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Shaker Exercise Rehabilitation in Head and Neck Cancer and Stroke Patients with Dysphagia - A Pilot Study

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Abstract

Background: Dysphagia is a common sequela post (chemo) radiotherapy ([C]RT) for head and neck cancer (HNC) and after stroke. The Shaker maneuver is a promising rehabilitative exercise for improvement of swallowing function by means of strengthening neck musculature. This pilot study primarily aimed to evaluate the feasibility of the Shaker exercise and, secondarily, to evaluate its impact on dysphagia and health-related quality of life in patients with radiation-induced or stroke-related dysphagia.

Method: A prospective pilot study incorporating six patients treated with (C)RT for HNC and four patients post stroke. Compliance to the training was documented in an exercise diary. Outcome measures included videoradiography (VRG), fiberendoscopic evaluation of swallowing (FEES) and patient-reported outcomes including the European Organisation of Research and Treatment for Cancer (EORTC) Quality-of-Life Questionnaire Core 30 (QLQ-C30) and Head and Neck 35 Module (H&N35) and M.D. Anderson Dysphagia Inventory (MDADI). Patients underwent Shaker training for eight weeks. Assessment was performed pre and post training with an additional follow-up at three months post training for patient-reported outcomes.

Results: Nine out of ten patients were able to perform the Shaker exercise. Patients reported improved scores in all domains of the MDADI and improvements in the EORTC Social eating post-training which remained or improved further at the three month follow-up. Similar results were not reflected by the objective measurements VRG and FEES, which demonstrated diverging results.

Conclusion: The intensified and extended Shaker exercise program was easy to learn and possible to perform. Improvements were reflected in the patient-reported outcomes but instrumental assessment showed diverging results and missing data making conclusions difficult to draw. To assess the actual effect of the Shaker exercise on dysphagia, randomised controlled studies are needed with a larger number of patients in more homogenous groups.

Key words: Dysphagia; Shaker exercise; Head and Neck cancer; Stroke patients; MDADI

List of abbreviations: (C)RT: (Chemo)Radiotherapy; HNC: Head and Neck Cancer; HRQL: Health- Related Quality of Life; UES: Upper Esophagus Sphincter; VRG: Videoradiography; PAS: Rosenbeck Penetration Aspiration Scale; ACE-27: Adult Comorbidity Evaluation-27; CCI: Charlson Comorbidity Index; FEES: Fiber Endoscopic Evaluation of Swallowing; PRO: Patient Reported Outcome; SLP: Speech Language Pathologist; AP: Anterioposterior; EORTC QLQ C30: The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; H&N35: Head and Neck 35 Module; MDADI: The M. D. Anderson Dysphagia Inventory; SPS: Swallowing Performance Scale

Introduction

Dysphagia is a commonsequela after (chemo) radiotherapy ([C]RT) for head and neck cancer (HNC) and after stroke [1,2]. Around 40% of patients with advanced HNC (stadium III and IV) experience dysphagia post treatment [3]. After a stroke, swallowing problems are reported in 37-78%, depending on assessment method and length of follow up [2]. Dysphagia complications can be severe and include aspiration pneumonia, malnutrition as well as permanent or long term feeding tube dependence [2,4] which decreases health-related quality of life (HRQL) [5] and increases the health economic burden [6].

Management of dysphagia is often compensatory, i.e. dietary, including individual advice regarding food consistency, eating rate and bolus size. Additionally, a large amount of postures, maneuvers and exercises that enhance swallowing exist and are part of the therapeutic arsenal. Studies have shown that the sarcopenic and/or neurally damaged neck- and tongue muscles of healthy elderly and of stroke patients can be strengthened by exercise, thereby improving swallowing function [7-10], enhancing HRQL and lowering the health economic costs [7]. In recent years, one promising treatment for dysphagia improvement is the Shaker

maneuver, due to that it is seemingly easy to perform and has few side effects [8,11]. It 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 upper esophagus sphincter (UES) [12,13].

The primary aim of this pilot study was to evaluate the feasibility of the Shaker exercise. Secondarily, the aim was to evaluate its impact on dysphagia and HRQL in patients with radiation induced dysphagia and stroke related dysphagia.

Materials and Methods

Study subjects

Patients who, as primary treatment, had received curatively intended (C)RT for oropharyngeal cancer (tonsil and base of tongue), cancer of the hypopharynx and laryngeal cancer were identified from patient records at Sahlgrenska University Hospital, Gothenburg, Sweden. The stroke patients were recruited from the Department of Logopaedics and Phoniatrics. Identified patients were assessed using four study specific questions regarding difficulties in eating, drinking or swallowing and/or coughing while eating. The patients reporting such symptoms were offered to undergo a Videoradiography examination of swallowing (VRG). Patients with penetration or aspiration to the larynx according to the Rosenbeck Penetration Aspiration Scale (PAS) [14], i.e. at least PAS 2, were offered to participate in the study, provided that six months had passed since HNC treatment or after the stroke incident.Exclusioncriteria were treatment (surgery or (C)RT) for previous HNC, tracheostomy, additional neurologic or neuromuscular disease, prior dysphagia problems and patients under the age of 18.

Study design

Sociodemographic and clinical data were collected from the patients and patient records, Table 1. To assess comorbidity, the Adult Comorbidity Evaluation-27 (ACE-27) [15,16] was used for HNC patients and the Charlson comorbidity index (CCI) [17] for stroke patients. All study participants underwent a fiber endoscopic evaluation of swallowing (FEES) and VRG examination. Questionnaires regarding dysphagia and HRQL were filled out. The Shaker exercise was then performed for eight weeks after which VRG and FEES were performed again and the questionnaires filled out. All patients were instructed to fill out an exercise diary given to them at the start of the exercise programme. The daily amount of exercise and any comments on the exercise was to be noted in the diary. The patients were then instructed to continue exercising three days weekly until the Patient Reported Outcome (PRO) follow-up three months after the exercise.

Patient HNC	Gender	Age	Disorder	TNM /stage	Months after CRT at inclusion	ACE 27
1	male	50	tonsil cancer	T4N3M0/IV	26	0
2	female	57	tonsil cancer	T1N2M0/IVa	10	0
3	male	67	tonsil cancer	T3N1cM0/IV	68	2
4	female	68	base of tongue cancer	T1N2aM0/IVa	14	1
5	male	68	tonsil cancer	T2N2M0/IVb	30	0
6	male	81	tonsil cancer	T3N3M0/IVa	28	2
Patient Stroke	**Gender**	**Age**	**Disorder**	**Stroke**	**Months after Stroke at inclusion**	**CCI**
7	male	61	right cerebral hemisphere stroke	hemorrhagic	36	0
8	male	69	right cerebellar hemisphere- and brainstem stroke	ischemic	17	1
9	female	72	left cerebral hemisphere stroke	ischemic	6	3
10	male	73	right cerebral hemisphere stroke	ischemic	19	0

HNC= Head and Neck Cancer; CRT= Chemoradiotherapy; ACE-27= Adult Comorbidity Evaluation 27; CCI= Charlson Comorbidity Index

Table 1: Patient demographics for HNC patients and stroke patients

The Shaker exercise

The Shaker exercise consists of isometric and isokinetic head lifts from the supine position where the patient is instructed to look at her toes without raising her shoulders, Figure 1. First, three one-minute sustained head lifts with one minute rest in between is performed, followed by 30 consecutive repetitions of head raisings [8,10]. For eight weeks, the patients exercised three times daily,

documenting the managed amount in an exercise diary. A speech language pathologist (SLP) individually instructed the patients in how to perform the Shaker exercise by showing the exercise on DVD and assist during three exercise sessions during the first two weeks. From the third week the SLP assisted at an exercise session every two weeks and had follow-ups by telephone in between.

Videoradiography

Fluoroscopy was performed with digital storage of high-resolution images (video matrix 1024 x 1024) at a rate of 15 frames per second. The oro- and hypopharynx were examined in the lateral and frontal projection and the oesophagus in the frontal position. For calibration purposes, a coin was attached under the chin (lateral projection) or on the side of the neck (frontal projection). The field of view in the lateral projection included the tip of the tongue anteriorly, the pharyngeal wall posteriorly, the soft palate superiorly, and the seventh cervical vertebra inferiorly. Two gastrointestinal radiologists trained in functional assessment of swallowing performed the investigations in cooperation with a SLP.Six different boluses were observed and analysed on the second swallow. Four boluses were observed in the lateral view (3 and 20 ml of barium liquid (thin) and 3and 5 ml of a thicker barium consistency) and two in the anterioposterior (AP) view (3 and 20 ml of barium liquid).

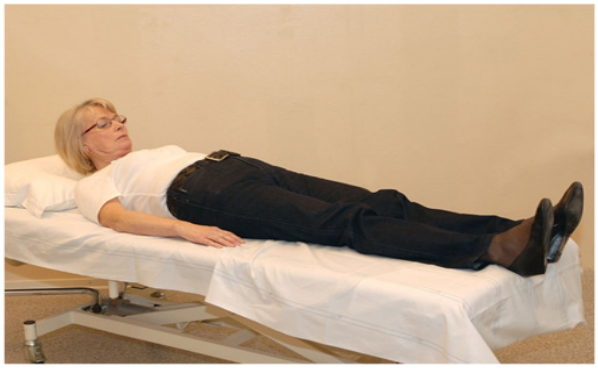

Figure 1: The Shaker exercise
A speech language pathologist is demonstrating how to perform the Shaker exercise, lifting her head from the supine position so that she is able to look at her toes without raising her shoulders. Used with permission

Image analysis

Videofluoroscopic recordings before and after the Shaker rehabilitation were analysed by two radiologists in a blinded fashion according to a predefined evaluation protocol. Discrepancies in the interpretation of findings between the observers were resolved by consensus. The digital technique used allowed for detailed evaluation of the act of swallowing by the combined use of slow motion analysis frame-by-frame and of static images. Objective indices of the swallowing function included timing of events and amount of movement. Timing characteristics were identified by frame counting (0.07 second interval between images). Measurements of movement were made at representative static images using electronic callipers correcting for the magnification factor.

Fiber endoscopic evaluation of swallowing

Fiberendoscopic evaluation of swallowing was performed according to Langmore, *et al.* [18]. An Olympus ENF-P4 fibernasoendoscope (Olympus Inc) with a diameter of four mm attached to a Wolf light source was used. The investigation was video-documented using a Wolf video camera. All subjects were given boluses of different volumes and consistencies according to a standard FEES protocol, i.e. 5 and 20 ml thin liquid, 5 and 10 ml of thick liquid and 1/4 size of a biscuit. A blinded, perceptual evaluation of the FEES videos pre- and post treatment were made in randomized order by two observers. Discrepancies in the interpretation of findings between the observers were resolved by consensus.

Patient Reported Outcome

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C30) [19] is a cancer-specific, multidimensional questionnaire which evaluates HRQL in cancer patients. The questionnaires consist of five functional domains, three symptom scales, six single items commonly reported by cancer patients and a global health scale, totalling 30 questions describing symptoms and functional level during the past week. To address additional symptoms specifically associated with HNC and its treatment, a complementary 35-item module, the EORTC QLQ-H & N35 [20], can be used. Calculated scalescores range from 0-100. A score of 100 represents maximum functioning considering the functioning scales and the global health scale, whereas a higher score for the symptomscales and single items, indicates an increased symptom burden. A change in score over time of ≥ 10 points can be interpreted as clinically significant [21]. To evaluate the HRQL in this study, questions typically associated with dysphagia were used.

The M. D. Anderson Dysphagia Inventory

The M. D. Anderson Dysphagia Inventory (MDADI) [22,23] is used to evaluate the impact of dysphagia on HRQL in patients who have undergone treatment for HNC. The questionnaire consists of nineteen questions divided into four subdomains; global, emotional, functional and physical and has a recall period of one week. When calculated, the scores range from 20 to 100, where 20 is the worst imaginable swallowing function and 100 optimal functions.

Outcome measures

The VRG variables included PAS, superior and anterior movement of the hyoid and larynx, UES measurements (maximum width and duration of opening) and were measured as previously described in the literature [13,14,24,25]. The FEES variables included

PAS and oropharyngeal residue evaluation. The degree of residue in the vallecula and sinus piriformis after the bolus was assessed on a four-point scale were one denotes no residue and four substantial residues, either filling the space to capacity or overflowing the available space [26-28]. An overall assessment of swallowing function was performed using the Swallowing Performance Scale (SPS), a 7-point scale were 1 denotes normal swallowing function and 7 severe dysfunction i.e. aspiration and nil per os [29]. Each scale step in all the rating scales were defined and explained in writing. Other outcomes included the patients´ self- perceived dysphagia and HRQL.

Statistical analyses

Descriptive statistics and analyses were presented with mean value and standard deviation. Amount of exercise was presented as percent. The software used for statistics were Microsoft Office Excel 2007. Since only a few patients were included in this pilot study, no statistical significance analyses were performed.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Regional Ethical Review Board in Gothenburg, Sweden. The authors report no conflict of interest.

Results

Subjects

The patient demographics are presented in Table 1. Ten patients were identified and included in the study, six with HNC and four with stroke. Seven were previous smokers, two non- smokers and one was still smoking. All included HNC patients had received CRT. At inclusion, nine of the patients had a feeding tube, three for supplementary nutrition (one HNC patient and two stroke patients) and six for complete nutrition (three HNC patients and three stroke patients). The remaining patient (HNC) was able to eat all types of consistencies except for crispy texture. After the exercise one of the subjects (a HNC patient) was able to use the feeding tube for partial instead of complete nutrition. The remaining subjects did not change their mode of nutrition.

Feasibility of the Shaker exercise

All patients were able to perform the Shaker exercise. Eight patients completed all eight weeks of exercise. One of the stroke patients discontinued exercising after seven weeks, due to a misunderstanding regarding the duration of the treatment period. One subject (stroke) chose to withdraw from the study during the first week due to general fatigue. The percent of achieved exercise per week for each patient is presented in Figure 2A and 2B. Five patients could perform all, or almost all, of the exercises, both isometric and isokinetic, already during the first week of training. Reasons for lack of compliance towards the end of the treatment period were lack of time to exercise (n=5), or forgetting to exercise (n=2). The remaining patients started out with a lower degree of exercise, i.e. as much as they could manage, but increased the amount of exercise over time. A sore neck (n=3), headache (n=1),

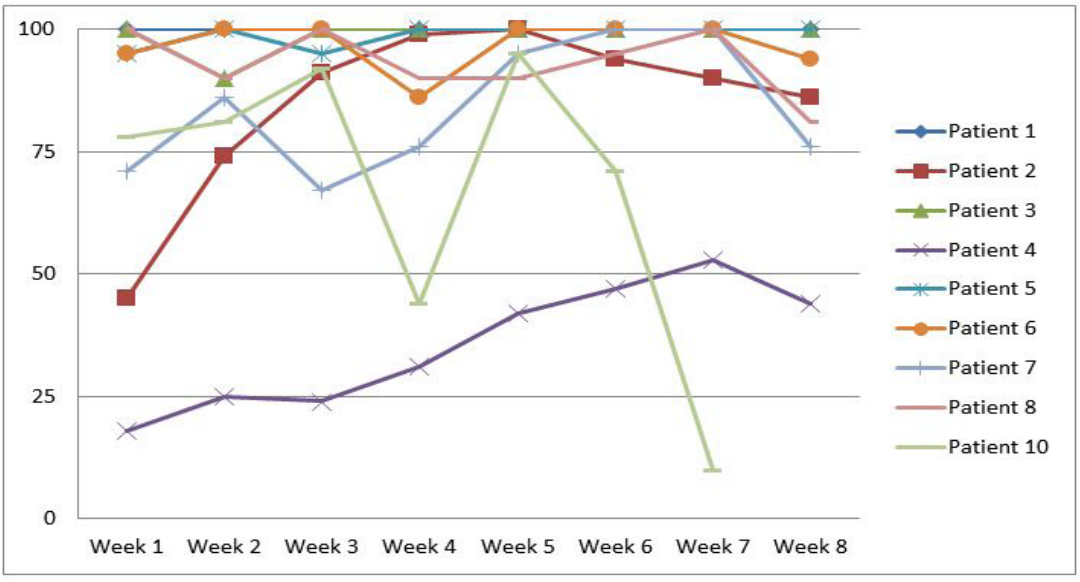

Figure 2A: Percent of managed isometric Shaker exercise per week for each patient
This figure describes the amount of the predefined time of sustained head-raisings achieved for each patient each week of the eight weeks Shaker training program in percent

nausea (n=1), and general fatigue (n=1) were reported causes for not being able to perform 100% of the training sessions. One of the patients reported all four of these symptoms and one gave no reason. The isometric training was slightly more difficult for three subjects, whereas one subject found the isokinetic training harder to perform.

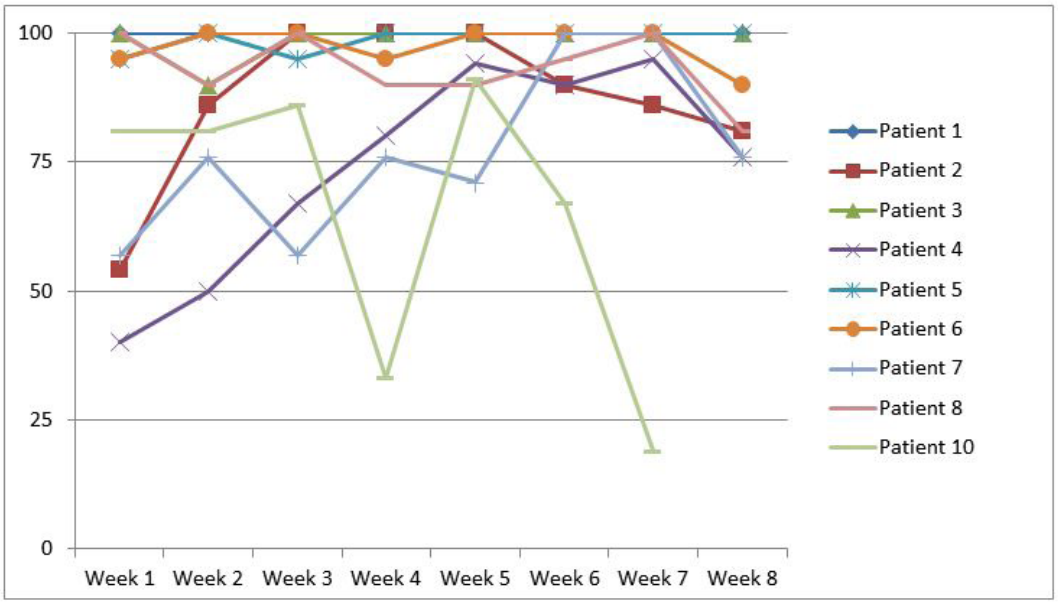

Figure 2B: Percent of managed isokinetic Shaker exercise per week for each patient
This figure describes the amount of the predefined number of head-raisings achieved for each patient each week of the eight weeks shaker training program in percent

Videoradiography

Three patients (two HNC and one stroke) contributed to almost all the results, based on a higher rate of completed swallows. Representative boluses are presented in Table 2. Due to the severity of swallowing difficulties and fear of aspiration, the PAS score was not possible to determine for more than 60% of the boluses in total. Data for comparison of PAS value before and after treatment was available for 26 of 60 boluses. For the HNC patients, PAS improved ≥ one score point in 32% of the evaluated boluses, deteriorated in 14% and remained unchanged in 54%. One of the stroke patients improved the PAS slightly on 3 ml thin liquid whereas two stroke subjects had a higher PAS score for 3 ml thin and 5 ml thick liquid after treatment. There was no change in the occurrence or degree of aspiration in the trachea in any of the patients after Shaker treatment. The UES opening during swallowing tended to decrease after treatment. Of the 21 boluses (approximately 30%) available for pair wise comparison before and after treatment, the AP diameter of the UES decreased ≥ 1 mm in 59% and increased ≥ 1 mm in 12% post treatment. The lateral UES opening diameter decreased in 50% and increased in 25% of the pair wise evaluated boluses in the HNC group. The duration of the UES opening in lateral view improved for four of six HNC patients in one or more boluses but there was no improvement in the stroke group. The UES opening duration in frontal view tended to increase for the 20 ml thin liquid bolus in the HNC group.

		HNC patients						Stroke patients		
Lateral view										
	Boluses	1	2	3	4	5	6	7	8	10
A. PAS	3 ml t	0	-	-	+	0	0		-	+
	20 ml t	+	+	+		0	+			
	3 ml th	0	+	0	0	0				0
	5 ml th					0	-	-		
B. Sup mov hyoid (mm)	3 ml t	-	+	+		+	+		+	+
	20 ml t		-							
	3 ml th	+	0	+	-	-				+
	5 ml th					+	+	-		+
C. Ant mov hyoid (mm)	3 ml t	-	-	+		0	+		0	
	20 ml t		-							
	3 ml th	-	-	0	-	-				-
	5 ml th					+	-	-		+

		HNC patients						Stroke patients		
Lateral view										
D. Sup mov larynx (mm)	3 ml t	-	+	+		-	-		+	-
	20 ml t		+							
	3 ml th	+	-	+	+	+				+
	5 ml th					0	-	+		+
E. Ant mov larynx (mm)	3 ml t	0	-	+		-	0		0	0
	20 ml t		-							
	3 ml th	-	-	+	-	-				-
	5 ml th					-	-	-		+
G. UES Dur open lat (sec	3 ml t	+	+	-		+	0			0
	20 ml t	+	+	+						
	3 ml th		+			-				0
	5 ml th					0	+	0		-
H. Max width UES AP (mm)	3 ml t	+	-	0		-	-		+	0
	20 ml t	-	0	0						
	3 ml th		+	0		-	-			0
	5 ml th					-	-			-
Anterioposterior view										
F. Max width UES lat (mm)	3 ml t		0	+		-	-			
	20 ml t		+	-		-	0			

Boluses are labeled as improved (+), impaired (-), unchanged (0) or blank, the latter that a bolus was not possible to perform before, after or both before and after the Shaker exercise period

Boluses in the lateral view; 3 ml t= 3 ml thin liquid; 20 ml t= 20 ml thin liquid; 3 ml th= 3 ml thick liquid; 5 ml th= 5 ml thick liquid

Boluses in the anterioposterior view; 3 ml t= 3 ml thin liquid; 20 ml t= 20 ml thin liquid

Abbreviations are explained in the following list;

A. The penetration/aspiration score according to Rosenbeck, et al.

B. Superior movement of hyoid.

C. Anterior movement of hyoid.

D. Superior movement of larynx.

E. Anterior movement of larynx.

F. The maximum width of the UES opening the lateral view.

G. Duration of UES opening in the lateral view.

H. The maximum width of the UES opening as viewed anteriorly.

Table 2: Improvement and impairment of VRG variables after eight weeks of Shaker exercise compared to inclusion

The superior movement of the hyoid appeared to increase somewhat after treatment. No clear pattern of change of the superior movement of the larynx was discerned. Twenty-two of 60 boluses were available for pair wise comparison of hyoid elevation. Sixty-eight percent of these had an increase of ≥ 1 mm, 27% a decrease of ≥ 1 mm, and five percent remained unchanged. The result of the laryngeal superior elevation was inconclusive. The anterior movement of both the larynx and the hyoid tended to somewhat decrease after treatment.

Fiber endoscopic evaluation of swallowing

PAS evaluations according to FEES are presented in Table 3. Due to technical problems with the recordings nearly 50% of the FEES data was missing. The PAS tended to improve somewhat in the stroke group, particularly for smaller volumes of thick liquid. Two of the stroke subjects improved on the PAS from eight to one for 5 ml thick liquid. However, none in the stroke group were able to swallow thin liquids or solids on the FEES evaluation after treatment. No apparent changes in PAS were found in the HNC group. One of five HNC patients improved on the PAS on 5 ml and one on 10 ml thick liquid after treatment as assessed with FEES. The remainder of patients had unchanged or higher PAS on thick liquids. Two of five in the HNC group improved the PAS on five ml thin liquids.

The median SPS score improved one scale step in both study groups (Table 3). The SPS score improved ≥ 1 point in two of five subjects in the HNC group and in two of three in the stroke group after treatment. Two HNC patients and one stroke patient had the same SPS score before and after treatment and one HNC subject was assessed to have inferior SPS score post treatment.

	Changes before vs. after treatment (number of patients)			
Group	**Improvement ≥ 1 score point**	**Unchanged**	**Deterioration ≥ 1 score point**	**Missing data***
PAS 5 ml thick liquid				
HNC	1	2	2	1
Stroke	2	0	1	0
Total	3	2	3	1
PAS 10 ml thick liquid				
HNC	1	2	0	3
Stroke	2	0	0	1
Total	3	2	0	4
PAS 5 ml thin liquid				
HNC	2	1	1	2
Stroke	0	0	0	3
Total	2	1	1	5
PAS 20 ml thin liquid				
HNC	1	1	1	3
Stroke	0	0	0	3
Total	1	1	1	6
PAS biscuit				
HNC	0	2	1	3
Stroke	**0**	**0**	**0**	**3**
Total	0	2	1	6
SPS				
HNC	2	2	1	1
Stroke	2	1	0	0
Total	4	3	1	1

PAS = Peneteration-Aspiration Scale
SPS = Swallowing Performance Scale
* Not possible to perform before or after treatment or not possible to evaluate

Table 3: Changes in FEES variables before vs. after treatment in HNC (n = 6) and stroke (n = 3) patients

Patient Reported Outcome

EORTC QLQ-C30 and EORTC QLQ-H&N35

Selected domains and single items hypothesised to impact dysphagia are presented in Table 4. There was a clinically significant improvement for the Social eating domain after eight weeks of Shaker training, also persisting at the three-month follow- up. At that time, clinically significant improvement were also found in the domain Role functioning and the single items dyspnea, problem with dry mouth, sticky saliva and less use of nutritional supplements. An improvement was also seen in the Swallowing domain and Global quality of lifedomain, however not reaching clinical significance.

EQRTC QLQ-C30	**Before Shaker rehab**	**After Shaker rehab**	**3 month follow-up**
	mean (SD)	**mean (SD)**	**mean (SD)**
Functional domains			
Role functioning	50 (39)	58 (36)	69 (36)
Social functioning	67 (31)	60 (36)	69 (30)
Global Quality of Life	56 (23)	63 (20)	61 (20)
Symptom domains			
Nausea and vomiting	8 (18)	10 (15)	6 (12)
Single items			
Dyspnea	46 (40)	48 (30)	25 (30)
Appetite loss	25 (39)	33 (40)	29 (45)
EQRTC QLQ-H & N35			
Symptom domains	mean (SD)	mean (SD)	mean (SD)
Swallowing	57 (27)	54 (28)	53 (34)

EQRTC QLQ-C30	Before Shaker rehab	After Shaker rehab	3 month follow-up
	mean (SD)	mean (SD)	mean (SD)
Social eating	57 (44)	46 (32)	46 (34)
Single items			
Problem with dry mouth	88 (17)	75 (30)	79 (25)
Sticky saliva	86 (35)	83 (25)	67 (36)
Use of nutritional supplements	75 (46)	75 (46)	57 (53)

Mean value and standard deviation (SD) for all pilot patients. Score range 0-100 points. High scores for a functional domain and the global quality of life domain represent high level of functioning or quality of life. High scores for symptom domains and single items represent high levels of symptoms. A change in score over time of ≥ 10 points could be interpreted as clinically significant

Table 4: Selected domains and single items hypothesised to impact dysphagia from EORTC QLQ-C30 and EORTC QLQ- H&N35 before Shaker rehabilitation and at follow-up

MDADI

Results from the dysphagia specific MDADI questionnaire are shown in Table 5. After Shaker training, improvement was reported in all domains with further improvement seen at the three month follow-up. The largest improvement was seen in the Global (Δ 13) and Total domain (Δ 14) at the three month follow-up.

MDADI	Before Shaker rehab	After Shaker rehab	3 month follow-up
	mean (SD)	mean (SD)	mean (SD)
Emotionaldomain	66 (17)	67 (19)	72 (19)
Functional domain	50 (22)	52 (21)	58 (19)
Physical domain	55 (18)	56 (15)	61 (17)
Global domain	40 (26)	45 (32)	63 (25)
MDADI Total	57 (17)	58 (17)	71 (16)

MDADI total score range from 20-100. A score of 100 indicates no dysphagia

Table 5: MDADI. Mean value and the standard deviation (SD) for all pilot patients

Discussion

Nine of ten patients were able to perform the Shaker exercise and the only patient (stroke) dropping out was due to general fatigue during the first week of exercise. In other Shaker exercise studies [11,30] the dropout rates have been higher, i.e. close to 30%. The study by Easterling, *et al.* [30], including healthy older adults, suggested the need of a structured follow-up during the Shaker exercise programme, especially during the first two weeks of exercise to attain the isometric and isokinetic exercise goals and to minimise drop-out rates. The lower dropout rate in our study might therefore be due to the more frequent SLP follow-up appointments, especially during the first two weeks of exercise.

Our study population was heterogeneous, with varying ages, comorbidity grades, types of HNC and stroke. Even so, most of the patients managed to perform the exercise for eight weeks at a high level. The severity of comorbidity did not seem to be related to the amount of exercise for these patients. Exercise performance was mostly associated with muscular discomfort in the head and neck muscles, as has been reported by others assessing the Shaker exercise [8,30]. For the patients who were able to perform all or almost all of the exercises during the first weeks, no apparent difference was noted in terms of in the amount of managed isometric versus isokinetic exercises. However, for those starting with a lower amount of completed exercise, the isometric exercise seemed more difficult to master. The latter has also been acknowledged in studies of healthy elderly [30].

The VRG results demonstrated that the patients generally had pronounced swallowing difficulties with nine of the patients having a feeding tube at inclusion. As a result, only some of the boluses were possible to analyse, as the patients were not able to swallow the others, mainly for fear of aspiration. With only 60% of all the boluses measurable for VRG, and of those, approximately 40% available for comparison before and after Shaker treatment, it seems difficult to draw any conclusions from the VRG results. There is no consensus on how many or which boluses that ought to be used when assessing swallowing function, and the percentage of boluses available for evaluation are commonly not reported in studies evaluating dysphagia making interpretation of the results of the results somewhat difficult. The use of 3 ml and 5 ml thin liquid boluses are most often reported in studies, probably because smaller amounts are easier to swallow. In our study we also tried a larger bolus of 20 ml as it might be more comparative to a normal bolus when for instance drinking water. This larger bolus was possible to swallow for five of the HNC patients but for none of the stroke patients. Further investigative studies are needed to decide which and how many boluses are best to use when assessing swallowing function in order to enhance the planning of future dysphagia studies.

On FEES PAS tended to improve for small volumes of thick liquid among the stroke subjects after the Shaker exercise period. There was no apparent improvement in the HNC group, however. Moreover, there was a slight improvement of the SPS in both subgroups. Similarly to the VRG, the FEES data should be interpreted with some caution due to the limited number of subjects. Only about 50% of the boluses according to the protocol could be given to the subjects due to the degree of swallowing impairment. It can be noted that only one of the subjects changed their mode of nutrition after treatment.

According to PRO evaluation selected domains and single items hypothesised to impact dysphagia from the EORTC QLQ-C30 and EORTC QLQ-H&N35 were reported in the study as well as the dysphagia specific instrument MDADI. Some improvement was found at the different follow-up periods. On average, the PRO score improved more than ten points for some items, which could be interpreted as clinically significant [21]. As complications of dysphagia can be severe the patient's own perspective cannot be the only assessment performed in these patients. Nevertheless, PRO can be an important complement to the more "objective" but time consuming variables. It may be used for detection of change over time in intervention studies or in clinical practice and might thereby be able to replace follow-up VRG if combined with e.g. cervical auscultation [31].

Limitations in this pilot study include its small sample size encompassing both HNC and stroke patients. However, the study was mainly performed for feasibility purposes according to the intensified and extended Shaker exercise program in two different patient groups and this purpose could be fulfilled despite of a small sample size, though we cannot exclude a small placebo effect due to the frequent contacts with the SLP.

To fully evaluate and understand the efficacy of the Shaker rehabilitation on dysphagia and quality of life larger, randomized studies selecting specific diagnosis are needed.

Conclusion

The intensified and extended Shaker exercise program was easy to learn and possible to perform in 90% of the patients in this pilot study consisting of two different patient groups. In order to assess the effect of the Shaker exercise on dysphagia, further randomised controlled studies are needed with a larger number of patients in more homogenous groups.

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