao, Packer, Lopez-Prieto, and Forsythe. Analysis and interpretation of data: Federman, Kao, and Forsythe. Drafting of the manuscript: Kotz. Critical revision of the manuscript for important intellectual content: Federman, Kao, Milman, Packer, Lopez-Prieto, Forsythe, and Genden. Statistical analysis: Federman and Forsythe. Administrative, technical, and material support: Kotz, Kao, Milman, Packer, Lopez-Prieto, Forsythe, and Genden. Study supervision: Kao, Milman, and Genden.

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