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ORIGINAL ARTICLE

The effect of the Shaker head-lift exercise on swallowing function following treatment for head and neck cancer: Results from a randomized, controlled trial with videofluoroscopic evaluation

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Abstract

Background: Dysphagia is common following treatment for head and neck cancer (HNC) and intervention to improve swallowing function is warranted. This study aimed to evaluate the efficacy of the Shaker head-lift exercise (HLE) to improve dysphagia in HNC patients.

Methods: Patients treated for HNC with radiochemotherapy and with subsequent dysphagia were randomly assigned to intervention (HLE, $n = 25$) and control (standard dysphagia management, $n = 27$) groups. Videofluoroscopic evaluation of penetration-aspiration, initiation, residue, movement of selected structures, and self-perceived swallowing function, before and after 8 weeks of treatment, were compared.

Results: Although adherence to training was high, no statistically significant differences in objectively measured swallowing function between the groups or within-group changes were found. Self-perceived swallowing function improved in the intervention group.

Conclusions: In this HNC population, neither HLE nor standard dysphagia management improved objectively measured swallowing function as evaluated after 8 weeks. Future research focusing on finding effective interventions for dysphagia is warranted.

KEYWORDS

deglutition disorders, head and neck neoplasms, intervention study, radiotherapy, randomized

1 | INTRODUCTION

In 2020, more than 900 000 persons were diagnosed with head and neck cancer (HNC) worldwide.[1] Surgery and/or chemoradiotherapy is the most common treatment regimen.[2] Oropharyngeal dysphagia is a frequent side effect after treatment. Following radiotherapy for HNC dysphagia has been reported to occur in up to 83% of patients.[3,4]

Dysphagia following HNC is attributed to radiation-induced fibrosis in structures related to swallowing as well as muscular atrophy and cranial neuropathy.[5–7] Soft-tissue fibrosis is caused by many factors and can partly be attributed to inflammation and reduced blood supply, resulting in reduced muscle strength and contractility.[8,9] Additionally, muscular atrophy and weakness may be caused by disuse of the oropharyngeal musculature during radiotherapy, as patients often stop eating normal food while acute toxicities are at their peak.[10]

Following radiotherapy for HNC, the swallowing mechanism may be affected in several ways, such as reduced oral motor activity, weakened tongue base retraction and strength, reduced pharyngeal contraction, impaired hyolaryngeal elevation, delayed closure of the larynx, and impaired opening of the upper esophageal sphincter (UES).[8,11–14] This may lead to residue in the pharynx after the swallow and/or aspiration of food, liquid, or even saliva to the airways.[15–19] Silent aspiration, that is, passage of liquid or food below the glottis without external signs such as coughing or choking, is prevalent after radiologic treatment for HNC.[20–22] As many as 35% of patients have been reported to present with silent aspiration.[21,22] Dysphagia also has negative consequences on a patient's medical recovery and may lead to prolonged hospitalization and long-term care.[23] Additionally, swallowing difficulties enhance the risk of malnutrition and mortality and reduce the health-related quality of life (HRQL).[4,24–28]

Dysphagia rehabilitation often focuses on compensation through altering of food consistency to improve safety of oral intake,[29–31] swallowing maneuvers,[29,32] or the use of different stretch exercises.[33] In addition, the effect of exercise-based intervention has been described in several studies.[14,23,34–37] However, differences regarding types of intervention and timing of rehabilitation, as well as a large variation of outcome measures, make it difficult to conclude which therapy is actually helpful.

The Shaker head-lift exercise (HLE) is a treatment originally developed to improve swallowing difficulties due to restricted UES opening.[38] The exercise aims to strengthen the suprahyoid muscles in the neck, which, during swallowing enhance the upward and forward movement of the hyoid bone and larynx, resulting in improved opening of the UES.[39,40] The HLE has been found to improve UES opening, maximum anterior hyoid excursion and anterior laryngeal excursion in healthy elderly subjects.[38,41] Previous studies have also shown that the HLE may decrease post-swallow aspiration,[42] improve thyrohyoid approximation,[43] and restore oral intake due to abnormal UES opening[44] in patients with dysphagia. However, the effectiveness of the HLE in a HNC population has not yet been established.

A pilot study preceding the present study,[45] including patients with previous treatment for HNC or stroke, indicated that self-reported swallowing function as well as HRQL improved after performing HLE for 8 weeks. However, analysis of swallowing function with videofluoroscopic evaluation of swallowing (VFSS) showed diverging results, indicating the need for a randomized controlled trial in a more homogenous group.

The aim of this randomized study was to evaluate the effect of the HLE on swallowing function examined with VFSS in patients with HNC following radiotherapy with or without chemotherapy.

2 | MATERIALS AND METHODS

2.1 | Participants

Patients with HNC treated with radiotherapy who were discussed at the weekly multidisciplinary tumor board meeting at Sahlgrenska University Hospital (Gothenburg, Sweden) were assessed for eligibility in this study. The inclusion period was between 2011 and 2018. Adult patients with tumors of the tonsil, base of tongue, hypopharynx, and larynx who were treated with curative external beam radiation therapy (EBRT) with or without brachytherapy and with or without chemotherapy as well as no previous history of dysphagia were eligible for inclusion in the study. Exclusion criteria were previous surgery for HNC (except tonsillectomy or diagnostic sample excision), previous radiotherapy or other treatment for HNC, tracheostomy, neurological or neuromuscular disease, inability to swallow any bolus, and/or inability to perform the HLE.

Patients who met criteria for inclusion were contacted by telephone and asked questions about their swallowing function after treatment. All were offered an examination of swallowing function with VFSS 6–36 months post-oncological treatment. Swallowing function was initially rated according to Rosenbek's Penetration Aspiration Scale (PAS).[46] The patients who received a PAS score of $\geq$2 (PAS Score 2: material enters the airway, remains above the vocal folds, and is ejected from the airway) on more than one swallow on the initial VFSS examination were invited to participate in the study. Patients were

eligible for analysis in the present study if they had completed the VFSS at baseline and at the 8-week follow-up.

2.2 | Design

The study was a randomized controlled trial consisting of a baseline assessment of swallowing function with a follow-up assessment after 8 weeks of treatment. Computerized randomization was performed through optimal allocation according to Pocock's sequential randomization method regarding tumor type, tumor stage, age, sex, comorbidity (Adult Comorbidity Evaluation-27, ACE-27[47]), and the PAS score at baseline. Patients were randomized into either an intervention group receiving standard dysphagia care in combination with performing the HLE or a control group who received standard dysphagia care alone according to clinical praxis. According to an 80% power calculation (Mann–Whitney *U*-test, alpha = 0.05), the sample size was calculated to 25 patients in each group ($n = 50$ in total), assuming a clinically relevant difference of one point on the PAS score between the study groups and a standard deviation of 1.2. To compensate for possible drop-outs, 60 in total were aimed to be recruited.

2.3 | Oncologic treatment

EBRT was given as 3D conformal radiation therapy (3DCRT) or intensity modulated/volumetric modulated radiation therapy (IMRT/VMAT) to total doses ranging typically between 64.6 and 68 Gy in 1.7–2 Gy fractions once or twice daily, 5 days a week. When applicable, brachytherapy was provided according to local guidelines, after completed ERBT, that is, to tumors of the tonsil or base of tongue. Pulse dose rate brachytherapy was given to total doses of 10–25 Gy. A majority of the patients also received chemotherapy, either induction or concomitant therapy. Induction chemotherapy generally consisted of two cycles of Cisplatin and 5-Fluorouracil. Concomitant chemotherapy generally consisted of six cycles of Cisplatin. No statistically significant differences were found between groups regarding oncologic treatment.

2.4 | Intervention

The Shaker HLE intervention consists of isometric and isokinetic head lifts performed while in the supine position.[38] The isometric training included sustained/static head lifts for 60 s three times with rest during 1 min between the lifts. This was followed by the isokinetic training which includes 30 consecutive repetitions of head lifts. The exercise should be performed three times daily during 8 weeks. All patients in the intervention group received individual instructions from a speech language pathologist (SLP) on how to perform the HLE and were also given an instructional video as well as an information pamphlet. During the 8 weeks of training, the patients met the SLP during five sessions for a control of the training performance with telephone follow-ups in between. During the first 2 weeks of the intervention, the SLP contacts were scheduled often, and more seldomly further on during the treatment period. More frequent support was provided in the beginning of the treatment period in order to improve compliance and reduce study drop-outs, based on the results from a previous study.[41] The patients in the intervention group documented the adherence to the recommended exercise in a diary.

All patients, both in the intervention and control group, were offered dysphagia management by SLPs according to local clinical praxis at the time of the study. The type of dysphagia management provided included, for example, advice regarding changing the consistencies of solid food or drink, head positioning such as the chin-tuck, swallowing maneuvers such as the supraglottic swallow, effortful swallow or the Mendelsohn maneuver, and eating/drinking slowly, in small sips or bites and with sips of water in between bites.

2.5 | Videofluoroscopic examination of swallowing

VFSS was performed by a radiologist in collaboration with an SLP. High-resolution images (video matrix 1024×1024) were collected at a rate of 15 frames per second in a lateral projection, with the patient comfortably seated. The field of view included the tip of the tongue anteriorly, the pharyngeal wall posteriorly, the soft palate superiorly, and the seventh cervical vertebra inferiorly. Five different boluses in different amounts and consistencies were tested, where swallowing of the liquid boluses was performed twice. Detailed bolus description is presented in Table 1, where bolus consistency is described in accordance with standardized terminology (the International Dysphagia Diet Standardization Initiative, IDDSI).[48] If a larger bolus volume of the same consistency was deemed not safe for the patient (i.e., risk of severe aspiration), it was excluded. A coin was attached to the patient's chin for calibration purposes.

Blinded analysis of the VFSS was performed independently by two SLPs with several years of professional experience in the field of dysphagia. Prior to analysis,

TABLE 1 Description of amounts and consistencies of boluses given at videofluoroscopic examination of swallowing

Bolus size and consistency	Consistency level according to the IDDSI framework[48]	Contrast
3 ml thin liquid	0	Mixobar Colon 1 g Ba/ml mixed with equal amount of water
20 ml thin liquid, drink freely	0	
5 ml mildly thick	2	Omnipaque 300 mg I/ml. 20 ml Omnipaque mixed with 2 ml instant thickener
3 ml extremely thick	4	Omnipaque 300 mg I/ml. 20 ml Omnipaque mixed with 15 ml instant chocolate pudding mix
Cookie	6	Piece of cookie dipped in mildly thick contrast

Abbreviation: IDDSI, International Dysphagia Diet Standardization Initiative.

they completed a 3-day consensus training, supervised by an experienced phoniatrician. As part of the consensus training, the raters were given clear definitions regarding the boundaries of the different volumes, found in Figures S1 and S2. Measurements of movement were made of representative static images using electronic calipers to correct for the magnification factor. With the help of electronic calipers, a value of the size of the coin in units is obtained. The known dimension of the coin (18 mm) is divided by the number of units to obtain the magnification factor at each occasion. The measured anatomical measurements are then multiplied by the magnification factor to obtain the calibrated measurements. Sixteen percent of the examinations were analyzed twice for intra-rater reliability purposes.

2.6 | Outcome measures

The primary outcome variable was the PAS,[46] a validated and commonly used scale ranging from 1 (material does not enter the airway) to 8 (material enters the airway, passes below the vocal folds, and no effort is made to eject). Initiation of swallowing was evaluated with a scale ranging from 0 (initiation when bolus head is at the posterior angle of ramus mandibulae) to 4 (no appreciable initiation at any location).[49] Vallecular and pyriform sinus residue was evaluated according to a version of the Yale Pharyngeal Residue Scale modified for VFSS[50,51] ranging from 1 (no residue) to 5 (more than 50% of the estimated volume of the vallecula and pyriform sinus). An overall assessment of swallowing function was performed according to the Swallowing Performance Scale (SPS)[52] where 1 represents normal swallowing and 7 represents severe impairment.

Additionally, the following kinematic variables were measured:

1. Anterior hyoid movement, that is, the distance of movement of the hyoid bone (the anterior, inferior border of the body of the hyoid) in a forward direction.[53] The higher positive value, the better the function.
2. Superior hyoid movement, that is, the upward movement of the anterior inferior border of the hyoid bone.[53] The higher positive value, the better the function.
3. Thyrohyoid approximation, that is, the decrease of the distance between the inferior anterior corner of the cricoid cartilage and the inferior anterior corner of the hyoid bone in resting position compared to the position at maximal laryngeal elevation during swallowing.[54] A larger negative value indicates a better thyrohyoid approximation.
4. The maximum width of the UES opening during swallow measured at the narrowest point between vertebrae C3 to C6 at transit of contrast through the UES during swallowing.[54] A high positive value indicates good swallowing function.

All measurements were made from the second attempt of each liquid bolus at baseline and 8 -week follow-up.

2.7 | Patient-reported outcomes

The European Organization for Research and Treatment of Cancer Quality of Life questionnaire, HNC module (EORTC QLQ-H&N35) measures symptoms associated specifically with HNC and its treatment.[55,56] Calculated domain scores range from 0 to 100. On the symptom domains and single items, a score of 100 equates to worst possible symptoms. In this study, only the symptom domains Swallowing and Social eating were included in the report.

2.8 | Statistical analysis

All statistical analyses were performed using SAS version 9.4. All tests were non-parametric and two-tailed with a significance level set to $p < 0.05$.

For descriptive purposes, the mean, standard deviation, median, and range are presented. For categorical variables, number and percentages are presented.

For comparison between groups, Fisher's Exact test was used for dichotomous variables, the Mantel–Haenszel Chi Square test was used for ordered categorical variables, the Chi Square test was used for non-ordered categorical variables, and the Fisher's non-parametric permutation test was used for continuous variables. For within-group comparisons of change, the Fisher's non-parametric permutation test for matched pairs was used for continuous variables, and for ordered categorical variables the Sign test was used. The association between time since radiotherapy and adherence to treatment and PAS and SPS values was calculated using the Spearman correlation coefficient.

The ratings of swallowing function were performed by two raters, and if the two ratings differed, the median of the two ratings was used. Inter- and intra-rater reliability was calculated using percent exact agreement, percent close agreement, and weighted kappa and was interpreted using Landis and Koch guidelines,[57] where 0.21–0.40 indicates fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and 0.81–1.00 almost perfect agreement.

2.9 | Ethical considerations

The study was conducted according to the Declaration of Helsinki and was approved by the Regional Ethical Review Board in Gothenburg, Sweden. All participants gave their written informed consent before inclusion in the study.

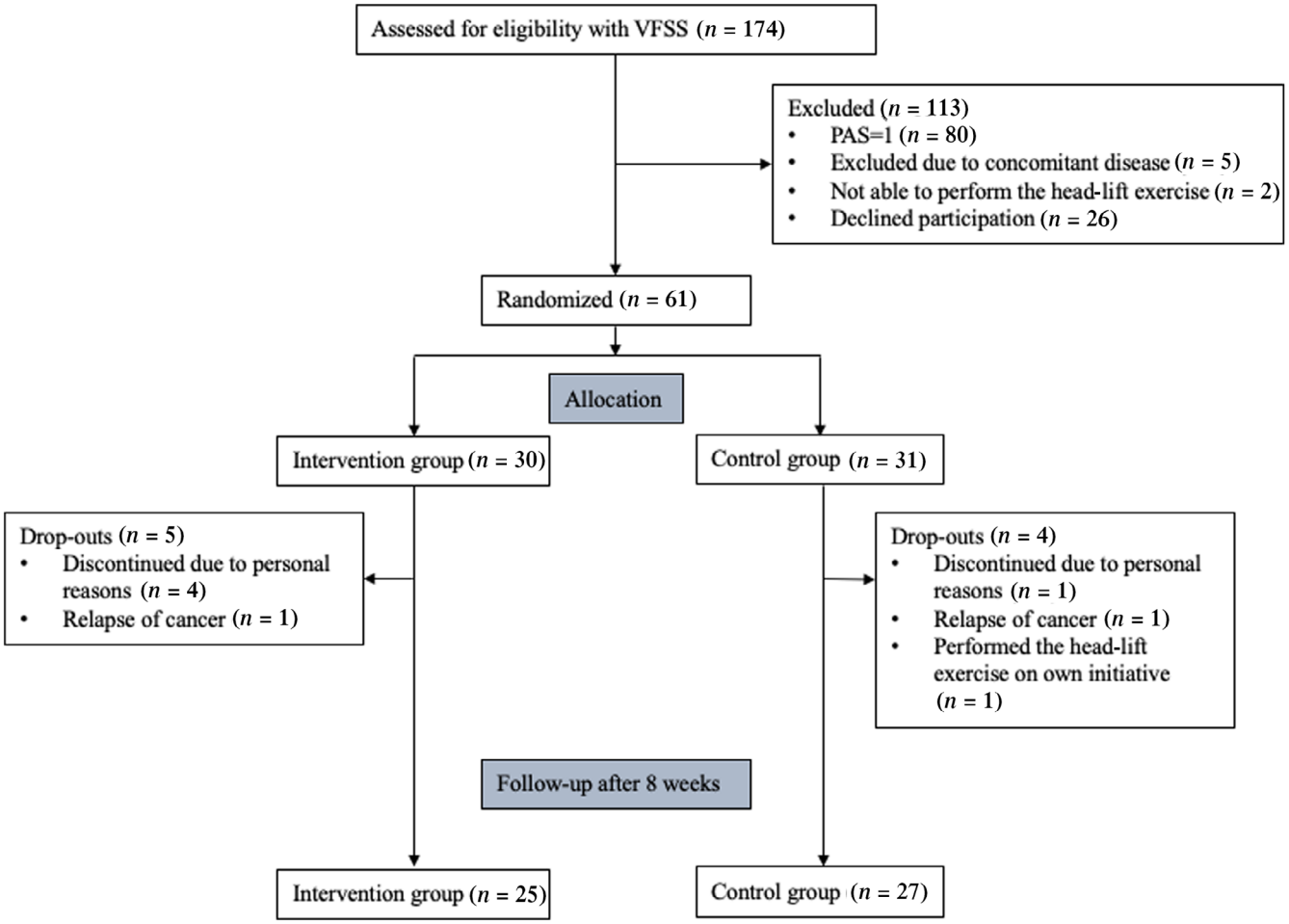

FIGURE 1 Overview of participants. PAS denotes the Penetration Aspiration Score on the initial examination with videofluoroscopic swallowing study (VFSS) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Descriptive characteristics of the participants in the intervention and control group, with comparisons between the groups

Variables	Intervention group ($n = 25$) Mean (SD) Median (min; max)	Control group ($n = 27$) Mean (SD) Median (min; max)	p-value
Age (years)	63.7 (8.4) 63 (45; 80)	63.7 (6.7) 63 (50; 75)	1.00
Time since completion of radiotherapy (months)	11.2 (5.9) 9 (6; 29)	13.0 (8.1) 9 (6; 37)	0.37
	No. of patients (%)	**No. of patients (%)**	***p*-value**
Sex			
Male	18 (72)	21 (78)	
Female	7 (28)	6 (22)	0.75
Smoking status			
Non-smoker	7 (28)	6 (22)	
Quit >12 months ago	11 (44)	14 (52)	
Quit <12 months ago	4 (16)	3 (11)	
Current smoker	3 (12)	4 (15)	0.81
Tumor location			
Tonsil	11 (44)	10 (37)	
Base of tongue	9 (36)	10 (37)	
Hypopharynx	3 (12)	3 (11)	
Larynx	2 (8)	4 (15)	0.87
TNM stage			
I	2 (8)	3 (11)	
II	3 (12)	2 (7)	
III	1 (4)	4 (15)	
IV	19 (76)	18 (67)	0.70
Radiotherapy			
Once daily	23 (92)	24 (89)	
Twice daily	2 (8)	3 (11)	0.54
Chemotherapy			
No chemotherapy	5 (20)	5 (18.5)	
Concomitant	16 (64)	17 (63)	
Induction	4 (16)	5 (18.5)	0.97
Brachytherapy	10 (40)	7 (26)	0.22
Comorbidity[a]			
None	15 (60)	12 (44)	
Mild	9 (36)	10 (37)	
Moderate	1 (4)	4 (15)	
Severe	0 (0)	1 (4)	0.10
Salivary flow			
Normal (>0.7 ml/min)	14 (56)	20 (74)	
Hyposalivation (≤ 0.7 ml/min)	11 (44)	7 (26)	0.17
Feeding tube use			
At baseline	1 (4)	4 (15)	
At 8-week follow-up	1 (4)	4 (15)	0.20

Abbreviations: SD, standard deviation; TNM, tumor location, nodular engagement, metastasis.
[a]According to Adult Comorbidity Index (ACE-27).

3 | RESULTS

One hundred and seventy-four individuals were assessed for eligibility during the years 2011–2018. Sixty-one patients were included in the study and randomized into either intervention group ($n = 30$) or control group ($n = 31$). An overview of patients is shown in Figure 1. Fifty-two patients were eligible for analysis, 25 in the study group, and 27 in the control group. Sociodemographic and clinical data of the recruited patients are presented in Table 2. There were no statistically significant differences between groups regarding any of the patient characteristics listed in Table 2. Drop-out analyses were performed where the patients included in the intervention and control groups, respectively, were compared with patients who were randomized but did not complete their participation. The drop-out analyses did not reveal any statistically significant differences in any of the variables reported in Table 2 in either group.

Participants in both groups were offered dysphagia management according to local clinical praxis as described in Table 3. There were no statistically significant differences between the groups regarding the standard dysphagia management.

The participants in the intervention group documented adherence to training daily in a diary. The diaries revealed patient adherence to treatment at between 80% and 93% of the recommended isometric and isokinetic training, with somewhat lower compliance during the first 3 weeks and thereafter a bit higher adherence during the following weeks (Table 4). Patients performed on average 2.6–2.8 of the prescribed three training sessions per day, with the highest exercise rates during Weeks 4–7.

Reasons according to the treatment diaries for not being able to complete or failing to perform the HLE as prescribed are presented in Table S1. Reasons for not performing the prescribed exercise were either not explicitly described (0.2%–19.8%), due to lack of time (0.8%–3.4%), inability to cope (0%–15.4%), or muscle soreness or pain after the exercise (0%–5.7%). Side effects of the treatment were reported during all weeks, but more commonly during the first 3 weeks of the treatment period (Table S1). No serious adverse events were reported.

At baseline, aspiration was present in 13 (25%) of the 52 patients. Residue in the vallecula or pyriform sinuses was present (<25% residue or more) in 48% of the baseline ratings. There were no statistically significant differences between the study groups at baseline or after the 8-week treatment period with regard to worst overall PAS and SPS (Table 5). Furthermore no significant differences in PAS scores for the different boluses were observed between groups, with the exception of the cookie bolus (Table 5). The control group demonstrated a statistically significant improvement of the PAS on cookie bolus ($p = 0.012$) compared to the intervention group at 8 weeks.

At baseline, the kinematic variables did not differ significantly between the study groups with the exception of superior hyoid movement, where the intervention group demonstrated less upward movement than the controls on 20 ml thin liquid and 5 ml mildly thick liquid ($p < 0.05$). There were no statistically significant changes after treatment within the intervention group for any of the kinematic variables. The control group showed a decrease in upward hyoid movement amplitude ($p = 0.022$) and a slightly improved maximal UES opening ($p = 0.047$) on the cookie bolus on the VFSS at 8 weeks compared to baseline. There were no significant differences regarding the change in any of the evaluated variables between the two study groups after 8 weeks. Detailed results are reported in Table S2.

The assessment of initiation of swallowing and residual after swallowing demonstrated no statistically significant differences at baseline or follow-up for any bolus except for sinus pyriform residue at follow-up, where the control group presented with a worse value than the intervention group. There were no statistically significant differences regarding initiation or vallecular or pyriform

TABLE 3 Description of speech language pathologist management of dysphagia

Standard care	Intervention group No. of patients (%) ($n = 25$)	Control group No. of patients (%) ($n = 27$)	*p*-value
Advice about food			
No	8 (32)	6 (22)	
Yes	17 (68)	21 (78)	0.54
Advice about drinking			
No	16 (64)	10 (37)	
Yes	9 (36)	17 (63)	0.10
Head position			
No	21 (84)	22 (81)	
Yes	4 (16)	5 (19)	1.00
Swallowing maneuver			
No	23 (92)	25 (93)	
Yes	2 (8)	2 (7)	1.00
Other advice[a]			
No	19 (76)	17 (63)	
Yes	6 (24)	10 (37)	0.38

[a]Other advice includes eating/drinking slowly, drink/eat in small sips/bites, swallow repeatedly, taking small sips between bites.

TABLE 4 Adherence to training and reported adverse effect, average exercise week by week

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Total weeks 1–8
% of isokinetic (mean)	80.0	86.3	86.8	90.5	91.7	91.0	90.2	81.4	87.2
% of isokinetic (median, range)	90.5 (35.0–100)	95.2 (0–100)	95.2 (0–100)	98.4 (0–100)	100 (0–100)	95.2 (0–100)	95.2 (0–100)	94.9 (0–100)	89.8
% of isometric (mean)	80.6	88.9	86.6	89.9	91.0	91.0	89.8	80.2	87.3
% of isometric (median, range)	90.5 (10.6–100)	95.2 (0–100)	95.2 (0–100)	97.6 (0–100)	100 (0–100)	97.4 (0–100)	95.2 (0–100)	95.2 (0–100)	90.2

Note: One participant only performed the exercise during the first week. Therefore, the range starts at 0 during Weeks 2–8.

sinus residue within or between the groups. The results are described in detail in Table S3.

Inter- and intra-rater agreement analyses are presented in Table 6. Inter-rater reliability demonstrated mainly moderate to substantial agreement. Intra-rater reliability demonstrated substantial to almost perfect agreement for both raters.

There were no significant correlations between percentage of adherence to treatment and the changes in PAS from baseline to follow-up. Neither were there any significant correlations between PAS or SPS and time since radiotherapy, except for a moderate positive correlation between the PAS on 5 ml mildly thick liquid and duration from radiotherapy in the intervention group (Spearmans rho = 0.68, $p = 0.026$).

The results from the selected domains of the EORTC QLQ-H&N35 are found in Table 7. No statistically significant differences were found between the intervention and control group at either baseline or follow-up of the Swallowing and Social eating domains. Within-group analysis revealed a statistically significant improvement in the Swallowing domain in the intervention group following intervention. Otherwise, no significant differences were found within the two study groups regarding self-reported swallowing function when comparing baseline and follow-up.

4 | DISCUSSION

The present study aimed to evaluate if the Shaker HLE could improve swallowing function in patients treated with radiotherapy for HNC, measured with VFSS and self-perceived swallowing and eating as measured by the EORTC QLQ-H&N35. There were no consistent significant differences in swallowing function between or within the two study groups before or after treatment. Thus, the findings in this study do not support HLE as an efficient treatment for dysphagia after radiotherapy in patients with HNC.

The cohort included in the present study seemed to be representative of the HNC population when comparing the aspiration rates. Before start of intervention, aspiration, that is, a PAS of 6 or more, was present in almost 25% of the participants. This number corresponds well to a recent meta-analysis that reported aspiration in 17%–29% of patients at 3–6 months following radiotherapy.[58] However, in the present study, pharyngeal residue was present to some extent in 48% of the cases, which is lower than the number observed in the same meta-analysis[58] at 6 months following radiotherapy (62%). This difference is possibly due to different methodology of rating of residue and different combinations of tumor localizations.

TABLE 5 Worst overall PAS scores, overall SPS scores, and PAS scores for each bolus for the intervention and control groups

	Intervention group ($n = 25$)				Control group ($n = 27$)				
	Baseline	Follow-up	Change between baseline and follow-up	Change within group	Baseline	Follow-up	Change between baseline and follow-up	Change within group	
	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)		
	Median (min; max)	Median (min; max)	Median (min; max)	*p*-value	Median (min; max)	Median (min; max)	Median (min; max)	*p*-value	*p*-value of differences of changes between groups
Worst overall PAS[a] score[b]	4.3 (2.1) 3.0 (2.0; 8.0)	3.4 (1.8) 3.0 (1.5; 8.0)	−0.9 (2.4) 0.0 (−6.5; 5.5)	0.094	4.2 (2.1) 3.0 (2.0; 8.0)	3.7 (1.7) 3.0 (1.0; 7.5)	−0.5 (1.9) 0.0 (−5.0; 4.0)	0.24	0.53
Overall SPS[b,c]	3.6 (1.2) 3.5 (1.5; 6.0)	3.2 (1.3) 3.0 (1.0; 6.0)	−0.4 (0.9) 0.0 (−3.0; 0.5)	0.45	3.8 (1.5) 4.0 (1.0; 7.0)	3.6 (1.5) 3.5 (1.0; 6.5)	−0.2 (1.0) -0.5 (−2.0; 1.5)	0.19	0.43
PAS 3 ml thin liquid[b]	2.9 (1.9) 2.0 (1.0; 7.5)	2.2 (1.5) 2.0 (1.0; 7.0)	−0.6 (1.7) -0.5 (−5.5; 2.5)	0.064	2.7 (1.2) 2.5 (1; 7.5)	2.5 (1.7) 20. (1.0; 7.5)	−0.2 (2.0) 0.0 (−4.5; 4.5)	0.52	0.42
PAS 20 ml thin liquid drink freely[b]	3.7 (2.2) 3.0 (1.0; 8.0)	3.1 (1.7) 3.0 (1.0; 7.5)	−0.6 (2.4) 0.0 (−6.5; 5.5)	0.63	3.8 (2.1) 3.0 (1.0; 8.0)	3.2 (1.2) 3.0 (1.0; 7.0)	−0.6 (2.1) −0.3 (−5.0; 4.0)	0.50	1.00
PAS 5 ml mildly thick liquid[b]	2.1 (1.3) 1.5 (1.0; 6.5)	2.1 (1.0) 2.0 (1.0; 5.0)	0.0 (0.9) 0.0 (−2.5; 1.5)	1.00	2.3 (1.5) 2.0 (1.0; 7.0)	2.4 (1.4) 2.0 (1.0; 7.0)	0.1(1.3) 0.0 (−3.5; 3.0)	0.33	0.81
PAS 3 ml extremely thick[b]	1.4 (0.8) 1.0 (1.0; 4.0)	1.7 (1.5) 1.0 (1.0; 8.0)	0.4 (1.5) 0.0 (−1.5; 7.0)	0.29	1.4 (0.6) 1.0 (1.0 3.5)	1.3 (0.5) 1.0 (1.0; 3.0)	0.0 (0.4) 0.0 (−1.0; 0.5)	0.55	0.43
PAS Cookie[b]	1.2 (0.4) 1.0 (1.0; 2.5)	1.3 (0.4) 1.0 (1.0; 2.5)	0.1 (0.4) 0.0 (−0.5; 1.5)	0.73	1.5 (0.6) 1.0 (1.0; 2.5)	1.2 (0.4) 1.0 (1.0; 2.5)	-0.3 (0.5) 0.0 (−1.5; 0.5)	0.039	0.012

Note: All measurements were made by two raters, and the median of the two ratings was used in the analysis.

Abbreviations: PAS, Penetration Aspiration Scale; SPS, Swallowing Performance Scale.

[a]PAS (1–8). One indicates swallowing without penetration/aspiration. A higher score indicates worse swallowing function.

[b]No statistically significant differences between groups at baseline or follow-up.

[c]SPS (1–7). One indicates normal swallowing. A higher score indicates worse swallowing function, Grades 5–7 indicate dysphagia with aspiration of different degrees.

TABLE 6 Inter- and intra-rater reliability for the Penetration Aspiration Scale for the two raters

	Inter-rater reliability		Intra-rater reliability rater 1		Intra-rater reliability rater 2	
	Weighted kappa	PEA (PCA)	Weighted kappa	PEA (PCA)	Weighted kappa	PEA (PCA)
3 ml thin	0.67	51.9 (88.5)	0.74	76.5 (94.1)	0.97	94.1 (100)
20 ml thin	0.73	57.7 (76.9)	0.69	58.8 (76.5)	0.80	70.6 (76.5)
5 ml mildly thick	0.48	55.8 (84.6)	0.68	76.5 (100)	0.85	82.4 (94.1)
3 ml extremely thick	0.23	63.5 (88.5)	0.81	76.5 (100)	0.95	94.1 (100)
Cookie	0.48	63.5 (75.0)	0.79	82.4 (94.1)	0.80	94.1 (94.1)

Note: Sixteen percent of evaluations were performed twice allowing for intra-rater reliability analysis. Interpretation of Kappa statistics: 0.21–0.40 indicates fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and 0.81–1.00 almost perfect agreement.
Abbreviations: PCA, percent close agreement; PEA, percent exact agreement.

Previous studies investigating the efficacy of the HLE in normal subjects have resulted in improved anterior movement of the hyoid bone, opening of the UES and thyrohyoid shortening.[38–41,43,59] Studies of stroke patients with dysphagia demonstrated improvement of penetration-aspiration scores following exercise with the Shaker HLE.[60,61] Additionally, a small randomized study including patients with dysphagia due to stroke or HNC found that there was significantly less post-swallow aspiration following 6 weeks of the HLE.[42] The results of the present study differed, since no statistically significant improvements were seen in any of the measured variables. It is possible that the difficulties found in patients treated for HNC are of a different character than patients after for example, a stroke, due to the physiological differences following fibrosis, with stiffness and a high prevalence of pharyngeal residue after swallowing.[58] The intervention in the present study was set to begin at least 6 months following completion of radiotherapy, in order to reduce the effect of spontaneous improvement due to recovery after radiotherapy. However, it is possible that the changes which occurred following radiotherapy, such as stiffness and fibrosis of the structures, were the primary causes of the observed swallowing difficulties (e.g., residue in the vallecular and sinus pyriform spaces) yet could not be targeted by the HLE. In comparison, Langmore et al.[62] evaluated the efficacy of electrical stimulation (e-stim) together with swallowing exercises versus swallowing exercises only (control group) in patients with dysphagia following treatment for HNC in a randomized controlled study. This study found few statistically significant differences after intervention, except better outcome regarding the PAS score in the control group. They concluded that neither e-stim nor swallowing exercises alone were effective in terms of dysphagia intervention. This suggests that once post-radiation dysphagia has occurred, current rehabilitation methods are limited in improving swallowing function. Similarly, the findings in the present study indicate that swallowing difficulties related to radiotherapy in the head and neck region are difficult to improve by using HLE therapy.

To a certain degree, the present study also confirms the results of the pilot study preceding this randomized study.[45] Likewise, no differences were seen before and after HLE treatment with regard to the instrumental swallowing evaluation, but some change for the better was noted in the patient-reported outcome. The present study included data on the EORCT QLQ-H&N35 domains Swallowing and Social eating. In the HLE group, improvement was seen in the Swallowing domain of the questionnaire, indicating a self-perceived decrease of swallowing difficulties after treatment. This change, however, was not statistically different compared to the function score in the control group, which indicates that the HLE did not improve self-perceived swallowing function more than standard dysphagia management.

Although our results suggest that the HLE does not improve objectively measured swallowing function after radiotherapy more than the standard management, it cannot be ruled out that the HLE could be of benefit for prevention of dysphagia in the HNC population, or used in combination with other intervention efforts. HLE is often included in preventive exercise programs for swallowing in HNC, which have resulted in less need for feeding tube use, greater tolerance of oral intake and improved self-perceived symptom experience.[63–65] However, since the HLE was combined with several other exercises it is impossible to determine to which extent, if any, it contributes proactively to the improvement in swallowing function.

The HLE focuses on exercising the extrinsic neck muscles, under the hypothesis that this consequently would improve swallowing function. In a normal swallow, the infra- and suprahyoidal muscles are activated.[66–68] The Shaker HLE has been evaluated in several studies regarding which muscles are involved the exercise, where the infra-, suprahyoidal, and the sternocleidomastoid muscles

TABLE 7 Results of selected domains of the European Organization for Research and Treatment of Cancer Head and Neck cancer module for the intervention and control groups

	Intervention group ($n = 25$)				Control group ($n = 27$)				
	Baseline	Follow-up	Change between baseline and follow-up	Change within group	Baseline	Follow-up	Change between baseline and follow-up	Change within group	*p*-value of differences of changes between groups
	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)		
	Median (min; max)	Median (min; max)	Median (min; max)	*p*-value	Median (min; max)	Median (min; max)	Median (min; max)	*p*-value	
Swallowing[a,b]	28.67 (23.46) 25.00 (0.00; 83.33)	21.33 (20.98) 16.67 (0.00; 75.00)	−7.33 (16.55) -8.33 (−50; 16.67)	0.041	29.63 (23.27) 33.33 (0.00; 75.00) $n = 27$	23.77 (23.19) 16.67 (0.00; 100.00) $n = 27$	−5.86 (19.31) 0 (−41.67; 33.33) (−13.46; 1.92) $n = 27$	0.15	0.82
Social eating[a,b]	24.33 (24.99) 16.67 (0.00; 91.67)	19.33 (26.10) 8.33 (0.00; 100.00)	−5.00 (16.32) 0 (−50; 25) (−11.67; 1.67)	0.17	20.99 (18.69) 16.67 (0.00; 58.33)	18.52 (23.49) 8.33 (0.00; 100.00)	−2.47 (14.02) 0 (−25; 50)	0.47	0.62

[a]No statistically significant differences between groups at baseline or follow-up.
[b]A higher value on the symptom domains indicates a higher degree of symptoms, that is, worse.

have been shown to be activated during the HLE,[69,70] indicating that the exercise should have a positive impact on swallowing function. However, several studies investigating the effects of the HLE compared to the chin tuck against resistance (CTAR) found that the HLE did not increase maximal suprahyoid muscle activation.[71–73] This could be one explanation to why the present study did not find any significant improvements of swallowing function, that is, that the Shaker HLE is not specifically strengthening the muscles active in swallowing.

Radiotherapy-induced fibrosis is generally said to be difficult to halt once the fibrotic process is activated.[7] A study investigating the presence of fibrotic tissue in HNC found that approximately 70% of patients were found to have some degree of fibrotic tissue as early as 3 months following radiotherapy, a number that remains also after 12 months.[74] Therefore, in these patients, where the musculature is encased in stiff fibrotic tissue, which is not likely made more pliable, rehabilitation through exercise is more difficult, since the exercise needs to strengthen the musculature enough so that they may possibly push through the fibrotic tissue. This may be one of the reasons that the HLE did not improve the swallowing outcomes, the exercise was not enough to strengthen the muscles in order to push through the stiff fibrotic tissue. In order to cause physiological changes crucial for successful rehabilitation in other muscle groups, such as the limbs, suprahyoid, and upper esophageal sphincter, muscle overload, among other parameters, is necessary.[23] A sign of muscle overload is neuromuscular fatigue induced by the exercise.[75] In the present study, only a few participants reported fatigue of the muscles following the exercise, especially at the beginning of the treatment period. It could possibly be beneficial to increase the resistance gradually by, for example, increasing the number of repetitions and time in isometric exercise, or, as previously suggested, perform the CTAR.[69]

The adherence to the HLE treatment was high, above 80% throughout the whole treatment period. The patient-reported exercise was, as expected, a little lower at the beginning, but improved over time. The drop-outs that occurred during this period were not due to the experiences of general fatigue, as previously reported,[45] but for other reasons as stated in Figure 1. This indicates that the exercises and study protocol, with more frequent contacts with an SLP during the first weeks of exercise as suggested by Easterling et al., was successful in targeting exercise adherence and preventing drop-out.[41]

A limitation of this study is that PAS of at least 2 (i.e. penetration to the laryngeal vestibule) on the initial VFSS examination was selected as an inclusion criterium. Thus, individuals with less severe dysphagia after HNC treatment as well as individuals with more severely

affected swallowing function were included. It may be that this gave less room for improvement than if the PAS for inclusion would have been set higher, that is, inclusion of only more severely affected patients. The power calculation of this study was made solely on the expected changes in PAS, which also could be considered a limitation. Moreover, the random allocation did not include time since oncologic treatment which may have had an impact on the results, since a recent study has found that swallowing therapy that was initiated within 1 year after radiotherapy resulted in better outcomes than for patients with later swallowing intervention.[76] However, no statistically significant differences were found between the groups regarding time from oncologic treatment. In the present study, several statistical analyses were made, while few statistically significant results were observed. Therefore, one cannot rule out that the significances that were found were due to chance, and not to true change. Another limitation is that the compliance to the advice given as standard dysphagia management was not measured, so we do not know how well the patients actually performed the prescribed maneuvers or used the techniques recommended to them.

A significant strength of the study is that it is the first randomized study on the therapeutic effect of HLE in dysphagia after radiotherapy of HNC patients. Additionally, the included cohort corresponds well to some of the most common tumor localizations within the head and neck area, and the results should therefore be representative to the HNC population in general.

5 | CONCLUSIONS

The results of the present study indicated that the Shaker HLE did not significantly improve swallowing function in patients treated with radiotherapy for tumors of the tonsils, base of tongue, larynx and hypopharynx, as measured by VFSS and patient reported outcomes. Therefore, the HLE should not be offered as a standalone dysphagia rehabilitation in this population. It is possible that the HLE given at an earlier stage, or in conjunction with other exercises might have resulted in different outcomes. However, this is an important result in order to prevent patients from performing unnecessary exercise, when they could rather focus on the symptoms and interventions that are effective, where the standard treatments such as head positioning, consistency alterations, and other swallowing maneuvers seem to maintain a stable swallowing function. Effective intervention for dysphagia remains needed; therefore, future studies investigating the effect of other intervention methods are warranted.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

Data not available due to privacy/ethical restrictions.

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SUPPORTING INFORMATION

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