Measurement and clinical evaluation of oropharyngeal dysphagia; a multidimensional approach

Heijnen, B.J.

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Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: Effects on quality of life

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BJ Heijnen[1], R Speyer[2], LWJ Baijens[3], HCA Bogaardt[4]

[1] Leiden University Medical Center, Dept. of Otorhinolaryngology and Head and Neck Surgery, Leiden , The Netherlands
[2] HAN University of Applied Sciences, Institute of Health Studies, Nijmegen, The Netherlands
[3] Maastricht University Medical Center, Dept. of Otorhinolaryngology and Head and Neck Surgery, The Netherlands
[4] Comprehensive Cancer Center West, Leiden, The Netherlands

ABSTRACT

This study compares the effects of traditional logopedic dysphagia treatment versus NMES as adjunct to therapy on quality of life in patients with Parkinson's disease and oropharyngeal dysphagia. Eighty-eight patients were randomized over three treatment groups. Traditional logopedic dysphagia treatment or traditional logopedic dysphagia treatment combined with NMES at sensor or motor level stimulation were compared. Three times (pre-, posttreatment, and three months following treatment), two quality of life questionnaires (Swal-QOL MD Anderson Dysphagia Inventory) and a single item Dysphagia Severity Scale were scored. The Functional Oral Intake Scale (FOIS) was applied to assess the dietary intake.

After therapy all groups showed significant improvement on the Dysphagia Severity Scale and restricted positive effects on quality of life. Minimal group differences were found. These effects remained unchanged three months following treatment. No significant correlations were found between the dietary intake and quality of life. Logopedic dysphagia treatment results in a restricted increased quality of life in patients with Parkinson's disease. In this randomized controlled trial, all groups showed significant therapy effects on the Dysphagia Severity Scale, as well as restricted improvements on the SWAL-QoL and the MDADI. However, only slight non-significant differences between groups were found.

INTRODUCTION

Oropharyngeal dysphagia is a common finding in patients with Parkinson's disease. It is estimated that up to 80% of all patients will suffer from oropharyngeal dysphagia during the first stages of the disease. In advanced stages of the disease, the incidence of dysphagia can increase up to 95%. [1,2]. Literature describes the main phenomena of dysphagia in patients with Parkinson's disease in terms of rigidity and bradykinesia of swallowing. Incomplete cricopharyngeal relaxation, reduced cricopharyngeal opening, and delayed initiation of the swallowing reflex have been suggested as possible mechanisms of dysphagia in this patient population [3,4]. Furthermore, delayed oropharyngeal transition time, reduced muscle strength, as well as aspiration are common findings in dysphagic Parkinson patients. [4,5,6].

Dysphagia is associated with malnutrition, dehydration, aspiration pneumonia, and sudden death [7,8,9]. Dysphagia is also associated with severe consequences for the quality of life of [10,11]. In patients with Parkinson's disease these consequences become more prominent when the disease becomes more invalidating and the ability to enjoy oral foods becomes less evident [12,13].

Currently, the treatment of dysphagia in patients with Parkinson's disease exists of traditional logopedic dysphagia treatment by a speech therapist. Usually, this treatment is provided once or twice a week, for several months or years. Oral motor exercises, airway protecting maneuvers, postural correction to facilitate bolus transition, and thermotactile stimulation are included in this therapy [14]. The literature regarding randomized controlled trials on the outcomes of speech therapy for swallowing dysfunction in patients with Parkinson's disease is scarce. Baijens et al., Nagaya et al. and Sharkawi et al. [15,4,16] describe a positive effect of speech therapy on patients with Parkinson's disease and dysphagia, but methodological issues may arise [15]. No information is provided about blinding of pre versus posttreatment condition [4] or the reliability of measurements using a single assessor or rater [16]. Furthermore, most studies base their conclusion on rather small subject populations (N ≤10 subjects).

Neuromuscular electrical stimulation (NMES) can be a therapeutic adjunct to known interventions in the treatment of dysphagia [17,18,19]. The rationale of NMES is the stimulation of muscle fibres by stimulating the nerve and the motor-end-plate of the nerve, resulting in a re-education of the functional muscle-contraction-patterns [19,20]. NMES has not been investigated in Parkinson patients with oropharyngeal dysphagia yet.

The aim of this randomized controlled trial is to investigate the effects of adjunctive NMES in dysphagic Parkinson patients compared to traditional logopedic dysphagia treatment with Health Related Quality of Life (HRQOL) as primary outcome measure.

It was hypothesized that NMES would not only contribute to a significant improvement of the swallowing function, but would also contribute to an increased quality of life in these patients.

METHODS

Patients and design

A three-arm open randomized trial was set-up to evaluate the hypotheses. Patients from diverse hospitals all over the Netherlands, with a diagnosis of idiopathic Parkinson's disease and dysphagic complaints, underwent a standardized clinical examination by a laryngologist as well as a clinical observation of the oral intake of various food consistencies and volumes by a speech and language pathologist at the outpatient clinic of dysphagia in the Maastricht University Medical Center. Only after objectifying the presence and severity of oropharyngeal dysphagia, patients were admitted to this study. The degree of dysphagic complaints ranged from mild to severe: For example, problems of bolus-forming, slow eating, oropharyngeal passage disorder, coughing while drinking, abnormal amounts of residue or, severe aspiration. The severity of the Parkinson's disease was assessed using the Hoehn and Yahr (H&Y) disability score [21]. The neurological diagnosis was confirmed by the patient's neurologist. Written informed consent was obtained from all patients prior to participation. The study protocol was approved by the medical ethical committee of the university medical center.

Inclusion and exclusion criteria

For inclusion in this study the following criteria had to be met:

1. Diagnosis of idiopathic Parkinson's disease as confirmed by a neurologist;
2. Patient's physical condition considered as in a 'stable' course of Parkinson's disease;
3. Unaltered protocol of antiparkinsonian medication for at least two months;
4. Age between 40-80 years old;
5. Presence of oropharyngeal dysphagia with preservation of the swallowing reflex;

Excluded were the following patients:

1. Patients with known other neurological diseases (such as Amyotrophic Lateral Sclerosis or Multiple Sclerosis);
2. Patients with severe mental depression or severe cognitive degeneration (Mini Mental State Examination < 23);
3. Patients with deep brain stimulation or malignancies, extensive surgery or radiotherapy of the head and neck region;

4. Patients with severe cardiopulmonary diseases, epilepsy, carotid sinus syndrome or dermatological diseases of the head and neck;
5. Patients who received dysphagia treatment during the past six months prior to randomization.

Sample size and randomization

After a conservative sample size calculation, three intervention groups were formed of at least thirty patients per treatment group. Parkinson patients were randomly assigned to one of the three treatment groups. Randomization was performed by assigning each consecutive patient to the next treatment group; Thus, the first patient was assigned to group 1, the second patient to group 2, the third patient to group 3, the fourth again to group 1, etc.

Treatment groups and treatment protocol

Group 1 received traditional logopedic dysphagia treatment (Group TT) by an experienced speech therapist. This treatment consisted of oral motor exercises, airway protecting maneuvers, and postural compensation based on the dysphagic findings as well as the therapist's individual preference and experience. Group 2 and Group 3 received the same treatment as Group 1 combined with neuromuscular electrical stimulation of the suprahyoidal musculature. In this study, Vitalstim© equipment was used (VitalStim® Therapy; frequency 80 Hz, pulse width 700 microseconds; Chattanooga Group, Chattanooga, TN, USA). The VitalStim stimulator cycles automatically off for one second every minute because of fixed settings by the manufacturer. NMES consisted of transcutaneous electrical stimulation by positioning electrodes bilaterally on the neck in order to facilitate contraction of the suprahyoidal muscles (Fig 1). Group 2 and 3 differed in the applied electrical current intensity of the NMES. The neuromuscular electrical stimulation of Group 2 (Group NMES-M) was set to stimulate at a motor level, to an extend that contractions of the underlying musculature were visible in combination with the subjective 'grabbing sensation' of the patient. Spasm of the musculature was avoided. Group 3 (Group NMES-S) received NMES on a sensory level [22]. Therapists received additional training and information on NMES by an experienced laryngologist certified to use surface electrical stimulation. The training was given according to the manual of the manufacturer, the VitalStim certification course (http://www.vitalstim.com) and the study of Ludlow et al. [20,22]. All patients were familiarized with the application of the electrical stimulator by their speech therapist during training sessions before the onset of the experiment. The therapists performed test treatment sessions with NMES on their Parkinson patients in the presence of the laryngologist and speech and language pathologist to ensure

standardized application of NMES. The correct placement of the electrodes, the application of the NMES unit, and the correct setting of the motorical and sensory electrical current thresholds were trained.
Therapies were administered at the patient's residence by experienced speech therapists trained in dysphagia management. In total, eighty-five speech therapists were involved in the study. All groups received 13 to 15 dysphagia treatment sessions of half an hour each, on five consecutive days per week within a period of three to five weeks. All patients were treated within 34 days (median = 23; 25th perc. = 21 and 75th perc. = 25 days). The variation in the number of treatment sessions and period duration, resulted from daily logistics in clinical practice.

EVALUATION MEASUREMENTS

Baseline characteristics

The following tools (or scales) were used to describe the patient characteristics; The Mini Mental State Examination (MMSE) was scored to assess the cognition [23]. The MMSE is scaled from 0 to 30, respectively. The Hoehn and Yahr Scale was used to judge the severity of Parkinson's disease [21]. The Hoehn and Yahr Scale ranges from 0 to 5, where 0 refers to absence of motor disabilities and 5 indicates bedridden or wheelchair dependant motor behavior. All baseline characteristics were determined by an experienced laryngologist trained to perform these tests.

Pre-, Post-, and Follow-up treatment evaluation

As dietary evaluation, the Functional Oral Intake Scale (FOIS) [24] was used (Table 6). Two questionnaires on quality of life related to oropharyngeal dysphagia were applied in this study: The SWAL-QOL [13] and the MD Anderson Dysphagia Inventory (MDADI) [25]. The Dutch translation of the SWAL-QOL, translated and validated by Bogaardt et al.[26], was used to determine the quality of life in dysphagic Parkinson patients. This 44-item questionnaire is a highly valid instrument in evaluating the quality of life concerning dysphagia and has a very reliable short-term reproducibility [13]. Its eleven subscales represent the different aspects of quality of life. The minimum and maximum score range per subscale from 0 to 100, indicating extremely impaired quality of life versus no impairment as experienced by the individual. The MDADI consists of 20 items and is composed of a global assessment (a single question) and three subscales: The emotional, the functional, and the physical subscale. It uses a five-point item scale, resulting in a minimum total score of 20 and maximum of 100. The original scoring uses a reversed coding in two items. In the Dutch consensus translation and validation

[27] all items are rated the same, thus, rewriting two questions. All three measurement tools were used to evaluate swallowing function at three time points: pretreatment, posttreatment, and at a three months follow-up. In addition, a visual analogue scale, the Dysphagia Severity Scale (DSS), was administered. Using the DSS, the patient self-reports his swallowing function with a score from 0 to 100 by rating a single question: 'How do you qualify your swallowing today?' Scores can vary from 0 ('Can't swallow at all') to 100 ('Normal swallow'). The DSS was filled in after every treatment session. Therefore, the DSS had a maximum of 15 measurement moments. The first two measurements were averaged as a baseline and the last two as a posttherapy result. The treatment sessions as well as all examinations were performed during the "on" motor phase of the Parkinson's disease [28]. All scales and questionnaires with the exception of the DSS, were rated during a patient's visit at the outpatient clinic for dysphagia in presence of a speech and language pathologist.

Apart from the above-mentioned evaluation tools, data were gathered on swallowing function using videofluoroscopy of the swallowing act and fiberoptic endoscopic evaluation of swallowing (FEES).

Statistical analysis

All data were formally tested for normality with the Kolmogorov-Smirnoff test prior to further analysis. The distribution of the data was not sufficiently normal to allow parametric statistics. Descriptive statistics of baseline data, effect data (post minus pretreatment data), and follow-up minus posttherapy data, were determined. Differences between posttherapy and baseline data were tested for significance by a Wilcoxon Signed Rank Test. Group differences were tested using a Mann-Whitney *U* test. All statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL).

RESULTS

Patient characteristics

After applying inclusion and exclusion criteria, a total of 109 subjects were included in this study. All patients were diagnosed with idiopathic Parkinson's disease having oropharyngeal dysphagia. All patients were assigned to one of the three treatment groups as described previously. During the period of intervention, 21 subjects were excluded because of diverse methodological reasons (change of antiparkinson medication N=17, dental surgery N=2, other reasons N=2). The excluded subjects did not experience adverse effects from therapy. Furthermore, no significant differences in baseline data were present between the group of excluded subjects and the group

of included subjects. Finally, 88 patients (65 males, 23 females) did accomplish the full period of therapy. The mean age was 68 years, with a range of 42 to 81 years. The MMSE ranged from 23 to 30 points (median 28), whereas the Hoehn and Yahr scores ranged from 1 to 4 (median 2). No differences were found between the baseline characteristics of the three treatment groups. In Table 1 the patients' characteristics for each treatment group separately as well as for all groups combined, are presented.

Table 1. Patient characteristics.
Descriptive statistics of patient characteristics for each group separately as well as for all groups combined.

Group[a]	Gender (N_{Male}; N_{Female})	Age (years)		MMSE		H&Y scale	
		Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.
Group TT (N=28)	22;7	69	62;74	28,0	26,0;29,0	2	1,0;4,0
Group NMES-M (N=27)	20;9	65	60;74	28,0	26,0;29,5	2	1,0;3,0
Group NMES-S (N=30)	23;9	66	60;69	28,0	26,5;29,0	2	1,5;3,0
Total Group (N=85)	65;25	68	60;73	28,0	26,0;29,0	2	1,0;3,0

[a] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation at a motor level, NMES-S = neuromuscular electrical stimulation at a sensory level.

Treatment effects

The median and the interquartile range of the stimulation intensities in the NMES-M and the NMES-S group were, respectively, 9,5 (7 to 13,75) and 3,25 (2,75 to 4,25) mA. Improvement on the Dysphagia Severity Scale during the treatment period is presented in Table 2. Table 2 presents the descriptive statistics of the baseline and the effect data (post- minus pretreatment data) of the Dysphagia Severity Scale: the median, the 25th, and the 75th percentile of a patient's self-evaluation of dysphagia. The median progress on the DSS is 14 points (range -33 to 70). The effect data have been tested for significance (Wilcoxon Signed rank test) resulting in a significant positive therapeutically effect for all groups. However, no statistically significant differences in effect data were found between the three treatment groups (Mann-Whitney *U* test).
Table 3 to 5 show the descriptive statistics of both quality of life measurement tools: The SWAL-QOL and the MDADI. For each group separately as well as for the total group, data are presented. Table 3 and 4 contain, respectively, descriptive statistics of the

Table 2. Dysphagia Severity Scale (DSS).
Descriptive statistics of the baseline data and the effect data (post- minus pretreatment data), the number of patients per treatment group, and the level of significance of the difference between posttherapy data compared to baseline data for all groups (Wilcoxon Signed rank test).

Group[a]	Baseline data[b]			Effect data			
	Median	25';75'perc.	N	Median	25';75'perc.	N	P-value
Group TT	59	41;88	28	19	3;44	28	0,000
Group NMES-M	72	52;88	27	10	0;31	27	0,000
Group NMES-S	74	49;87	30	6	-2;24	30	0,005
Total Group	67	49;88	85	14	0;30	85	0,000

[a] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation at a motor level, NMES-S = neuromuscular electrical stimulation at a sensory level.
[b] The maximum score of the scale is 100.

baseline data, the effect data, and the follow-up minus posttherapy data of the SWAL-QOL. A Wilcoxon signed rank test was used to test for significant changes between baseline and posttherapy measurements (Table 4). In table 4, only dysphagia-concerning subscales of the SWAL-QOL are given. Applying a Bonferoni correction, both the total group and the TT group showed a significant change on the Symptom Index. The total group also presented a significant effect on the Burden scale. No other statistically significant results were found. Because of the minimally increased medians during the period following therapy (Table 4), no tests were performed to test for significant differences between the post- and follow-up data.

Table 5 shows the descriptive statistics of the baseline data, the effect data, and the follow-up data minus the posttherapy data for the MDADI and its subscales. To test for significant changes between baseline and posttherapy measurements, a Wilcoxon signed rank test was used. Following Bonferoni correction, significant therapy effects were found for the total group on the total score, the global assessment, and both the physical and emotional subscales. None of the groups reached significance on the functional subscore. The only other significant effects were found for the TT group and the NMES-M group on, respectively, the global assessment score and the total score. No significant group differences were found. After three months, the follow-up measurement showed ignorable median changes in all treatment groups. Only total group changes were tested for significance and indicated at a minor deterioration of the global assessment score.

Descriptive statistics of baseline data and of the effect data, and follow-up minus posttherapy data of the Functional Oral Intake Scale, are given in Table 7. The range of scores of the FOIS is one to seven, indicating nothing by mouth to total oral diet with no restrictions.

Table 3. SWAL-QOL.
Descriptive statistics of the baseline data and the number of patients per treatment group.

SWAL-QOL [a]	Base-line Data	Burden		Food selection		Eat duration		Eat desire		Fear		Sleep		Fatigue		Communication		Mental Health		Social effects		Symptom	
Group[b]	N	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.	Median	25';75' perc.
Group TT	30	57	38;75	75	75;100	50	25;75	83	67;100	100	81;100	75	38;88	67	33;77	63	38;75	80	68;86	75	54;81	64	54;70
NMES-M	29	50	25;88	75	75;94	38	13;69	83	54;100	88	75;100	50	38;82	58	46;75	63	44;88	75	60;95	75	58;95	59	41;68
NMES-S	29	63	31;82	75	50;88	38	25;63	88	63;100	88	75;100	75	25;94	75	46;79	63	38;75	75	65;85	75	65;85	59	48;71
Total group	88	63	38;75	75	66;88	44	25;63	83	67;100	94	81;100	69	38;88	67	42;75	63	38;75	80	60;90	75	60;90	61	50;70

[a] The maximum score of each scale is 100.
[b] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation at a motor level, NMES-S = neuromuscular electrical stimulation at a sensory level.

Table 4. SWAL-QOL

		N	SWAL-QOL Subscale[a]																
			Burden			Food selection			Eat duration			Eat desire			Social effects			Symptom		
	Group[b]		Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value	Median	25';75' perc.	P-Value
Effect data	Group TT	14	0	-13;9	N.S.	0	0;25	N.S.	6	-15;12	N.S.	0	-8;0	N.S.	0	0;6	N.S.	10	1;19	0.004
	NMES-M	17	0	0;25	N.S.	0	-6;13	N.S.	12	0;25	N.S.	0	-8;4	N.S.	0	-3;15	N.S.	4	-2;10	N.S.
	NMES-S	18	6	0;37	N.S.	0	-16;0	N.S.	12	-3;37	N.S.	0	-8;17	N.S.	0	-8;16	N.S.	4	-5;11	N.S.
	Total group	49	0	0;25	0,009	0	-12;6	N.S.	12	0,25	N.S.	0	-8;8	N.S.	0	0;15	N.S.	5	0;11	0,001
Follow-up minus posttreatment	Group TT	6	19	9;53	N.A.	-13	-31;6	N.A.	-12	-19;3	N.A.	0	-2;2	N.A.	0	-9;6	N.A.	10	-22;14	N.A.
	NMES-M	6	0	-12;6	N.A.	-19	-38;0	N.A.	0	-16;25	N.A.	0	0;6	N.A.	0	-4;5	N.A.	-4	-12;-2	N.A.
	NMES-S	7	0	-25;0	N.A.	0	0;12	N.A.	-13	-25;0	N.A.	0	-41;0	N.A.	0	-25;5	N.A.	0	-4;2	N.A.
	Total group	19	0	0;12	N.A.	0	-25;0	N.A.	-12	25;0	N.A.	0	0;0	N.A.	0	-10;5	N.A.	-2	-1-;7	N.A.

Descriptive statistics of the effect data (post- minus pretreatment data), the number of patients per treatment group, and the level of significance of the difference between posttherapy data compared to baseline data for all groups (Wilcoxon Signed rank test).

[a] The maximum score of each scale is 100.

[b] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation at a motor level, NMES-S = neuromuscular electrical stimulation at a sensory level.

Table 5. MD Anderson Dysphagia Inventory (MDADI).
Descriptive statistics of the baseline data, the effect data (post- minus pretreatment data), and the follow-up minus posttherapy data, the number of patients per treatment group, and the level of significance of the difference between posttherapy data compared to baseline data for all groups as well as the level of significance of the difference between follow-up data compared to posttherapy data for all groups combined.

		Baseline data			Effect data				Follow-up minus posttherapy data			
MDADI[a]	Group[b]	Median	25';75 perc.	N	Median	25';75' perc.	N	P-value	Median	25';75' perc.	N	P-value
Global assessment	Group TT	3	2;4	29	0	0;2	29	0,012	0	-1,0	17	N.A.
	NMES-M	4	2;4	29	0	0;1	28	N.S.	0	0;0	13	N.A.
	NMES-S	4	2;5	27	0	0;1	27	N.S.	0	-1;0	13	N.A.
	Total Group	4	2;4	85	0	0;1	84	0,000	0	-1;0	43	0,011
Functional subscale	Group TT	21	19;22	27	0	-2;3	25	N.S.	0	-1;3	16	N.A.
	NMES-M	21	18;22	29	0	-2;4	27	N.S.	0	-5;0	11	N.A.
	NMES-S	20	18;24	25	0	-1;2	25	N.S.	1	-2;2	13	N.A.
	Total Group	21	18;23	81	0	-2;4	77	N.S.	0	-2;2	40	N.S.
Physical subscale	Group TT	28	24;31	28	2	-1;5	24	N.S.	0	-5;3	15	N.A.
	NMES-M	26	22;30	29	1	-2,7	28	N.S.	0	-3;2	13	N.A.
	NMES-S	28	22;32	25	2	-5;6	25	N.S.	-2	-5;1	12	N.A.
	Total Group	28	23;30	82	2	-1;6	77	0,000	-1	-4;2	40	N.S.
Emotional subscale	Group TT	21	18;24	27	1	-3;3	27	N.S.	0	-3;2	16	N.A.
	NMES-M	21	17;24	28	2	0,4	26	N.S.	-1	-4;2	13	N.A.
	NMES-S	20	18;24	27	1	-1;3	26	N.S.	-2	-5;2	12	N.A.
	Total Group	21	18;24	82	1	-1;3	79	0,002	-1	-3;2	41	N.S.
Total score	Group TT	72	63;80	26	2	-4;8	22	N.S.	1	-4;6	13	N.A.
	NMES-M	69	63;81	28	7	2,13	25	0,007	-3	-10;3	11	N.A.
	NMES-S	74	65;82	24	4	-1;9	23	N.S.	-2	-11;3	11	N.A.
	Total Group	72	64;81	78	4	-1;11	70	0,000	0	-10;3	35	N.S.

[a] The range of the Total Score, the Global Assessment, and the Emotional, Functional, and Physical subscale is, respectively, 20 to 100, 1 to 5, 6 to 30, 5 to 25 and, 8 to 40. [b] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation on a motor level, NMES-S = neuromuscular electrical stimulation on a sensory level.

Table 6. Functional Oral Intake Scale (FOIS)

Functional Oral Intake Scale for Dysphagia (Crary et al.)	
Level 1	Nothing by mouth
Level 2	Tube dependent with minimal attempts of food or liquid
Level 3	Tube dependent with consistent oral intake of food or liquid
Level 4	Total oral diet of a single consistency
Level 5	Total oral diet with multiple consistencies, but requiring special preparation or compensations
Level 6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
Level 7	Total oral diet with no restrictions

Table 7. Functional Oral Intake Scale (FOIS).
Descriptive statistics of baseline data and effect data (differences in post- minus pretherapy) and follow-up minus posttherapy data.

Functional Oral Intake Scale[a]	**Baseline Data**			**Post- minus pretreatment data**			**Follow-up minus post data**		
	Median	**25';75' perc.**	**N**	**Median**	**25';75' perc.**	**N**	**Median**	**25';75' perc.**	**N**
Group TT	7	6;7	29	0	0;0	29	0	0;0	17
Group NMES-M	7	6;7	29	0	0;0	29	0	-1;0	13
Group NMES-S	7	6;7	29	0	0;0	29	0	0;0	13
Total group	7	6;7	87	0	0;0	87	0	0;0	43

[a] The maximum score of the scale is 7.
[b] TT = traditional therapy, NMES-M = neuromuscular electrical stimulation on a motor level, NMES-S = neuromuscular electrical stimulation on a sensory level.

No significant correlations were found between the dietary intake and the quality of life questionnaires or the Dysphagia Severity Scale (all R <.2). This finding was also observed in the study of Plowman-Prine et al. [11].

DISCUSSION

The aim of this study is to investigate the effects of NMES in patients with Parkinson's disease and oropharyngeal dysphagia compared to traditional logopedic dysphagia treatment with Health Related Quality of Life (HRQOL) as primary outcome measure. This study provides positive effects of dysphagia therapy in patients with Parkinson 's disease as found in other studies [15]. One hundred nine subjects have been randomly assigned to one of three different treatment groups. All groups show significant therapy effects on the Dysphagia Severity Scale, as well as restricted improvements on the SWAL-QoL and the MDADI. Using the SWAL-QoL, both the total group and the TT group display a significant improvement on the Symptom Index. The total group also presents a significant effect on the Burden scale. Using the MDADI, significant therapy effects are found for the total group on the total score, the global assessment, and both the physical and emotional subscales. For the TT group and the NMES-M group, improvements are found on, respectively, the global assessment score and the total score. However, only slight non-significant differences between groups are found. Additionally, in this study oral-intake related clinical scales do not correlate significantly (all R <0.2) with HRQOL related scales. The question arises if the FOIS scale is a satisfactory measure for dysphagia severity in this patient population, given the normal scores in the present study. The discrepancy between symptoms of dysphagia in daily life and oral intake versus the dysphagic findings using swallowing assessment tools like FEES or VFS, are known in Parkinson's disease [29]. The hypothesis that electrical stimulation would provide a better outcome on HRQOL can not be confirmed. Remarkably is the fact that irrespective of the applied quality of life measurement tool, no group differences are found regarding effect data nor follow-up minus posttherapy data, thus suggesting the lack of any adjunct therapy effect of NMES.
However, these findings might be explained by other causes as well. One concern might lie in the sample size (power). However, according to the sample size calculation, the total group (N=88) used for statistical analyses is sufficient. For several, mainly logistic reasons, only few patients with severe Parkinson disease (H&Y>3) have been included. Usually, this group of patients is admitted to nursing homes, thus not visiting outpatient clinics. The moderate severity of Parkinson's disease in our patient population (H&Y scale: median = 2) might have contributed to less significant group differences. If

patients would have shown more severe impairments at the beginning of therapy, therapy outcome might have been more evident; Theoretically, severely impaired subjects can show more improvement on a questionnaire or rating scale than subjects who show minor impairments prior to therapy. However, based on literature, it is unclear which treatment group would have gained the most benefit in case of a group of patients with more severe symptoms of Parkinson's disease. Furthermore, the population of included patients is a realistic representation of Parkinson patients consulting speech therapists for dysphagic complaints. Another explanation for the absence of group differences can be the treatment period of three weeks. Probably, this treatment period is not long enough to observe significant group differences in therapy outcome, in spite of the high treatment intensity. Furthermore, the fixed stimulation variables (frequency and pulse width) of the VitalStim electrical stimulator might not have been optimal for treatment of deglutition disorders in Parkinson's disease. Different stimulation variables can cause different effects in oropharyngeal excitability [31]. In Parkinson's disease swallowing problems can be due to loss of neurological control of swallowing rather than muscle weakness or peripheral sensory dysfunction [5]. Although sensory and motor effects of this type of electrical stimulation have been reported [32,22], this adjunct to traditional logopedic dysphagia treatment can be less appropriate for these patients compared to other patient groups. The possible effect of electrical stimulation on dysphagia in these patients might be too small to be detected at a HRQOL-level. In this study, no adverse effects were observed; Ludlow et al. [22] observed that aspiration and pooling were significantly reduced in chronically dysphagic patients during surface electrical stimulation with low sensory threshold levels of stimulation, whereas almost all subjects showed depression of the hyoid bone during motor-level stimulation at rest. The authors hypothesized a higher risk of further decreased hyolaryngeal elevation during electrical stimulation in dysphagic patients who were already suffering from reduced hyolaryngeal elevation. Finally, the lack of significance can not be explained by incompetence of a restricted number of speech therapists, since eighty-five speech therapists experienced in dysphagia treatment have been involved in this study.

The application of statistical analyses has been rather conservative in the present study; The large number of statistical tests has led to a major impact of the Bonferroni-correction on the data.

Summarizing, no convincing arguments or evidence have been found in favor of any of the three treatment options studied. Possibly, the use of larger patient groups may have revealed minor differences in therapy effects. However, based on our preliminary data, no further conclusions can be made.

CONCLUSION

This study is one of the first attempts to evaluate the effects of adjunct NMES in the treatment of Parkinson patients with oropharyngeal dysphagia. In this randomized controlled trial, all groups (TT, NMES-S, and NMES-M) show significant therapy effects on the Dysphagia Severity Scale, as well as restricted improvements on the SWAL-QoL and the MDADI. However, only slight non-significant differences between groups have been found. Although some methodological and clinimetrical issues might arise, most of these can be explained by ethical or logistical restrictions. In future, a larger study might be needed to clarify these preliminary findings.

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