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ORIGINAL ARTICLE

Neuromuscular Electrical Stimulation Versus Traditional Therapy in Patients with Parkinson's Disease and Oropharyngeal Dysphagia: Effects on Quality of Life

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Abstract This study compares the effects of traditional logopedic dysphagia treatment with those of neuromuscular electrical stimulation (NMES) as adjunct to therapy on the 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 and traditional logopedic dysphagia treatment combined with NMES at sensor or motor level stimulation were compared. At three times (pretreatment, post-treatment, and 3 months following treatment), two quality-of-life questionnaires (SWAL-QOL and MD Anderson Dysphagia Inventory) and a single-item Dysphagia Severity Scale were scored. The Functional Oral Intake Scale was used 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 3 months following treatment. No significant correlations were found between 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 and restricted improvements on the SWAL-QOL and the MDADI. However, only slight nonsignificant differences between groups were found.

Keywords Parkinson's disease · Quality of life · Deglutition · Deglutition disorders · Dysphagia · Neuromuscular electrical stimulation

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]. The literature describes the main phenomenon 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, and aspiration are common findings in dysphagic Parkinson's patients [4–6].

Dysphagia is associated with malnutrition, dehydration, aspiration pneumonia, and sudden death [7–9]. Dysphagia is also associated with severe consequences for the quality

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of life [10, 11]. In patients with Parkinson's disease these consequences become more prominent when the disease becomes more debilitating and the ability to enjoy oral foods becomes less evident [12, 13].

The current treatment of dysphagia in patients with Parkinson's disease is the traditional logopedic dysphagia treatment by a speech therapist. Usually this treatment is provided once or twice a week for several months or for 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. [15], Nagaya et al. [4], and Sharkawi et al. [16] describe a positive effect of speech therapy on patients with Parkinson's disease and dysphagia, but there are methodological issues [15]. No information is provided about blinding of pre- versus post-treatment condition [4] or about the reliability of measurements using a single assessor or rater [16]. Furthermore, most studies base their conclusions on rather small subject populations ($\leq$10 subjects).

Neuromuscular electrical stimulation (NMES) can be a therapeutic adjunct to known interventions in the treatment of dysphagia [17–19]. The rationale of NMES is the stimulation of muscle fibers 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 yet been investigated in Parkinson's patients with oropharyngeal dysphagia.

The aim of this randomized controlled trial was to investigate the effects of adjunctive NMES in dysphagic Parkinson's patients compared to those of traditional logopedic dysphagia treatment, with health-related quality of life (HRQOL) as primary outcome measure. It was hypothesized that NMES would contribute not only to a significant improvement of the swallowing function, but also 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, who had a diagnosis of idiopathic Parkinson's disease and dysphagic complaints, underwent a standardized clinical examination by a laryngologist and a clinical observation of the oral intake of various food consistencies and volumes by a speech and language pathologist at the outpatient dysphagia clinic of Maastricht University Medical Center. Only after objectifying the presence and severity of oropharyngeal dysphagia were patients admitted to this study. The degree of dysphagic complaints ranged from mild to severe, from problems with bolus-forming, slow eating, oropharyngeal passage disorder, coughing while drinking, abnormal amounts of residue, or severe aspiration. The severity of 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 to be in a "stable" course of Parkinson's disease, (3) unaltered protocol of antiparkinsonian medication for at least 2 months, (4) age between 40 and 80 years old, and (5) presence of oropharyngeal dysphagia with preservation of the swallowing reflex.

Patients were excluded for the following reasons: (1) other neurological diseases (such as amyotrophic lateral sclerosis or multiple sclerosis), (2) severe mental depression or severe cognitive degeneration (Mini Mental State Examination $<$ 23), (3) deep brain stimulation or malignancies, extensive surgery, or radiotherapy of the head and neck region, (4) severe cardiopulmonary disease, epilepsy, carotid sinus syndrome, or dermatological diseases of the head and neck, and (5) received dysphagia treatment during the preceding 6 months prior to randomization.

Sample Size and Randomization

After a conservative sample size calculation, three intervention groups were formed, with at least 30 patients per treatment group. 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, and so on.

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 NMES of

the suprahyoid musculature. In this study, VitalStim© equipment was used (VitalStim® Therapy; frequency 80 Hz, pulse width 700 μs; Chattanooga Group, Chattanooga, TN, USA). The VitalStim stimulator automatically cycles off for 1 s every minute because of fixed settings by the manufacturer. NMES consisted of transcutaneous electrical stimulation which was given by positioning electrodes bilaterally on the neck in order to facilitate contraction of the suprahyoid muscles (Fig. 1). Groups 2 and 3 differed in the intensity of the applied electrical current of the NMES. The NMES of Group 2 (Group NMES-M) was set to stimulate at a motor level, to an extent such 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 stimulation by their speech therapist during training sessions before the onset of the experiment. The therapists performed test treatment sessions with NMES on their Parkinson's 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 motor and sensory electrical current thresholds were shown.

Therapies were administered at the patient's residence by experienced speech therapists trained in dysphagia management. In total, 85 speech therapists were involved in the study. All groups received 13–15 dysphagia treatment sessions of half an hour each, on five consecutive days per week within a period of 3–5 weeks. All patients were treated within 34 days (median = 23, 25th percentile = 21, and 75th percentile = 25 days). Variation in the number of treatment sessions and period duration resulted from daily logistics in clinical practice.

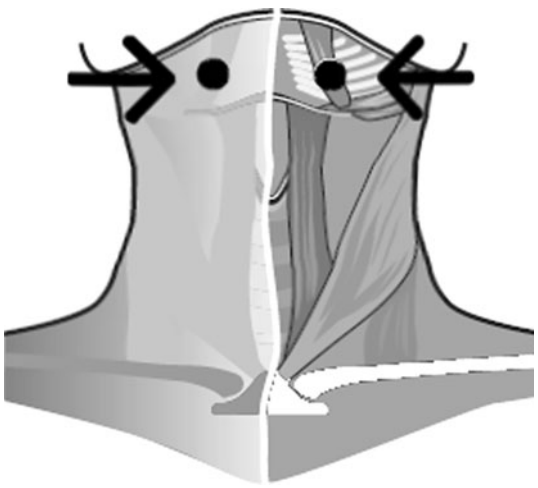

Fig. 1 Position of the electrodes bilaterally on the neck in order to facilitate contraction of the suprahyoid muscles

Evaluation Measurements

Baseline Characteristics

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

Pre-, Post-, and Follow-up Treatment Evaluation

To evaluate diet, the Functional Oral Intake Scale (FOIS) [24] was used (Table 1). Two questionnaires on quality of life with respect to oropharyngeal dysphagia were used in this study: The SWAL-QOL [13] and the MD Anderson Dysphagia Inventory (MDADI) [25]. The Dutch version of the SWAL-QOL, translated and validated by Bogaardt et al. [26], was used to determine the quality of life of dysphagic Parkinson's patients. This 44-item questionnaire is a highly valid instrument for evaluating the quality of life concerning dysphagia and has a very reliable short-term reproducibility [13]. Its 11 subscales represent the different aspects of quality of life. The minimum and maximum score per subscale ranges from 0 to 100, indicating extremely impaired quality of life versus no impairment experienced by the individual. The MDADI consists of 20 items that include a global assessment (a single question) and three subscales: emotional, functional, and physical. 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 by rewriting two questions. All three measurement tools were used to evaluate swallowing function at three time points: pretreatment, post-treatment, and 3 month follow-up. In addition, a visual analog 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

Table 1 Functional oral intake scale (FOIS) for dysphagia [24]

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

("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 post-therapy result. The treatment sessions as well as all examinations were performed during the "on" motor phase of the disease [28]. All scales and questionnaires, with the exception of the DSS, were rated during the patient's visits at the outpatient dysphagia clinic 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 fiber-optic 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 post-therapy data were determined. Differences between post-therapy 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 the inclusion and exclusion criteria, a total of 109 subjects were included in this study. All patients were diagnosed with idiopathic Parkinson's disease with oropharyngeal dysphagia. All patients were assigned to one of the three treatment groups as described above. During the period of intervention, 21 subjects were excluded because of diverse methodological reasons [change of antiparkinsonian 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 finish the full period of therapy. Their mean age was 68 years, with a range of 42–81 years. The MMSE ranged from 23 to 30 points (median = 28), and 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. The patients' characteristics for each treatment group, separately and for all groups combined, are presented in Table 2.

Treatment Effects

The median and the interquartile range of the stimulation intensities in the NMES-M and the NMES-S group were,

Table 2 Descriptive statistics of patient characteristics for each group separately and for all groups combined

Group	Gender[a]	Age (years)		MMSE		H&Y scale	
		Median	25;75[b]	Median	25;75	Median	25;75
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

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation at a motor level; *NMES-S* neuromuscular electrical stimulation at a sensory level

[a] Number of males; number of females

[b] 25th percentile; 75th percentile

respectively, 9.5 (range = 7–13.75) and 3.25 (range = 2.75–4.25) mA. Table 3 presents the descriptive statistics of the baseline and the effect data (post-minus pretreatment data) of the Dysphagia Severity Scale: the median and the 25th and 75th percentiles of a patient's self-evaluation of dysphagia. The median progress on the DSS was 14 points (range = 33–70). The effect data have been tested for significance (Wilcoxon signed-rank test) resulting in a significant positive therapeutic effect for all groups. However, no statistically significant differences in effect data were found between the three treatment groups (Mann-Whitney *U* test).

Tables 4, 5 and 6 give the descriptive statistics of both quality-of-life measurement tools: the SWAL-QOL and the MDADI. Data are presented for each group separately and for the total group. Table 4 gives the descriptive statistics of the baseline data, the effect data, and the follow-up minus post-therapy data of the SWAL-QOL. A Wilcoxon signed-rank test was used to test for significant changes between baseline and post-therapy measurements. Table 5 presents dysphagia-concerning subscales of the SWAL-QOL. Applying a Bonferroni 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 5), no tests were performed to test for significant differences between the post- and follow-up data.

Table 6 gives the descriptive statistics of the baseline data, the effect data, and the follow-up data minus the post-therapy data for the MDADI and its subscales. To test for significant changes between baseline and post-therapy measurements, a Wilcoxon signed-rank test was used.

Table 3 Dysphagia severity scale (DSS)

Group	Baseline data[a]			Effect data			
	Median	25;75[b]	*N*	Median	25;75	*N*	*P*
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

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 post-therapy data compared to baseline data for all groups (Wilcoxon signed-rank test)

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation at a motor level; *NMES-S* neuromuscular electrical stimulation at a sensory level

[a] The maximum score of the scale is 100

[b] 25th percentile; 75th percentile

Table 4 SWAL-QOL: descriptive statistics of the baseline data and the number of patients per treatment group

SWAL-QOL[a]	Baseline data	Burden		Food selection		Eat duration		Eat desire		Fear		Sleep		Fatigue		Communication		Mental health		Social effects		Symptom	
Group	*N*	Med.	25;75[b]	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75	Med.	25;75
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

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation at a motor level; *NMES-S* neuromuscular electrical stimulation at a sensory level; *Med.* median; 25;75 = 25;75%

[a] The maximum score of each scale is 100

[b] 25th percentile; 75th percentile

Table 5 SWAL-QOL

Group	*N*	SWAL-QOL subscale[a]																
		Burden			Food selection			Eat duration			Eat desire			Social effects			Symptom		
		Med.	25;75[b]	*P*	Med.	25;75	*P*	Med.	25;75	*P*	Med.	25;75	*P*	Med.	25;75	*P*	Med.	25;75	*P*
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 post-treatment																			
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		−19	−38;0		0	−16;25		0	0;6		0	−4;5		−4	−12; − 2	
NMES-S	7	0	−25;0		0	0;12		−13	−25;0		0	−41;0		0	−25;5		0	−4;2	
Total group	19	0	0;12		0	−25;0		−12	25;0		0	0;0		0	−10;5		−2	−1;7	

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 post-therapy data compared to baseline data for all groups (Wilcoxon signed-rank test)

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation at a motor level; *NMES-S* neuromuscular electrical stimulation at a sensory level; *Med.* median. *N.S.* not significant; *N.A.* not applicable

[a] The maximum score of each scale is 100

[b] 25th percentile;75th percentile

Table 6 MD Anderson dysphagia inventory (MDADI)

MDADI[a]	Group	Baseline data			Effect data				Follow-up minus post-therapy data			
		Median	25;75[b]	*N*	Median	25;75	*N*	*P*	Median	25;75	*N*	*P*
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	
	NMES-S	4	2;5	27	0	0;1	27	N.S.	0	−1;0	13	
	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	
	NMES-S	20	18;24	25	0	−1;2	25	N.S.	1	−2;2	13	
	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	
	NMES-S	28	22;32	25	2	−5;6	25	N.S.	−2	−5;1	12	
	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	
	NMES-S	20	18;24	27	1	−1;3	26	N.S.	−2	−5;2	12	
	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	
	NMES-S	74	65;82	24	4	−1;9	23	N.S.	−2	−11;3	11	
	Total group	72	64;81	78	4	−1;11	70	0.000	0	−10;3	35	N.S.

Descriptive statistics of the baseline data, the effect data (post-minus pretreatment data), and the follow-up minus post-therapy data, the number of patients per treatment group, and the level of significance of the difference between post-therapy data compared to baseline data for all groups as well as the level of significance of the difference between follow-up data compared to post-therapy data for all groups combined

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation on a motor level; *NMES-S* neuromuscular electrical stimulation on a sensory level; *N.S.* not significant; *N.A.* not applicable

[a] The range of the Total Score, the Global Assessment, and the Emotional, Functional, and Physical subscales is, respectively, 20–100, 1–5, 6–30, 5–25, and 8–40

[b] 25th percentile;75th percentile

Following Bonferroni 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 3 months, the follow-up measurement showed ignorable median changes in all treatment groups. Only total group changes were tested for significance and indicated a minor deterioration of the global assessment score.

Descriptive statistics of baseline data, the effect data, and follow-up minus post-therapy data of the Functional Oral Intake Scale are given in Table 7. The range of scores of the FOIS is 1–7, indicating nothing by mouth to total oral diet with no restrictions.

No significant correlations were found between the dietary intake and the quality-of-life questionnaires or the Dysphagia Severity Scale (all $R < 0.2$). This finding was also observed in the study of Plowman-Prine et al. [11].

Discussion

The aim of this study was to investigate the effects of NMES in patients with Parkinson's disease and oropharyngeal dysphagia compared to the effects of traditional logopedic dysphagia treatment with health-related quality of life (HRQOL) as the primary outcome measure. This study shows positive effects of dysphagia therapy in patients with Parkinson 's disease, as found in other studies [15]. One hundred nine subjects were randomly assigned to one of three different treatment groups. All groups showed 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 displayed a significant improvement on

Table 7 Functional oral intake scale (FOIS)

Functional Oral Intake Scale[a]	Baseline data			Post- minus pretreatment data			Follow-up minus post data		
	Median	25;75[b]	*N*	Median	25;75	*N*	Median	25;75	*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

Descriptive statistics of baseline data and effect data (differences in post- minus pretherapy) and follow-up minus post-therapy data

TT traditional therapy; *NMES-M* neuromuscular electrical stimulation on a motor level; *NMES-S* neuromuscular electrical stimulation on a sensory level

[a] The maximum score of the scale is 7

[b] 25th percentile;75th percentile

the Symptom index. The total group also presented a significant effect on the Burden scale. Using the MDADI, significant therapy effects were 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 were found on, respectively, the global assessment score and the total score. However, only slight nonsignificant differences between groups were found. Additionally, in this study oral intake-related clinical scales did not correlate significantly (all $R < 0.2$) with HRQOL-related scales. The question arises of whether the FOIS scale is a satisfactory measure for dysphagia severity in this patient population given the normal scores in the present study. It is known that there is a discrepancy between symptoms of dysphagia in daily life and oral intake versus the dysphagic findings of swallowing assessment tools like FEES or VFS in Parkinson's disease patients [29]. The hypothesis that electrical stimulation would provide a better outcome for HRQOL cannot be confirmed. It is remarkable that irrespective of the applied quality-of-life measurement tool, no group differences were found regarding effect data or follow-up minus post-therapy 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 a few patients with severe Parkinson's disease (H&Y > 3) were included. Usually this group of patients is admitted to nursing homes and thus would not visit an outpatient clinic. 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 had shown more severe impairments at the beginning of therapy, the 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 the literature, it is unclear which treatment would have been more beneficial for patients with more severe symptoms of Parkinson's disease. Furthermore, the population of included patients is a realistic representation of Parkinson's patients consulting speech therapists for dysphagic complaints. Another explanation for the absence of group differences might be the treatment period of 3 weeks. This treatment period is probably not long enough to observe significant group differences in therapy outcome despite the high intensity of the treatment. 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 [30]. 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 [22, 31], 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 cannot be explained by incompetence of a

restricted number of speech therapists since 85 speech therapists experienced in dysphagia treatment were 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 has been found in favor of any of the three treatment options studied. Perhaps larger patient groups might 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's disease patients with oropharyngeal dysphagia. In this randomized controlled trial, all groups (TT, NMES-S, and NMES-M) 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 have been found. Although some methodological and issues might arise, most of these can be explained by ethical or logistical restrictions. A larger study might be needed to clarify these preliminary findings.

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