Movement Disorders

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Sensor-based motor state detection in Parkinson's disease to approach personalized therapy delivery

L.P. Roncoroni, M. Scholten, I. Hanci, A. Gharabagi, D. Weiss (Tuebingen, Germany)

Objective: As primary objective, we acquire a data pool of medically-treated PD patients with motor fluctuations to determine the sensitivity and specificity of algorithms capable to classify the motor state in time.

Background: Motor fluctuations in Parkinson's disease are often unpredictable and transitions between motor states (e.g. between hypokinesia and dyskinesia) often occur in short time intervals. Continuous therapies like medication pumps and subthalamic nucleus deep brain stimulation alleviate these fluctuations, however, provide rather rigid treatment regimens. Closed-loop applications might pave the way towards more personalized regimens in future, however, critically depend on valid biomarkers.

Methods: In first pilot recordings, we captured motor transitions between motor states under ongoing clinical survey and additional video documentation allowing for accurate clinical categorization. For cross-validation, we record accelerometry and gyrometry in terms of mobile inertial sensors (APDM mobility lab). We performed first exploratory analysis on these signals based on power spectral estimates.

Results: In these first preliminary analyses, we found that dyskinesias (resting position) were paralleled by a low-frequency activity increase below 4Hz. However, we expect relevant confounding from voluntary movements under daily life conditions, and expect to refine the motor state detection by adding more sophisticated classification algorithms. To this end, we plan to validate independent component analyses, and supervised learning algorithms to render the motor state classification more robust.

Conclusions: Biomarkers for automated motor state detection shall be obtained and are believed to assist personalized therapy in future.

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Randomized controlled trial protocol: Balance training with rhythmical cues to improve and maintain balance control in Parkinson's disease

T.T.C. Capato, J. Tornai, V.F. Gianguiagi, R.R. Firmino, E.R. Barbosa, M.E. Piemonte (São Paulo, Brazil)

Objective: Is to evaluate the effects of balance training with rhythmical(BRT) which is a motor program to improve balance associated with rhythmical auditory cues (RACs). This study is ongoing in the stage 1 to 2.

Background: Postural instability is a particularly incapacitating disorder, where loss of motor independence by pelope with Parkinson's Disease (PD) marks a significant stage of disease onset. Evidence suggests that deficits in automatic motor control, sensory integration and attention are associated with lack of balance in PD. Physiotherapy, together with medication, plays an important role in the treatment of this state.

Methods: A total of 150 PD patients at H&Y stages II–III and asymptomatic for depression and dementia were enrolled in a single-blind randomized study. Randomization was achieved via a computer-generated random-sequence table. All patients should also present a fall history. They were assigned into one of three groups, and their balance and gait were assessed before and after 10 training sessions, and after 4 and 30 weeks subsequent to the end of the training. The BRT group received a motor program to improve balance associated with RACs, the MT group performed motor training with the same aims as those in the BRT group but without RACs, and the control group (CG) was trained only in orientations. The exercise program specific to balance is of 5 weeks' duration with two sessions per week, 45 minutes each, and consists of general physiotherapy exercises. Each session is divided into five warm-up minutes—30 minutes for the main part and 10 minutes for the cool down. The training progresses and intensifies each week depending on the individual's performance. The subjects should be able to execute 10 repetitions of the exercise sequences correctly to progress to the next movement. Clinicaltrials.gov NCT02488265; Ethics Committee of the University of São Paulo Faculty of Medicine Clinics Hospital 1.102.464.

Results: The preliminary results showed improvement on BRT and MT Groups TUG (p=0,01), 6 min walk (p=0,00). To BBS (p=0,00), Mini BESTest (p=0,00) only to BRT showed difference.

Conclusions: This protocol could be effective to improve balance and gait; evaluate the effects of a motor program to improve balance associated with RACs and assess whether balance training leads to activation of balance reactions.

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Utilizing remote blood pressure monitoring in a phase III clinical drug trial for Parkinson's disease

J.L. Adams, R.A. Biemiller, K.L. Andrzejewski, S. Sharma, R.L. Rockhill, B.L. Greco, K.C. Hodgeman, P. Singh, S. Khanuja, T. Simuni, K.M. Biglan (Rochester, NY, USA)

Objective: To determine the feasibility and value of remote blood pressure (BP) monitoring during a clinical trial of isradipine (a dihydropyridine calcium channel antagonist) in early Parkinson's disease (PD).

Background: Orthostatic hypotension is common in PD and clinical trials evaluating blood pressure lowering treatments may require BP monitoring for safety. This monitoring has traditionally been in the form of home BP logs, which allow for frequent readings, but cannot be reviewed in real time for safety and are unable to ensure data integrity or protocol compliance. Remote real time BP monitoring can increase study safety, validity and compliance. Steady-PDIII is a phase III randomized placebo-controlled trial of the efficacy of isradipine on the progression of PD disability that utilized remote BP monitoring to ensure safety and to facilitate dosage titration.

Methods: Subjects were required to take sit and stand BP readings twice daily during screening and drug titration. BP readings are sent from the BP monitor to an online database in real time, which is reviewed by a clinical BP monitor. BP readings outside the safety range (90-160mm of Hg systolic, 60-90mm of Hg diastolic) were flagged by the system with orthostatic reads identified manually. We evaluated the frequency of BP monitoring, participant compliance with the BP protocol, and the frequency of clinical interventions necessitated by BP readings.

Results: 382 Participants completed 17,682 days of monitoring and 70,956 total BP readings. Review of protocol compliance revealed that readings were not taken the required number of times on 26% of the days and 48% of participants did not take BP readings as specified in the protocol. The clinical monitor contacted sites for 48 subjects (12.6%) for out of range or orthostatic readings. As a result, 2 subjects re-initiated home BP readings, 7 subjects were excluded based on out of range BP readings, and 3 subjects had study drug dosage reductions.

Conclusions: Remote BP monitoring in a clinical trial is feasible and allows for faster response to potential safety concerns. Subjects are capable of managing the technical issues of home monitoring and compliance to the BP protocol was fair. Improvements in participant protocol education may minimize barriers to compliance and further improve patient safety in clinical trials.

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Therapeutic protocol for Parkinson's patient with freezing based on action observation plus sonification: Preliminary results

S. Mezzarobba, M. Grassi, M. Catalan, L. Pellegrini, R. Valentini, B. Krüger, P. Manganotti, P. Bernardis (Trieste, Italy)

Objective: To evaluate the effects of a *novel* experimental protocol to treat patients with Parkinson's disease (PwP) and freezing of gait (FoG), using functional, and clinical scales, and gait analysis.

Background: FoG is a disabling symptom strictly associated to falls. The little or no pharmacological responsiveness of FoG has led to an increasing interest in rehabilitation interventions aimed at functional recovery and autonomy. Currently, standard protocols employed for rehabilitation are based on the use of external sensory cues. However, cued strategies generate an important dependence on the environment. Teaching motor strategies without cues (i.e. *action observation*) can be an alternative/innovative approach to rehabilitation that matters most on appropriate allocation of attention and lightening cognitive load.

Methods: We compared the effects of two different therapeutic protocols on three gait movements: walk, step initiation, and sit-to-step. The experimental protocol was based on action observation plus *sonification*; patients re-learned 8 motor gestures watching video-clips
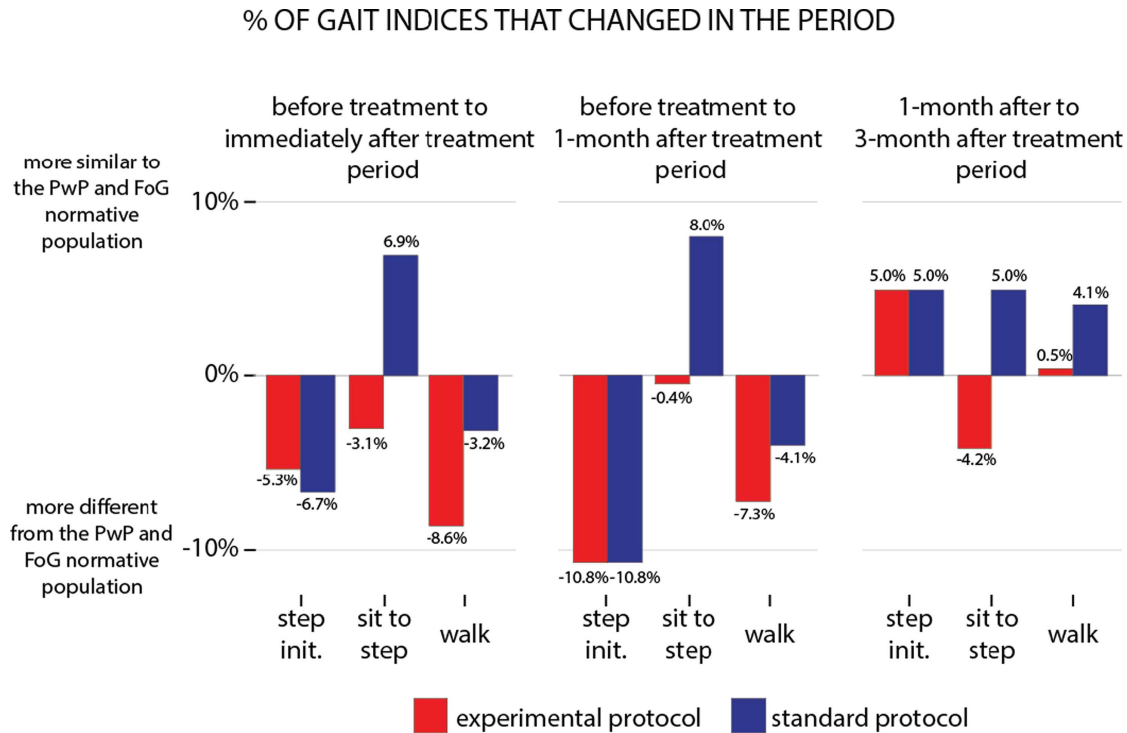
Fig. 1 (2083). % of gait indices that changed in the period. Positive and increasing values correspond to a gait profile that is more similar to the normative population. Negative and decreasing values correspond to a gait profile that is more different from the normative population. A value of 0% means that no changes ware occurred in the period. Before treatment the % of indices in common with the PwP and FoG population was comparable (34% - experimental protocol, 32% - standard protocol).

showing an actor performing the same gestures, and then tried to repeat the gesture. Each video-clip was composed by images and sounds of the gestures. The sounds of gestures were obtained with the sonification technique, by transforming kinematic data (velocity) recorded during the execution of gesture, into pitch variations (for an example see: bit.ly/sonif_example). The same 8 motor gestures were re-learned in the standard protocol, with a common sensory stimulation method. We evaluated patients with functional and clinical scales before, immediately after, at 1 month, and 3 months after the treatment. We also compared gait indices with those of a normative sample of PwP and FoG (Mezzarobba et al. 2015). Preliminary data are based on two patients.

Results: Overall, data showed that both protocols have positive effects on functional and clinical tests. Larger performance improvements were seen with the experimental protocol. In the after treatment evaluations, the number of indices that differed from those of the normative sample, were larger in the experimental protocol than the baseline protocol.

Conclusions: These preliminary data suggest that a multisensory approach could help PwP with FoG to re-learn gait movements, to reduce freezing episodes, and that these effects could be prolonged over time.

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The effects of intensive speech treatment on intelligibility in Spanish dysarthria secondary to Parkinson's disease

G. Moya-Gale, E. Levy (New York, USA)

Objective: To examine the effects of intensive speech treatment (LSVT-LOUD; Ramig et al., 2001) on intelligibility at conversational level in Spanish dysarthria secondary to Parkinson's disease (PD).

Background: The Lee Silverman Voice Treatment (LSVT-LOUD) has been shown to improve vocal function in speakers with PD. However, its efficacy has only been established for English. Little is known about its effects on other languages, such as Spanish.

Methods: Sixteen Spanish-speaking individuals with PD (11 males and 5 females) received one month of LSVT-LOUD treatment. They were native speakers of Castilian Spanish, ranging in age from 58 to 82

years (M = 70, SD = 8). Speakers were recorded producing a one-minute emotional monologue one month and one week before treatment, as well as one week and one month post-treatment. Twenty-one listeners (nine men and 12 women) orthographically transcribed utterances from the monologues produced by speakers with PD pre- and post-treatment. Utterances were also rated for ease of understanding on a 9-point Likert scale (1 = unintelligible; 9 = very intelligible). Thirteen healthy controls were recorded twice throughout the study for later comparison.

Results: The mean transcription accuracy scores for speakers with PD at baseline were significantly lower than for healthy controls (F(1,1737) = 164.5, p = <.001). The mean transcription accuracy scores for speakers with PD were 32.28% (SD = 39.62%) for the first pre-treatment and 28.55% (SD = 33.64%) for the second pre-treatment sessions. Performance did not differ significantly at baselines (p > .05). Median intelligibility ratings were 2 and 3 at pre-tests. Positive effects of intensive speech treatment on speech intelligibility were found (p = <. 001). The mean transcription scores immediately post-treatment were 71.72% (SD = 35.14%) and 66.08% (SD = 37.12%) at the one-month follow-up. The increase in post-treatment performance was statistically significant (p = <.001). Median intelligibility ratings were 8 immediately post-treatment and 7 at follow-up, also representing a statistically significant increase from baseline (p = < .001).

Conclusions: Our data indicated an increase in intelligibility at the conversational level as a function of intensive speech treatment for Spanish speakers with dysarthria.

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STEADY-PD III. A phase 3 study of isradipine as a disease modifying agent in patients with early Parkinson's disease. Baseline characteristics of the enrolled cohort

T. Simuni, K.M. Biglan, J. Lowell, K. Hodgeman, B. Greco, R. Rockhill, D. Oakes (Chicago, IL, USA)

Objective: To evaluate the efficacy of isradipine 10 mg daily on PD disability.

Background: Isradipine, a dihydropyridine calcium channel antagonist with excellent penetration of the blood brain barrier, has been shown