

SWALLOWING MUSCLE TRAINING FOR OROPHARYNGEAL DISFAGIA. A NON INFERIORITY STUDY OF ONLINE VS. FACE-TO-FACE THERAPY

ORIGINAL ARTICLE

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ABSTRACT

Introducción: The purpose of this study is to show the non-inferiority of the telemedicine therapy versus face-to-face using the exercise therapy of oropharyngeal muscles in 183 patients treated consecutively from 2010 to 2020.

Method: We conducted a retrospective study comparing two dysphagia treatment groups: online versus face- to- face. Patients were distributed in a non-random way but according to patient's preferences. All patients followed the same pathway and were evaluated at the beginning and at the end of the study using the Dysphagia Outcome and Severity Scale (DOS) and the Functional Oral Intake Scale (FOIS). A non-Inferiority analysis approximation was done with delta = 1 in both variables.

Results: Within a total of 183 patients, 114 (62.3 %) used the online treatment and 69 (37.7%) the face to face one. The main cause of dysphagia was neurological in the total sample (60.7%) and within both groups. When we evaluate the clinical response, we find that both groups improved regardless of the type of therapy, The confidence interval of the difference between the beginning and the end of treatment did not reach the inferior limit of the delta defined, therefore supporting the no inferiority of online vs presential.

Discussion: This study shows the no inferiority of the online therapy versus the face-to-face one for the oropharyngeal training of the swallow muscles.

KEYWORDS

Telemedicine, telerehabilitation, dysphagia, exercise, swallow.

INTRODUCTION

Swallowing is a complex sensorimotor sequence that is controlled by cortical, subcortical, and brainstem mechanisms that allow a coordinated action of the orofacial, pharyngeal, laryngeal, respiratory, and esophageal muscles. It is a complex motor event with a sequential and ordered activation that is influenced by sensory and cortical stimuli. The sequential muscle activation is not altered in its cranio-caudal progression from the perioral muscles to the cricopharyngeus muscle, which is part of the upper esophageal sphincter.

When swallowing is impaired due to neurological, head and neck surgery, or respiratory diseases amongst others, dysphagia occurs. Oropharyngeal dysphagia is defined as an alteration in the passage of the food bolus from the mouth to the esophagus. It can occur at any age but its prevalence increases with age.

Oropharyngeal dysphagia affects more than 30% of patients who have suffered a stroke. In Parkinson's disease its prevalence is between 52-82%; it is the initial symptom of 60% of patients with amyotrophic lateral sclerosis; it affects 40% of patients with myasthenia gravis, 44% of patients with multiple sclerosis, up to 84% of Alzheimer's disease patients, and more than 60% of the elderly institutionalized. Oropharyngeal dysphagia affects up to 80% of patients who have received surgical or radiotherapy treatment for oropharyngeal, laryngeal and maxillofacial area tumors. Furthermore, dysphagia has two major complications: malnutrition and respiratory infection¹.

There are several strategies to treat dysphagia and one of them is the exercise of the oropharyngeal muscles²⁻⁵. The swallowing muscles can atrophy when they are not used in a context of a disease or aging. Geniohyoid muscle atrophy has been associated with aspiration, a major complication of dysphagia⁶. Muscle atrophy is reversible with exercise^{4,5}.

Whithin the dysphagia treatment, the training of the oropharyngeal muscles is a fundamental part regardless of the type of oropharyngeal swallowing disorder.

Since 2010, an online program has been used to train the oropharyngeal musculature in the context of oropharyngeal dysphagia treatment. The purpose of this study is to show the non-inferiority of the telemedicine training of oropharyngeal muscle versus the tradicional face to face treatment in 183 patients treated consecutively from 2010 to 2020 by the same speech therapist and using the same protocol.

METHOD

Study design

After Institutional Review Board approval, we conducted a retrospective study of the dysphagia database of the Physical Medicine and Rehabilitation Department at University Hospital of Sant Pau (Barcelona, Spain) comparing two oropharyngeal dysphagia treatment groups: online versus face to face. Patients were distributed according to their preferences in a non-random way. The dysphagia database includes all patients diagnosed by modified barium swallow (MBS) of oropharyngeal dysphagia who have undergone either online or face-to-face treatment with oropharyngeal exercise from the 1st of July of 2010 to the 31st of January of 2020.

Except for the treatment (online vs. face to face) all patients had follow the same clinical pathway during the timeframe of 10 years: doctor's first evaluation and MBS done the same day; speech therapist evaluation between 4-6 weeks after the MBS followed by 13 days of oropharyngeal muscle training either online or presential; speech-therapist final evaluation and doctor's evaluation with MBS study at the end done in one single appointment between 4-6 weeks after the completion of therapy.

The 13 therapy sessions is an imposition on providers by the public insurer of Catalan Health System. Such model only allows for 15 speech therapy visits that include evaluation and treatment for oropharyngeal dysphagic patients.

Study population. Inclusion and exclusion criteria

One hundred and eightythree (n=183) patients were treated consecutively during a 10 year period.

Our study population included adult patient ≥ 18 years old who underwent either online or face to face treatment for oropharyngeal dysphagia.

From September 2010 to January 2020 all patients diagnosed with oropharyngeal dysphagia were given the option to do the therapy either, online or presential, at the hospital's Rehabilitation Department.

The inclusion criteria for the online group were: age ≥ 18 years; to be diagnosed with oropharyngeal dysphagia by modified barium swallow (MBS) evaluation with ≤ 5 level at the Dysphagia Outcome and Severity Scale⁷; having Internet connection at home or using a mobile device to access the network (3-4G) and using email (the patient or their relative-caregiver); signing the consent to accept the photo-video recording of the Rehabilitation Department of our Hospital, and accepting online therapy.

The inclusion criteria for the face-to-face group were: age ≥ 18 years, to be diagnosed with oropharyngeal dysphagia by MBS with ≤ 5 level at the Dysphagia Outcome and Severity Scale⁷, not meeting the inclusion criteria for online therapy and accepting conventional face-to-face therapy.

Treatment

The patients in the online group used different Internet tools over the years. From 2010 to 2015 used platforms specifically programmed to perform the job, and from September 2015 to today oropharyngeal all exercises are free of access in Youtube and patients are followed by Whatsapp using a hospital cellular phone. The exercises are available at https://www.youtube.com/channel/UCCrloHDinvBcF5c_8LcfZ2A. Each patient did a selection of 12 to 16 of those exercise depending on their clinical and MBS results. The duration of the exercise program is 45-60 minutes per day and was to be performed under the supervisions of speech therapist during 13 days distributed in 3 consecutive weeks. The follow up has always been identical and asynchronous: patients recorded videos after looking at the video of the exercise, recorded a video performing the same exercise, and also sent comments and/or questions; the speech therapist evaluated them and sent feed-back the following working day.

The patients in the “face to face” group came to the hospital’s Rehabilitation Department for treatment and used the same exercises recorded for the online group. Also, they all did 13 therapy sessions with 14-16 exercises per session and during 45-60 minutes working days during 3 consecutive weeks.

Both groups had the recommendation of doing all the exercises trained in therapy every working day until the physiatrist evaluation.

Data collection and analysis

The main outcome measures were: (1) the Dysphagia Outcome and Severity Scale⁷ that classifies the severity of dysphagia according de modified swallow evaluation results in a scale graded from 1 to 7, being 1 a severe dysphagia with recommendation of non-oral feeding and 7 a normal swallow with no food restriction per mouth, 6 is a functional swallow and the different levels of disphagia are from 5 to 1. The scale grading system is based on penetration/aspiration and mouth-pharyngeal residue. (2) The Functional Oral Intake Scale that classifies clinically the type of oral diet the patient is actually doing, it’s a 1 to 7 point scale being 1 only tube feed and 7 full oral with no restrictions for any type of solids or liquids⁸.

The variables described are median, mean and standard deviation. To evaluate both treatments we calculated the difference between the initial and the final value. Also we calculated the difference of such difference, with a confidence interval of 95%, to be able to evaluate the no inferiority approximation. We have established the delta value for a no inferiority in 1 point for DOS and FOIS. For the statistical analysis we used the statistical package IBM-SPSS (V26.0)

RESULTS

A total of 183 patients underwent oropharyngeal dysphagia treatment with exercise of swallow muscles. 114 (62.3 %) patients did the online treatment and 69 (37.7%) the face to face one. The mean age of the total sample was 58.53 years (14-89). Among the online group the mean age was 56.04 years (SD 14.852) and the mean age of the face-to-face group was 64.42 (SD 14.628) Analyzing the age with Levine equal variance test ($p=0.539$) showed no significative age differences among both groups, eventhough the online group is younger.

Table 1 summarizes the frequencies of the different online programmes that we have used thru these 10 year period.

There were 108 (59%) men and 75 (41%) women. Within the total of 108 men, 41 (59.4%) choose the face-to-face therapy and 67 (58.8%) choose the online one. Among the 75 women, 28 (40.6%) picked the presential treatment and 47 (41.2%) the online option. Using the Pearson's chi-squared test we obtain a $p=0.931$ showing no significative differences in sex distribution among the face-to-face and the online group.

The diagnoses were grouped in neurological, structural from otorhynolaringology surgeries, structural from neurosurgery, pneumological and others. Table 2 summarizes the diagnoses and the distribution among presential and online group with a $p=0.069$ on the Pearson's chi-squared test showing no significative differences in diagnoses among groups.

The number of respiratory infeccctions during the year prior to treatment was similar in both groups as is shown in table 3. There were no respiratory infeccctions reported on any grup after completion of treatment.

The face-to-face and the online group analyzed accordign to DOS and FOIS before starting treatment showed no statistical differences in the DOS scale ($p= 0.068$), but there was statistical difference according to the FOIS ($p < 0.001$). Table 4 summarizes those results.

All patients, regardless the group, underwent MBS and were classified according to the severity of their oropharyngeal dysphagia based on the DOS. Table 5 summarizes the results of the DOS before training (DOS 1) and after training (DOS 2) in both groups.

The intake of food per mouth was assessed in all patients using the FOIS. Table 6 summarizes the results of the FOIS done before training (FOIS 1) and after training (FOIS 2) in both groups.

Considering the clinical response by evaluating the median of the change between the beginning and the end for the variables FOIS and DOS, and with a CI 95% of the difference between the medians of this change [0-1] with the minimum delta of 1 point between groups, we can assume that online treatment is not inferior than the face-to-face one. Table 5 and 6 show those calculations.

Adherence to oropharyngeal exercise was also analyzed. Adherence was considered to be correct if the patient exercised daily while being followed by the speech therapist. This means that after completing the 13 online or face-to-face therapy sessions, the patient continued 5 days a week until the MBS was performed 4-6 weeks later. The results, which show no differences, are summarized in Table 7.

DISCUSSION

There are an emerging number of telerehabilitation studies on dysphagic patients⁹⁻¹⁴. However, this study is the first one that compares online and face-to-face care reporting swallowing outcomes and/or swallowing improvements, which are both essential to verify the effectiveness of a treatment. The randomized control trial of Wall et al¹⁵ studied adherence to a prophylactic swallowing exercise protocol, and if clinical and demographic factors influence adherence but it doesn't report swallowing outcomes and/or improvements.

In our study, the baseline characteristics of the face-to-face and online group are comparable in terms of: cause of the swallowing disorder, initial severity of their oropharyngeal swallow according to the Dysphagia Outcome and Severity Scale (which rates the modified barium swallow evaluation) and comparable respiratory infections prior to therapy. The FOIS evaluation showed that the online group had taken a less restricted oral diet at the beginning of the program probably because this group was younger and didn't have any prior recommendation about it. After performing the therapy, both groups improve, even though there is a slight better improvement in the presential group, when is calculated the confidence interval of the improvement between the two therapies the limit value does not overpass the level of delta defined as no inferiority for both variables DOS and FOIS. The slight better improvement of the presential group could be secondary to daily therapy encourage of face-to-face therapy.

We think that the improvement of both groups is based on the fact that they used the same series of oropharyngeal exercises with the same intensity, and also had exactly the same medical and therapeutic evaluation protocol. The adherence to therapy in both groups is also equivalent.

A limitation of the study is that was not designed as a randomized control trial. The patients decided which modality of treatment they preferred according to their technological possibilities. Our study shows the digital divide in relation to age. The face-to-face group had a mean age of 64.42 and the online group 56.04 years. In Europe, 83% of its population uses the Internet and this increases to 96% for the youth (15-24 year old individuals)¹⁶. In the age group from 55 to 74 years, only 46% are Internet users, according to Seybert 2013 study. Almost all patients in the study were within that age group, but the group that went online was 8 years younger.

The study also has other limitations such as the assessments used and the number of patients that could be recruited over the 10-year period.

CONCLUSION

In recent years, telerehabilitation has become an alternative to face-to-face therapy in the field of speech therapy, which has been examined by several studies.^{3,11}. Telemedicine offers the potential to improve access to clinical rehabilitation medicine services ensuring an appropriate level of service to people with swallowing disorders. Face-to-face therapy has always been considered the 'gold standard' of care, and this study, even though is not a randomized control trial, shows that the outcomes of online therapy are not inferior to face-to-face assessed with DOS and FOIS. These results contribute to the endorsement of the online therapy.

Further studies should be done to define the additional benefits and risks eventually associated with the telerehabilitation of oropharyngeal dysphagia.

DECLARATION OF CONFLICTING INTERESTS

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Table 1. Different online programs used overtime

	Frequency	Percent	Valid Percent
Edis	32	17.5	27.8
TRHLAB	25	13.7	21.7
Whatsapp	58	31.7	50.4
Total	115	62.8	100.0

Table 2. Medical diagnoses of therapy groups

Diagnoses	Presential tx	Online tx	Total
Neurological	39 (56.5%)	72 (63.2%)	111 (60.7%)
ENT pt	8 (11.6%)	17 (14.9%)	25 (13.7%)
Neurosurgical	2 (2.9%)	5 (4.4%)	7(3.8%)
Pneumological	13 (18.8%)	6 (5.3%)	19 (10.4%)
Others	7 (10.1%)	14 (12.3%)	21 (11.5%)
Total	69 (37.7%)	114 (62.3%)	183
Tx: treatment ENT: otorhinolaryngologist surgeries Pt: patients			

Table 3. Respiratory infeccions prior to treatment.

Adherence	Presential tx	Online tx	Total
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NO	49 (71.0 %)	95 (83.3)	144 (8.2%)
YES	20 (29.0%)	19 (16.7%)	39 (21.3%)
Chi-Square Test Likelihood Ratio 3,801			

Table 4. DOS and FOIS before treatment

Presential (N = 69)	Percentiles		DOS 1	FOIS 1
		25	2.00	4.00
		50	3.00	5.00
		75	4.50	6.00
Online (N = 114)	Percentiles	25	2.00	5.00
		50	4.00	6.00
		75	5.00	7.00
Mann-Whitney Test				
DOS 1 p=0,068				
FOIS 1 < 0.001				

Table 5. Summary of the results of DOS 1 and DOS 2 and median/mean differences

		DOS 1	DOS 2	DIF 2-1
Presential (N = 69)	Median	3.00	4.00	Median difference 1
	Mean	3.07	4.28	Mean difference 1.20
	St deviation	1.478	1.822	1.26 (SD mean difference)
Online (N = 114)	Median	4,00	4,00	0
	Mean	3.50	4.27	0.77
	St deviation	1.489	1.897	1.14

Median difference (P-O) and [CI 95%]	1 [0 – 1]
Mean difference (P-O) and [CI 95%]	0.43 [0.06 – 0.80]

Table 6. Summary of the results of FOIS 1 and FOIS 2 and median/mean differences

		FOIS 1	FOIS 2	FOIS 2-1
Presential	Median	5.00	6.00	1
	Mean	4.78	5.65	0.87
	St deviation	1.598	1.443	1.10
	N	69	69	
Online	Median	6.00	6.00	0
	Mean	5.59	5.78	0
	St deviation	1.394	1.335	0.19
	N	114	114	
Median difference (P-O) and [CI 95%]				1 [0 – 1]
Mean difference (P-O) and [CI 95%]				0.68 [0.39 – 0.96]

Table7. Adherence to oropharyngeal exercise.

Adherence	Presential tx	Online tx	Total
NO	7 (10.1%)	8 (7.0%)	15 (8.2%)
YES	62 (89.9%)	106 (93%)	168 (91,.8%)
Chi-Square Test Likelihood Ratio 0.546			