Impact of Opicapone and Foslevodopa/Foscarbidopa on sleep quality and mobility in Fluctuating Parkinson's Disease: preliminary insights from a longitudinal pilot study.

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Objective

Impaired nocturnal mobility (i.e., nocturnal hypokinesia, NH) is frequent in fluctuating people with Parkinson's disease (PwPD) [1]. Wearable sensors could enable clinicians to detect this symptom and guide its management [2]. However, only a few studies have objectively assessed the treatment response of NH in PwPD [3].

Methods

Ambulating PwPD without dementia and with an indication to initiate treatment with either Opicapone (OPC) or foslevodopa/foscarbidopa (fLD/fCD) subcutaneous infusion for motor fluctuations were recruited. Participants underwent a clinical baseline evaluation (T0) including the Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Parkinson's Disease Sleep Scale 2 (PDSS-2), Epworth Sleepiness Scale (ESS), Insomnia Severity Index (ISI), and the Nocturnal Hypokinesia Questionnaire (NHQ). Participants were also instructed to wear a lower-back-mounted inertial sensor (McRoberts MoveMonitor, The Hague, The Netherlands) for seven consecutive nights at home to assess nocturnal mobility. A follow-up evaluation was performed 4 weeks after treatment stabilization (T1) (**Fig 1**). Data from a convenience sample of 9 healthy subjects (HS) were used for comparison. Between-group comparisons (PwPD vs HS) were conducted using the Mann-Whitney U test, and within-group comparisons (T0 vs T1) were performed using the Wilcoxon signed-rank test.

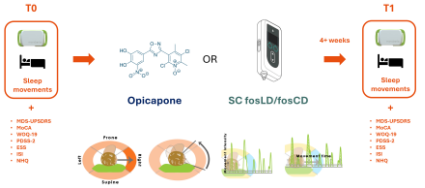

Figure 1. Study design.

Results

Sixteen PwPD were enrolled, and nine completed the follow-up evaluation (4 OPC; 5 fLD/fCD) (**Tab 1**). Compared to HS, PwPD showed significantly reduced movement intensity, more time spent in the prone position, and a lower number of total, medium, large, and extra-large transitions, as well as reduced transition velocity and increased transition duration. In PwPD, PDSS-2 scores showed a statistically and clinically significant improvement between T0 and T1. However, no significant changes were observed in the objective mobility parameters.

Table 1. Characteristics of PwPD who completed the evaluation.

	PwPD (N=9)	
	T0	**T1**
MDS UPDRS I	14.5 (10-18)	10 (8-11.5)
MDS UPDRS II	18 (10.75-23.5)	13.5 (9.75-17.25)
MDS UPDRS III	37 (27-48.75)	35 (27-43)
MDS UPDRS IV	5.5 (4.75-12)	5 (4.75-6.75)
MDS UPDRS TOT	67.5 (61.5-100.75)	68 (53.5-71.25)
WOQ19	4.5 (2-7.5)	2 (1.5-5.5)
PDSS2	18.5 (11.75-27.25)	10 (7-12)
ESS	3.5 (1-6.5)	4 (2-6.5)
ISI	7.5 (2-10.25)	3 (0.5-5.5)
NHQ	3.5 (3-4)	4 (3.5-5)
MoCA	23.5 (21.25-24.25)	24 (20-24)
BDI II	14.5 (7-20.5)	14 (2-20.5)
Mean movement intensity (g)	0.05 (0.04-0.05)	0.04 (0.03-0.05)
Total movement duration (s)	1.2 (1.03-1.89)	1.71 (1.3-2.15)
Times out of bed (#)	1.67 (1-2.67)	2.14 (1.33-2.29)
Left (%)	42.77 (19.47-54.26)	18.42 (11.16-34.04)
Right (%)	25.13 (10.39-35.14)	28.9 (7.69-41.8)
Prone (%)	0 (0-1.21)	0 (0-0)
Supine (%)	31.41 (25.77-41.18)	43.77 (29.01-53.16)
Small (#)	15.29 (12.86-21)	16.43 (11.33-19.71)
Medium(#)	5 (3.67-7.14)	2.71 (2.43-3.33)
Large (#)	0.43 (0.29-1.71)	0.33 (0-0.67)
Extra Large (#)	0 (0-0.29)	0 (0-0.14)
Sitting (#)	7 (6.29-8.14)	6.14 (6-8.14)
Total transitions (#)	30.86 (24-34.43)	28.57 (21-41.57)
Transitions frequency (#/min)	3.9 (3.32-4.48)	3.94 (3.05-5.36)
Transitions velocity (°/s)	7.28 (6.81-7.72)	6.21 (6.06-7)
Transitions duration (s)	7.39 (5.78-7.69)	6.56 (5.19-7.07)

Discussion

PwPD exhibited marked impairments in bed mobility compared with HS (**Fig 2**), consistent with previous findings [2]. Treatment with OPC or fLD/fCD led to a clinically meaningful improvement in perceived sleep quality but did not significantly alter objective measures of nocturnal mobility (**Fig 3-4**) . These findings support the hypothesis that dopaminergic therapies may enhance sleep quality through broader neurophysiological mechanisms beyond the mere improvement of nocturnal mobility.

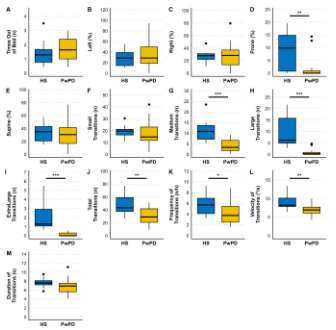

Figure 2. Comparisons between HS and PwPD.

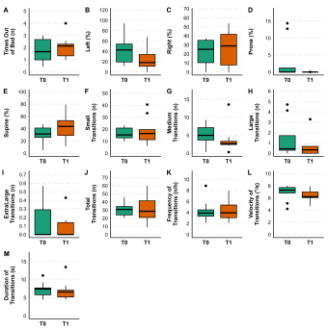

Figure 3. Mobility variables between T0 and T1 in PwPD.

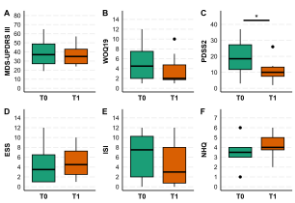

Figure 4. Clinical variables between T0 and T1 in PwPD.

Conclusions

Our results suggest that OPC and fLD/fCD may improve subjective sleep quality in fluctuating PwPD, even in the absence of measurable improvements in bed mobility, as measurable with current ecological wearable technology.

References

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