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Overground robot assisted gait trainer for the treatment of drug-resistant freezing of gait in Parkinson disease

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ABSTRACT

Freezing of Gait (FOG) is a frequent and disabling feature of Parkinson disease (PD). Gait rehabilitation assisted by electromechanical devices, such as training on treadmill associated with sensory cues or assisted by gait orthosis have been shown to improve FOG. Overground robot assisted gait training (RGT) has been recently tested in patients with PD with improvement of several gait parameters. We here evaluated the effectiveness of RGT on FOG severity and gait abnormalities in PD patients. Eighteen patients with FOG resistant to dopaminergic medications were treated with 15 sessions of RGT and underwent an extensive clinical evaluation before and after treatment. The main outcome measures were FOG questionnaire (FOGQ) global score and specific tasks for gait assessment, namely 10 meter walking test (10 MWT), Timed Up and Go test (TUG) and 360° narrow turns (360 NT). Balance was also evaluated through Fear of Falling Efficacy Scale (FFES), assessing self perceived stability and Berg Balance Scale (BBS), for objective examination. After treatment, FOGQ score was significantly reduced ($P = 0.023$). We also found a significant reduction of time needed to complete TUG, 10 MWT, and 360 NT ($P = 0.009$, 0.004 and 0.04, respectively). By contrast the number of steps and the number of freezing episodes recorded at each gait task did not change. FFES and BBS scores also improved, with positive repercussions on performance on daily activity and quality of life. Our results indicate that RGT is a useful strategy for the treatment of drug refractory FOG.

1. Background

Freezing of gait (FOG) is a disabling feature of Parkinson disease (PD), characterized by sudden and unwanted arrests of gait, which frequently occurs when initiating walking and in presence of obstacle or narrow tracks [1]. In the early PD about 20% of patients report FOG, but the prevalence of this phenomenon raises up to 50% in the advanced disease stages [2]. Moreover, while in early patients, FOG occurs during the off periods and is relieved by levodopa administration, with disease progression it often becomes refractory to dopaminergic therapy [3], and shows poor or no response to advanced treatments, including deep brain stimulation [4].

Different rehabilitative strategies have been proposed for the treatment of FOG. Walking training with visual or auditory cues showed variable results in different studies [5]: generally the number of FOG episodes recorded during laboratory assessment did not change [6] and only few studies showed an improvement in anamnestic FOG questionnaire [7–9]. Recently, Frazzitta et al. showed that training on treadmill, combined with visual and auditory cues, is more efficacious than unspecific physical therapy [10]. Similarly, robot assisted treadmill training improved FOG in limited cohorts of PD patients [11,12].

Over-ground robot-assisted Gait Training (RGT) has been shown to be equally or even more efficacious than treadmill training in improving several gait parameters and balance in moderate to severe PD [13,14]. However, the effect of RGT on FOG has not been specifically assessed.

The primary aim of the present study was to evaluate the effectiveness of RGT on FOG severity and gait abnormalities in PD patients with FOG resistant to dopaminergic medications. Moreover we investigated the impact of this treatment on global motor impairment, functional ability and health related quality of life.

2. Methods

2.1. Patients

In this open label study we enrolled PD patients consecutively hospitalized for rehabilitative therapy at Movement Disorder Unit of the Hospital San Camillo in Venice between March 2012 and March 2013.

The protocol was approved by local Ethical Committee.

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The inclusion criteria were diagnosis of PD according to United Kingdom Brain Bank Criteria, presence of FOG refractory to pharmacological therapy, H&Y stages 2.5–4 in on medication condition, stable antiparkinsonian treatment in the 4 weeks before enrolment in the study, and willingness to participate to the study expressed through written informed consent. The presence of severe dyskinesias was an exclusion criterion, since abnormal movements might interfere with training performance. We also excluded patients with medical conditions which could preclude training execution or affect treatment safety, such as severe painful musculoskeletal disease, severe orthostatic hypotension, uncontrolled hypertension, ischemic cardiopathy or other serious cardiovascular comorbidities.

Patients with weight >90 Kg were excluded from the study, according to the bearing limit of the RGT device.

2.2. Study treatment

All patients included in the study were trained on RGT (Rehastim, Berlin). This device consists in over-ground motor driven footboards moving at a constant speed (ranging from 0 to 2 Km/h), regulated according to patient capabilities. The footboards run on a constant trajectory, and wideness can be individually adjusted to obtain a step length ranging from 28 to 48 cm. The machine is provided with a harness for body-weight support.

Walking speed was set for each patient at a comfortable velocity (ranging from 0.5 to 2 Km/h). Progressive increase of gait speed was allowed in successive training session according to patient tolerability. Step length was individually adjusted according to patient stature (from 40 to 48 cm), in order to allow comfortable leg movements. Patients were ensured to the harness and body weight support was set at 5 Kg for all the patients. Training sessions were supervised by a physiotherapist for correct performance of the exercise and eventual speed modulation. During exercise patients were repeatedly reminded to adjust posture and to maintain an active control on the legs, avoiding to passively follow the footboard movements.

Thirty minutes training sessions were performed 5 days a week for three consecutive weeks.

Pharmacological treatment was kept stable throughout the study period.

2.3. Clinical assessments

The same clinical assessments were performed before starting and one week after the end of treatment. Motor evaluations were performed in the morning, 60 to 90 min after levodopa intake; a trained neurologist (MP) verified that patients were in “on phase” at the time of evaluation.

Primary outcomes were FOG severity, assessed by FOG questionnaire (FOGQ) [15] and gait parameters measured by objective clinical evaluation, including Timed Up and Go test (TUG), 10 m walking test (10-MWT), 10 MWT associated with a cognitive task (patients were asked to list words starting with the same letter while performing walking test) (DT 10 MWT), 360° narrow turns (360 NT) to the left and to the right side [16]. For each clinical objective evaluation we recorded: 1) number of FOG episodes occurring during the task, 2) time taken to complete the task (seconds) and 3) number of steps.

Secondary outcome measures were the Fear of Falling Efficacy Scale (FFES) to assess the fear of falling during daily activities [17] and the Berg Balance Scale (BBS), which evaluates balance abilities while sitting, standing and during positional changes [18]. Global motor impairment and performance in activities of daily living were assessed by the validated Italian version of the Movement Disorder's society Unified Parkinson's Disease Rating Scale [19] (UPDRS) part III and part II, respectively.

Moreover, quality of life was measured by the Parkinson's Disease Questionnaire-8 (PDQ-8) [20].

Antiparkinsonian therapy was recorded for each patient and levodopa equivalent daily dose was calculated according to a pubblished formula [21].

2.4. Statistical analysis

Statistical analysis was carried out using the IBM-Statistical Package for the Social Sciences (SPSS 20.0). Non-parametric Asymptotic Signed (2-tailed) Wilcoxon Signed Rank Test was used to assess differences in the distribution of clinical continuous variables between pre and post evaluation.

3. Results

Twenty PD patients fulfilled selection criteria and entered the study. Two patients dropped out after the first session, due to inability to follow trainer's instructions and insufficient collaboration while the remaining 18 completed the study without any adverse event.

Patients' demographic and clinical data are reported in Table 1.

Among primary outcome measures, FOGQ score was reduced from 13 ± 3.39 at baseline to 9.2 ± 5.44 after treatment (P 0.023) time needed to perform TUG,10 MWT and 360 NT was reduced (P = 0.009, 0.004 and 0.04, respectively). The number of steps needed to carry out each gait task was also decreased, but did not reach statistical significance. Only 360 NT showed a trend for lower number of FOG episodes (P = 0.06); DT 10 MWT did not change after treatment for any of the observed variables (Table 2).

Results for secondary outcomes are reported in Table 2. After treatment, FFES was significantly decreased (P = 0.04) and BBS significantly increased (P = 0.04) indicating an improvement of self perceived steadiness and objective balance performances.

PDQ-8 improved from 10.2 ± 5.7 to 7.9 ± 5.2 (P = 0.03), while MDS-UPDRS II improved from 13.6 ± 4.3 to 10.6 ± 5.2 (P = 0.005). Global motor score (UPDRS III) was unchanged (Table 3).

4. Discussion

FOG increases the risk of falls and negatively impacts on quality of life [22]. The development of rehabilitative strategies to improve this phenomenon is crucial for the management of Parkinson's disease, especially when FOG is refractory to pharmacological therapy. In patients with severe FOG traditional rehabilitative strategies, such as ground or treadmill gait training, can be limited by the onset of FOG episodes and patients need to be carefully monitored during training to prevent falls.

Overground RGT has been shown to improve several gait parameters in patients with PD, but it has been never specifically studied in patients with drug refractory FOG.

Our study demonstrates that RGT is feasible and safe in this particular subgroup of patients. Indeed, 18 out of 20 patients included in the study, despite severe motor disability (all the patients had an H&Y score included between 3 and 4). Two patients were unable to complete the rehabilitation protocol because they could not understand training

Table 1
Clinic and demographic data.

	Median	Range
Age (years)	64.5	45–71
Disease duration (years)	11.5	8–22
Levodopa equivalent dose (mg)	903.3	300–1744
MMSE	27.5	24–30
Hoehn and Yahr stage	Number of patients	
3.0	10	
4.0	8	

This table illustrates clinic and demographic characteristics of study population.