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A Swallow Preservation Protocol Improves Function for Veterans Receiving Chemoradiation for Head and Neck Cancer

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Abstract

Objective. Determine the efficacy of a swallow preservation protocol (SPP) on maintaining swallow function in patients undergoing chemoradiation (CRT) or radiation therapy alone (RT) for head and neck squamous cell carcinoma (HNSCC).

Study design. Retrospective case series.

Setting. Veterans Affairs medical center.

Subjects and Methods. Patients treated with CRT or RT for HNSCC between February 2006 and November 2013 were studied. Those enrolled in the SPP participated in swallowing, jaw, and tongue exercises during cancer therapy. The comparator group received no swallowing intervention during CRT. A previously described functional outcome swallowing scale (FOSS; 0 = no symptoms and 5 = nonoral feeding for all nutrition) was used to quantify dysphagia prior to and at the completion of cancer therapy, and an analysis was performed to compare swallowing function.

Results. Forty-one (all male; mean age, 66 years) and 66 patients (all male; mean age, 61 years) were included in the SPP and comparator groups, respectively. In the SPP group, mean pre- and posttreatment FOSS scores were 2.2 and 2.2, respectively, while the corresponding scores in the comparator group were 1.8 and 2.7, respectively, with posttreatment FOSS scores being significantly worse than pretreatment FOSS scores in the comparator group only.

Conclusion. Patients enrolled in the SPP demonstrated preserved swallowing function over the course of cancer treatment compared with a comparator group. This confirms the importance of early evaluation and intervention for dysphagia prior to and during CRT or RT alone.

Keywords

dysphagia, head and neck cancer, chemoradiation, swallow preservation

Dysphagia is a debilitating side effect of organ-sparing treatment for head and neck squamous cell carcinoma (HNSCC).[1-3] Risk factors for development of dysphagia after combined chemotherapy and radiation therapy (CRT) for HNSCC include an oropharyngeal primary site, cessation of per os (PO) intake during treatment, and conventional 2D or 3D-conformal radiation therapy.[4-7] Manifestations of dysphagia include prolongation of mealtime, aspiration, weight loss, dietary limitations, and the need for nonoral nutrition.[8,9] Acute dysphagia during the course of cancer treatment may pose life-threatening challenges, particularly with regard to inadequate hydration and nutrition.[10] Late dysphagia may manifest as a pharyngoesophageal stricture or aspiration, and intensive therapy may be required to reverse gastrostomy tube dependence.[11-13]

Intensity-modulated radiation therapy with optimization of radiation dose to avoid constrictor musculature has emerged as an important technique to avoid both early and late dysphagia, in part by ameliorating inflammation, fibrosis, and eventual diminished mobility of pharyngeal structures.[7,14-17]

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Table 1. Functional Outcome Swallowing Scale (FOSS).[a]

Stage	Description
0	Normal function; asymptomatic
1	Normal function; episodic or daily symptoms of dysphagia
2	Compensated abnormal function manifested by significant dietary modifications or prolonged mealtime, without weight loss or aspiration
3	Decompensated abnormal function, with weight loss of 10% or less of body weight over 6 months due to dysphagia, or daily cough, gagging, or aspiration during meals
4	Severely decompensated abnormal function with weight loss of more than 10% of body weight over 6 months due to dysphagia, or severe aspiration with bronchopulmonary complications; nonoral feeding recommended for most of nutrition
5	Nonoral feeding for all nutrition

[a]Adapted from Salassa, 1999. (© 2000 Karger Publishers, Basel, Switzerland.)

Notwithstanding this, dysphagia remains a common complaint following cancer therapy.

Subjective measures of dysphagia include the Performance Status Scale for Head and Neck Cancer patients (PSS-H&N) and the M.D. Anderson Dysphagia Inventory (MDADI).[6,18] However, disadvantages of these subjective scales include patient bias and inconsistency among subjects. Objective measures, including the modified barium swallow study (MBSS) and the videofluoroscopic swallow study (VFSS), offer detailed information about swallowing anatomy and physiology.[5,19] However, time and resource constraints may preclude the clinician from performing these studies at each consecutive visit, and the complexity of findings may make numerical grading and subsequent statistical analyses difficult. Therefore, to stage dysphagia, we elected to use an objective, clinician-determined scale of oropharyngeal dysphagia, the functional outcome swallowing scale (FOSS), first proposed by Salassa (**Table 1**).[20]

Strategies for rehabilitation of swallowing during and following CRT include postural adjustments, diet modification, range-of-motion exercises, and the strengthening of pharyngeal and suprahyoid musculature.[21,22] At our institution, we have implemented a swallow preservation protocol (SPP) comprising swallowing, jaw, and tongue exercises presented to patients prior to or within 2 weeks of beginning CRT. Exercises are performed for 10 repetitions 3 times daily for a total of 30 repetitions per exercise per day. A jaw motion rehabilitation system is used as necessary in patients who demonstrate trismus prior to or at any point during CRT, and patients are asked to self-report compliance with the SPP using a diary. Patients are seen by speech pathology practitioners every 1 to 2 weeks during CRT; following completion of CRT, patients are seen on a variable basis ranging from once every few weeks to once every several months.

In this study, we sought to investigate the effect of our SPP on dysphagia following CRT or radiation therapy (RT) alone for HNSCC and hypothesized that veterans participating in a SPP during CRT or RT would demonstrate better posttreatment swallowing outcomes compared with a comparator population.

Methods

Subjects

The Institutional Review Board of the Greater Los Angeles Veterans Affairs Health System approved this study. A retrospective chart review was conducted of all patients treated with CRT or RT alone for HNSCC at a Veterans Affairs Medical Center between February 2006 and November 2013, including both patients who did and did not participate in the SPP. Demographic and clinical information was gathered. Using clinical documentation by speech pathology and head and neck surgery, swallowing function was assessed using the FOSS within 1 to 2 weeks prior to the beginning of CRT/RT (''pretreatment'') and within 2 to 4 weeks after the termination of CRT/RT (''posttreatment''). Compliance to the SPP was also noted.

Swallow Preservation Protocol

Patients were enrolled in the SPP beginning in September 2010; by July 2013, nearly all veterans undergoing CRT or RT for HNSCC were enrolled in the SPP. No specific clinical factors influenced the decision to enroll a patient in the SPP.

The SPP consists of 2 jaw exercises, 2 tongue exercises, and 4 swallowing exercises. Jaw exercises include the jaw stretch and the lateral jaw stretch, comprising jaw opening and lateral jaw displacement in both directions 10 times in a row, 3 times daily. Tongue exercises include the tongue press (forced contraction of the tongue against the anterior hard palate) and anterior and lateral tongue stretch (forced contraction of the tongue anteriorly and to the left and right), also 10 times in a row, 3 times daily.

The 4 swallowing exercises, which compose the majority of the SPP, are the Shaker exercise, the Mendelsohn maneuver, the Masako tongue-hold, and the effortful swallow. The Shaker exercise, designed to strengthen the suprahyoid musculature and enhance opening of the upper esophageal sphincter (UES), consists of prolonged, forced flexion of the neck in a supine position followed by 3 fast repetitions of the same.[23] The Mendelsohn maneuver, designed to prolong

hyolaryngeal elevation at the peak of the swallow, also facilitates UES opening. Patients are instructed to palpate the cartilaginous laryngeal framework as they swallow without food (''dry swallow'') and develop voluntary motor control of hyolaryngeal elevation.[24]

In the Masako tongue-hold, the patient bites firmly but comfortably on the anterior oral tongue using the upper and lower incisors, thus rendering it immobile, and then performs dry swallows.[25] This procedure augments the anterior excursion of the posterior pharyngeal wall. Finally, in the effortful swallow, the patient imagines swallowing a large object (''swallow a large vitamin,''''swallow a ping-pong ball''), theoretically strengthening all muscle groups involved in swallowing.

With the exception of the Shaker exercise, which is performed 3 times each in prolonged and repetitive fashion, the swallowing exercises are performed 10 times in a row, 3 times daily, for a total of 30 repetitions daily. Patients were asked to log performance of jaw, tongue, and swallowing exercises in a provided diary.

Patients displaying trismus prior to, during, or following cancer therapy were also provided with and instructed in the use of a TheraBite Jaw Motion Rehabilitation System (Atos Medical AB, Hörby, Sweden) to maximize jaw opening.

Objective Assessment of Swallow Function

As described above, the FOSS, yielding ordinal scores, was used to quantify swallowing function prior to and following CRT or RT for HNSCC. The MBSS was variably performed on patients in the SPP and the comparator group, and these data were therefore excluded from analysis.

Statistical Analysis

Initially, subjects were analyzed in an intention-to-treat manner, and all patients enrolled in the SPP were included in the treatment cohort regardless of compliance. Student *t* tests and the *z* test were used to compare differences between the SPP and comparator groups. The FOSS scores were compared using Mann-Whitney *U* and Wilcoxon signed-rank tests. Statistical analysis was performed with SPSS 20 (SPSS, Inc, an IBM Company, Chicago, Illinois). Thereafter, patients who were compliant and noncompliant with the SPP were analyzed separately.

Results

The SPP and comparator groups comprised 41 and 66 patients, respectively. All subjects were male; there were no significant differences between the 2 groups with respect to mean age, mean TNM stage group at time of cancer diagnosis, and distribution of treatment modality (CRT vs RT; P = .26). Similarly, no significant difference was seen when comparing pretreatment FOSS scores between the SPP and comparator group (2.15 and 1.78, respectively; P = .068, Mann-Whitney *U;* **Table 2**). In the SPP group, compliance with treatment was 71%.

Pretreatment and posttreatment FOSS scores were compared pairwise for each subject within the SPP and comparator groups. In the SPP group, there was no significant difference between pre- and posttreatment FOSS (2.15 and 2.23, respectively; Wilcoxon signed-rank, P = .343). In the comparator group, a significant difference was observed between pre- and posttreatment FOSS (1.78 and 2.73, respectively; P = .000), consistent with worse swallow function posttreatment (**Table 3**).

Compliant and noncompliant patients in the SPP group were then analyzed separately. The compliant cohort had no statistically significant difference in swallowing function when comparing pretreatment with posttreatment FOSS score (P = .887, Wilcoxon signed-rank), while the noncompliant cohort demonstrated a trend toward worse swallowing function that did not reach significance (P = .102, Wilcoxon signed-rank).

As increasing age has previously been implicated in worse swallowing function after CRT, we stratified patients by age, considering patients 55 years and younger separately from those older than 55 years. In the SPP group, both age groups revealed no significant difference when comparing pre- and posttreatment FOSS (P = .435 and .655 for the younger and older age groups, respectively). In the comparator group, both age groups revealed statistically significantly worse swallowing function after treatment (P = .000

Table 2. Patient Characteristics.[a]

	SPP (n = 41)	Comparator (n = 66)
Age, y		
Mean (range)	66 (48-88)	61 (27-80)
≤55	3 (7)	10 (15)
>55	38 (93)	56 (85)
Cancer treatment received		
CRT	32 (78)	57 (86)
RT	9 (22)	9 (14)
Compliant with SPP	29 (71)	NA

Abbreviations: CRT, chemoradiation; NA, not applicable; SPP, swallow preservation protocol; RT, radiation therapy.
[a]Values are presented as number (%) unless otherwise indicated.

Table 3. Functional Outcome Swallowing Scale (FOSS) Scores Prior to ("Pretreatment") and following ("Posttreatment") Therapy for Head and Neck Cancer.

	SPP[a]	Comparator[b]
Pretreatment,[c] mean (SD)	2.15 (1.24)	1.78 (1.55)
Posttreatment, mean (SD)	2.23 (1.37)	2.73 (1.59)

Abbreviation: SPP, swallow preservation protocol.
[a]No statistically significant difference between pretreatment and posttreatment FOSS in the SPP group (P = .343, Wilcoxon signed-rank).
[b]Posttreatment FOSS was statistically significantly worse than pretreatment FOSS in the comparator group (P = .000, Wilcoxon signed-rank).
[c]No statistically significant difference between pretreatment FOSS in the SPP and comparator groups (P = .068, Mann-Whitney *U*).

and .017 for the younger and older age groups, respectively). Thus, no notable difference was seen when stratifying patients by age.

Discussion

Dysphagia following chemoradiation or radiation therapy alone for head and neck cancer is a significant detriment to quality of life following curative therapy.[2] Rehabilitation of swallowing after prolonged disuse is difficult, and recent strategies focus on early intervention to ameliorate acute symptoms as well as prevent the late sequelae of fibrosis and atrophy of involved musculature.[21]

At our institution, we have implemented an SPP for veterans undergoing CRT or RT for HNSCC. This protocol includes swallowing exercises, jaw exercises, and tongue exercises that are performed 3 times daily. The 4 swallowing exercises—the Shaker maneuver, the Mendelsohn maneuver, the Masako tongue-hold, and the effortful swallow—are the core of the protocol. Together, the swallowing exercises augment and prolong UES opening, enhance posterior pharyngeal wall excursion, and globally strengthen the pharyngeal musculature. When necessary, a jaw motion rehabilitation device is provided to treat trismus. Patients were prospectively enrolled in this SPP beginning in September 2010; by July 2013, nearly all veterans undergoing CRT or RT for HNSCC were enrolled in this protocol and underwent weekly to biweekly follow-up with speech pathology providers during the course of cancer therapy.

On intention-to-treat analysis, veterans enrolled without randomization in the SPP demonstrated no significant difference compared with a comparator group with respect to demographic parameters, cancer treatment, cancer stage, and pretreatment swallowing function as quantified by FOSS score. In contrast, following CRT or RT, the comparator group demonstrated statistically worse swallowing function compared with the beginning of cancer treatment; in the SPP group, there was no significant difference between pretreatment and posttreatment swallowing function. Overall, compliance in the SPP was 71%. When analyzing patients compliant with and not compliant with the SPP separately, compliant patients demonstrated no significant difference between pre- and posttreatment swallowing function. Noncompliant patients, however, demonstrated a trend toward worse swallowing function, approaching statistical significance. Taken together, these data suggest that participation in the SPP maintained swallowing function during CRT or RT.

Limitations of the current work include lack of randomization to the SPP. The comparator group did receive cancer therapy chronologically earlier, on average, than did the SPP group, and advances in CRT or even changes in oncologic protocols may have had an unidentified influence in producing the observed differences between the SPP and comparator groups. Furthermore, patients were not stratified by primary site, and future research must probe the efficacy of the SPP, and specifically the swallowing exercises, in patients with primary tumors involving sites other than the oropharynx and hypopharynx. Finally, posttreatment follow-up in our study was 2 to 4 weeks following completion of cancer therapy; long-term swallowing function must be assessed and compared.

Conclusion

Compared with a comparator group, participants in a swallow preservation protocol during chemoradiation or radiation therapy alone for head and neck squamous cell carcinoma demonstrated preservation of swallow function during and shortly following cancer treatment.

Author Contributions

Kevin A. Peng, data acquisition, drafting manuscript, approval of manuscript, accountability to accuracy and integrity; **Edward C. Kuan**, data acquisition, drafting manuscript, approval of manuscript, accountability to accuracy and integrity; **Lindsey Unger**, data acquisition, manuscript revision, approval of manuscript, accountability to accuracy and integrity; **William C. Lorentz**, data acquisition, manuscript revision, approval of manuscript, accountability to accuracy and integrity; **Marilene B. Wang**, conception and design of work, manuscript revision, approval of manuscript, accountability to accuracy and integrity; **Jennifer L. Long**, conception and design of work, manuscript revision, approval of manuscript, accountability to accuracy and integrity.

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