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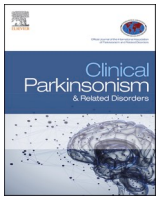

Original Articles

Home-based peroneal electrical transcutaneous NeuroModulation (peroneal eTNM®) in Parkinson's disease as "add-on" treatment – Results of a pilot study

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ABSTRACT

Introduction: Currently, there is no causal cure for Parkinson's disease (PD), and medications and other therapeutic procedures only allow for the reduction of symptoms. Noninvasive neuromodulation is among the potentially promising treatments for PD patients. The present pilot study aimed to evaluate the safety and efficacy of peroneal electrical Transcutaneous NeuroModulation (peroneal eTNM®) in the treatment of PD symptoms with a particular emphasis on disease-related quality of life.

Methods: Twelve patients with clinically established Parkinsońs disease (8 males; mean age 59.5 ± 11.6 years) were enrolled. In addition to state-of-the-art background pharmacotherapy for PD, patients were treated with peroneal eTNM® daily for 30 min for 6 weeks followed by 6 weeks of follow-up without stimulation. The primary endpoint was safety and tolerability, the secondary endpoint was the response of the condition on the 'add-on' peroneal eTNM®.

Results: Peroneal eTNM® proved to be feasible for home treatment in the PD population. Treatment-related adverse events were not reported throughout the study. Along with an excellent safety profile, peroneal eTNM® showed considerable positive trends in terms of improvement in quality of life as measured by EQ-5D-5L questionnaire. There was a definitive trend toward a reduction in Section III of the Unified Parkinson's Disease Rating Scale showing positive changes in tremor-related items. At the end of the study, 50 % of the patients were considered clinical responders.

Conclusions: Larger and more rigorously designed studies are needed to validate the utility and position of peroneal eTNM® in the treatment of patients with PD.

1. Introduction

Treatment of motor symptoms in Parkinsońs disease (PD) is based on systemic administration of levodopa. Despite its clear benefits, there are many limitations associated with initial levodopa treatment (e.g., nausea, drowsiness, orthostatic lightheadedness) and with chronic levodopa therapy (e.g., motor fluctuations and dyskinesia, hallucinations, and other psychiatric side effects) [1]. In patients whose motor fluctuations are refractory and in those with poorly controlled disabling tremor, deep brain stimulation (DBS) might be considered. Although there is consistent evidence showing improvement of motor control, all potential associated risks must be considered [2]. Given the limitations of currently available therapies, the development of a new method with high efficacy, minimal incidence of side effects, and good accessibility is highly desirable.

Peroneal electrical Transcutaneous NeuroModulation (peroneal eTNM®) using the URIS I® neuromodulation system was originally invented as a noninvasive treatment of the overactive bladder (OAB) –

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clinical syndrome defined as sudden desire to void, with or without urgency urinary incontinence. This method is based on highly selective noninvasive bilateral stimulation of the peroneal nerve in popliteal fossa. Its safety and efficacy in OAB treatment was documented in several previous studies [3]. We anecdotally observed that PD patients, treated for OAB with peroneal eTNM® reported a positive effect on symptoms of movement disorders. Therefore, the aim of this pilot study is to investigate the safety and efficacy of peroneal eTNM® in the treatment of PD motor symptoms.

2. Methods

The study protocol was approved by the independent Institutional Review Board of the University Hospital Ostrava, Czech Republic. The study was registered at ClinicalTrials.gov database (reg. Nr. NTC06036368). All patient provided written informed consent to participate in the study.

2.1. Subjects

This study enrolled adult PD patients [4] with currently ongoing long-term pharmacological treatment who presented with bradykinesia, hand tremor and/or rigidity in the 'on' period.

The inclusion criteria at baseline were stable dose of any chronic medications for 30 days prior to study entry and proven ability to independently use the URIS I™ device.

Exclusion criteria included implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator, diagnosed epilepsy or other seizure disorder, dementia [5], lower limb peripheral neuropathy, chorea and/or dyskinesia, major depressive disorder [5], botulinum toxin injection within 6 months prior to study enrolment, and known active malignant disease.

2.2. Intervention

Patients were treated with peroneal eTNM® using the URIS I™ neuromodulation system (STIMVIA®, Ostrava, Czech Republic) at their home. The self-adhesive neutral electrode was attached to the skin in the lower abdomen. Active electrodes were placed over the peroneal nerves in the popliteal fossa bilaterally. Correct placement of active electrodes was confirmed by eliciting rhythmic reflex movements of both feet upon initialization of the stimulation. The stimulation frequency was initially set to 4 Hz and then continuously adjusted based on data from the biofeedback foot sensor. The pulse width was set at 2 ms, and the voltage was adjusted to the level of motor threshold. The device is shown in Supplementary Fig. 1.

2.3. Study design and procedures

This prospective pilot study evaluated the "add-on" effect of peroneal eTNM® on currently ongoing long-term pharmacological treatment (at stable dose) in patients with PD. All study assessments were performed in "on" state. In total, six visits at the center were scheduled during the study – Screening visit at Day 14 (SC), Baseline (BL) visit at Day 0, Week 1 visit (W1) at Day 7, Week 3 visit (W3) at Day 21, End of treatment visit (EoT) at Day 42 and End of study visit (EoS) at Day 84. During BL, all baseline data were obtained. Subsequently, eligible participants were instructed how to perform the peroneal eTNM® and dispensed with the URIS I™ neuromodulation device. The patients were advised to use peroneal eTNM® daily for 30 min at home for 6 weeks (42 days) starting from Day 1. Clinical evaluations were performed during EoT at least 24 h after the last stimulation. EoS data were collected after 6 weeks follow-up without stimulation. The study design is summarized in Supplementary Fig. 2.

2.4. Endpoints

The primary endpoint was safety and tolerability. The secondary endpoint was the response of the condition on the 'add-on' peroneal eTNM® measured by Patient's global impression of improvement (PGI-I). PGI-I response scale ranged from 1 to 7, with 1 being "very much improved" and 7 being "very much worse" [6]. The exploratory endpoints included: (a) change in The Movement Disorders Society-Sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) total score and subscores; (b) change in severity/amplitude of rest tremor as measured visually in all extremities; c) change in health specific quality of life measured by Parkinson's Disease Questionnaire (PDQ-39); (d) quality of life measured by European Quality of Life 5 Dimensions Questionnaire (EQ-5D-5L) [7].

2.5. Statistical analysis

The statistical analyses were performed using SAS Studio (version 9.04.01). Since the data are not normally distributed, analyses included descriptive statistics using median and interquartile ranges, unless indicated otherwise. At the same time the mean and standard deviation are listed to indicate the effect size and allow comparison to other studies. To evaluate the difference at the baseline demographic data between the responders and non-responders, Hedges' g effect size was calculated [8,9]. Effect size value >0.25 does not satisfy equivalence. No formal hypothesis testing was carried out, instead 95 % confidence intervals are shown to indicate the effects compared to the baseline at various endpoints.

3. Results

In total, 12 patients (8 males; mean age 59.5 ± 11.6 years) were enrolled. The patients were on long-term treatment with levodopa (n = 3), dopamine agonists (n = 2) or combination (n = 7) with constant dose throughout the study from Baseline to the End of Study. Patient demographic and baseline characteristics are shown in Supplementary Table 1.

The average number of stimulation sessions was 40 ± 1.2 (40–41; 95 % CI) out of 41 possible. All patients were able to stimulate themselves at home without assistance. Peroneal eTNM® was very well tolerated; no patient reported pain or any uncomfortable sensations during stimulation. Seven adverse events were reported during the study, all of them were considered mild and not related to treatment – three cases of clinically not significant findings on the ECG, one case of laboratory findings of increased creatinine, one case of increased level of non-fasting glucose, one case of low back pain, and one case of intestinal infection. All patients who had reported adverse events were able to complete treatment according to the study protocol.

Change in Patient global impression of improvement (PGI-I) was defined as secondary endpoint of the study. The proportion of responders based on reported PGI-I score (PGI-I $\leq$ 3) was 42 % patients at EoT and 50 % patients at EoS visit.

We observed a definitive trend toward a reduction in the Movement Disorders Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Section III (Motor Examination) subscore. The main positive changes were observed in the postural, kinetic, and particularly in the rest tremor-related items. The results are summarized in Table 1 and Supplementary Tables 2 and 3.

The visual assessment of rest tremor showed that the left upper limb was the most affected, with 9 out of 12 subjects exhibiting tremors. A reduction of at least 50 % in rest tremor was observed in 6 out of 9 subjects (67 %) at EoT and in 8 out of 9 subjects (89 %) at EoS (Table 2).

We also observed an improvement in the Parkinson's Disease Questionnaire (PDQ-39) total score and its individual subscores, especially in Bodily Discomfort, Emotional, Cognition, and Stigma. The results of the European Quality of Life 5 Dimensions Questionnaire (EQ-

Table 1
Results of the Movement Disorder Society-Sponsored Revision of the Unified Parkinson's Disease Rating Scale Total Score and Subscore III, PDQ-39 Questionnaire, and EQ-5D-5L for the Full Analysis Set (n = 12).

	Baseline	End of Treatment		End of Study	
	median (IQR) mean ± SD	median (IQR) mean ± SDmedian (IQR)	(95 % CI)	median (IQR) mean ± SDmedian (IQR)	(95 % CI)
MDS-UPDRS					
Total score	38.0 (29.5; 46.0)	30.5 (29.0; 41.0)		30.5 (29.0; 41.5)	
	37.8 ± 9.4	34.5 ± 10.4		35.2 ± 11.7	
Change from BL		−1.0 (−5.5; 0.5)	(−8.5; 2.0)	0.0 (−4.5; 0.5)	(−8.2; 3.0)
Subscore III	29.5 (21.0; 31.5)	24.0 (20.0; 26.5)		24.5 (20.0; 29.5)	
Change from BL	27.5 ± 7.6	24.3 ± 7.8		24.9 ± 8.4	
		−1.0 (−4.5; 1.5)	(−8.1; 1.8)	0.5 (−3.5; 2.0)	(−7.8; 2.7)
PDQ-39					
Total score	16.0 (12.8; 26.4)	11.5 (6.1; 19.4)			
	20.6 ± 15.2	15.3 ± 14.4			
Change from BL		−0.5 (−9.1; 1.8)	(−12.2; 1.5)		
Mobility	13.8 (6.3; 43.8)	10.0 (5.0; 27.5)			
	24.2 ± 23.5	19.2 ± 21.6			
Change from BL		−2.5 (−8.8; 2.5)	(−12.3; 2.3)		
ADL	27.1 (8.3; 43.8)	18.8 (4.2; 35.4)			
	27.1 ± 21.2	23.6 ± 23.1			
Change from BL		0.0 (−12.5; 4.2)	(−11.1; 4.2)		
Emotional	12.5 (4.2; 27.1)	4.2 (0.0; 12.5)			
	17.0 ± 17.2	10.4 ± 16.2			
Change from BL		−2.1 (−10.4; 0.0)	(−14.0; 0.8)		
Stigma	21.9 (3.1; 50.0)	15.6 (0.0; 28.1)			
	29.7 ± 29.8	19.8 ± 25.8			
Change from BL		−6.3 (−9.4; 0.0)	(−21.1; 1.3)		
Social	0.0 (0.0; 8.3)	0.0 (0.0; 12.5)			
	8.3 ± 14.2	6.9 ± 9.9			
Change from BL		0.0 (−4.2; 0.0)	(−5.8; 3.0)		
Cognitional	15.6 (6.3; 25.0)	9.4 (0.0; 21.9)			
	16.1 ± 10.5	12.5 ± 13.6			
Change from BL		−3.1 (−9.4; 6.3)	(−12.8; 5.5)		
Communication	8.3 (0.0; 16.7)	8.3 (0.0; 16.7)			
	11.1 ± 14.8	11.1 ± 14.8			
Change from BL		0.0 (−4.2; 8.3)	(−9.6; 9.6)		
Bodily Discomfort	29.2 (16.7; 45.8)	16.7 (12.5; 20.8)			
	31.3 ± 21.4	18.8 ± 12.9			
Change from BL		−8.3 (−20.8; 0.0)	(−24.8; −0.2)		
EQ-5D-5L					
Index score	0.664 (0.566; 0.893)	0.781 (0.627; 0.953)			
	0.706 ± 0.204	0.763 ± 0.204			
Change from BL		0.063 (−0.004; 0.127)	(−0.069; 0.182)		
VAS	60.5 (47.5; 85.5)	67.5 (60.0; 92.5)			
	62.7 ± 24.4	74.2 ± 19.4			
Change from BL		5.0 (0.0; 16.5)	(−0.7; 23.7)		

ADL – Activity of Daily Living; BL – Baseline; CI – Confidence Interval; EoT – End of Treatment; EQ-5D-5L – European Quality of Life 5 Dimensions Questionnaire; FAS – Full Analysis Set; IQR – Interquartile Range; MDS-UPDRS – Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; PDQ-39 – Parkinson's Disease Questionnaire; SD – Standard Deviation; VAS – Visual Analog Scale.

5D-5L) showed an improvement in patient general health quality after therapy. The most evident improvement was in the domains of Self-Care and Anxiety/Depression. A notable positive trend was also observed in the Mobility and Pain/Discomfort domains. The EQ-5D-5L index increased from 0.664 (95 % CI: 0.566 to 0.893) at baseline to 0.781 (95 % CI: 0.627 to 0.953) after therapy.

4. Discussion

This study confirmed the safety, tolerability and feasibility of peroneal eTNM® in home settings, which is a critical factor for its accessibility. No adverse events related to the treatment were observed during the study period. In addition, all patients were able to stimulate themselves at home without assistance. Adherence to the treatment was very high, reaching well over 90 %.

We achieved notable positive effects on rest, postural and kinetic tremor in MDS-UPDRS. In addition, we observed the reduction of tremor amplitude during visual and accelerometer assessment in all extremities except the right leg. This variation is likely attributable to the small sample size, as only three study participants presented with rest tremor in the right leg at baseline. Importantly, as evident from the data obtained at the EoS visit 6 weeks after the end of stimulation, most of the patients reported a sustained improvement in their tremor indicating persistence of the effect. This aligns with our previous observations in

Table 2
Visual assessment of the rest tremor over the study period.

	n	Baseline (mm)	EoT (mm)	EoS (mm)	EoT – Baseline change (mm)	EoS – Baseline change (mm)	EoT – Baseline Relative change (%)	EoS – Baseline Relative change (%)
Left hand/arm	9							
Median (IQR)		10 (10; 20)	5 (0; 10)	5 (0; 7.5)	−5.0 (−16; 2.5)	−5 (−15; −5)	−50 (−100; −17)	−67 (−100; −50)
(Min; Max)		(5; 30)	(0; 10)	(0; 10)	(−25; 0)	(−25; −5)	(−100; 0)	(−100; −33)
(95 % CI)					(−16; −1.6)	(−16; −4.2)	(−87; −25)	(−94; −51)
Right hand/arm	5							
Median (IQR)		10 (5; 23)	0 (0; 11)	5 (0; 13)	−5.0 (−19; 2.5)	−5 (−19; 2.5)	−70 (−100; 25)	−80 (−100; 50)
(Min; Max)		(5; 25)	(0; 15)	(0; 20)	(−20; 5)	(−20; 5)	(−100; 50)	(−100; 100)
(95 % CI)					(−21; 6)	(−23; 9.2)	(−127; 39)	(−143; 71)
Left leg/foot	5							
Median (IQR)		10 (5; 18)	0 (0; 10)	0 (0; 2.5)	−10 (−18; 5)	−10 (−18; −2.5)	−100 (−100; 100)	−100 (−100; 50)
(Min; Max)		(5; 20)	(0; 15)	(0; 5)	(−20; 10)	(−20; 0)	(−100; 200)	(−100; 0)
(95 % CI)					(−22; 8)	(−20; −0.18)	(−182; 142)	(−136; −24)
Right leg/foot	3							
Median (IQR)		5 (5; 10)	7.5 (0; 15)	5 (0; 20)	2.5 (−5; 5)	−0 (−5; 10)	50 (−100; 50)	0 (−100; 100)
(Min; Max)		(5; 10)	(0; 15)	(0; 20)	(−5; 5)	(−5; 10)	(−100; 50)	(−100; 100)
(95 % CI)					(−12; 14)	(−17; 21)	(−215; 215)	(−248; 248)

CI – Confidence Interval; EoS – End of Study; EoT – End of Treatment; IQR – Interquartile Range; n- Number of patients presenting with tremors in each respective extremity.

OAB patients.

Along with symptom improvement, we observed a improvement in both disease-specific and general health-related quality of life. It should be noted that these results were achieved in hard-to-treat patients with state-of-the-art background pharmacotherapy. Given that all medications were administered at a constant dose over the entire study period, we believe that the treatment effect is related to the neuromodulation rather than to the medication.

Tremor is a physical, psychological, and socially detrimental symptom of PD, with a large impact on overall quality of life. Although dopaminergic medication effectively treats bradykinesia and rigidity, its effect on tremor is unpredictable and varies greatly between patients. It has been documented that this medication improves the tremor only in about 50 % of PD patients [10]. Other drugs available for tremor control include anticholinergics, monoamine oxidase B inhibitors, clozapine, and beta-blockers. Their variable effects on tremor and the frequent occurrence of adverse events limit their widespread use [11]. Therefore, if proven effective and safe, peroneal eTNM® would be a highly beneficial noninvasive treatment for tremor and other motor symptoms in these patients.

There are several possible mechanisms that could explain the effect of peroneal eTNM® on motor symptoms in PD patients. Evidence suggests that peroneal eTNM® elicits a hemodynamic response in brain regions including the brain stem, the thalamus, and the basal ganglia [12]. Therefore, peroneal eTNM® might affect structures such as the ventral intermediate nucleus of the thalamus, which plays a key role in the tremor pathophysiology and/or pedunculopontine nucleus of the pons which plays a modulatory role in gait. In addition, the effect of neuromodulation on nonspecific neural networks and their functional connectivity (e.g., attentional, salience, sensorimotor networks, and others) should be considered. Although the peroneal eTNM® was originally invented for treatment of OAB, this study focused on addressing tremor, and lower urinary tract symptoms (LUTS) were not included in the inclusion criteria. None of the patients enrolled in the study presented with LUTS. As a result, we were unable to assess the effect of peroneal eTNM® on LUTS in this study.

Along with strengths, such as the novelty of this noninvasive technology, the use of comprehensive validated diagnostic tools, and the prospective study design with 6-week follow-up post treatment, it is essential to acknowledge several limitations. These include the short duration of treatment, the limited number of patients, the absence of a control group, and open-label design with certain risk of investigators bias and placebo effect. Despite these limitations, we believe that this study provides convincing initial data and justification for future larger studies using this treatment method.

5. Conclusion

In conclusion, peroneal eTNM® showed promising trends in terms of improving quality of life and PD symptoms including tremor. Future studies, with larger sample sizes are crucial to validate these preliminary findings and demonstrate the full potential benefits of peroneal eTNM® in the treatment of PD-related motor symptoms.

CRediT authorship contribution statement

Petra Bártová: Writing – review & editing, Methodology, Investigation. **Eva Augste:** Project administration, Methodology, Investigation. **Filip Strouhal:** Methodology, Investigation. **Jan Krhut:** Writing – review & editing, Writing – original draft, Supervision, Conceptualization. **Martin Slovák:** Writing – review & editing, Formal analysis, Data curation. **Roman V. Dvorak:** Writing – review & editing, Validation. **Lukáš Peter:** Writing – review & editing, Validation. **Martin Schmidt:** Methodology, Formal analysis, Data curation. **David Školoudík:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Conceptualization.

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy or ethical restrictions.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: David Skoloudik reports administrative support and equipment, drugs, or supplies were provided by STIMVIA. Jan Krhut reports a relationship with STIMVIA that includes: consulting or advisory. Jan Krhut reports a relationship with Medtronic Inc that includes: consulting or advisory. Jan Krhut reports a relationship with Promedon SA that includes: consulting or advisory. Jan Krhut reports a relationship with Coloplast Slovakia that includes: Martin Slovak reports a relationship with STIMVIA that includes: consulting or advisory and employment. Lukas Peter reports a relationship with STIMVIA that includes: employment. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.prdoa.2025.100321.

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