Implementation of sub-cutaneous foslevodopa-foscarbidopa in advanced Parkinson's disease: experience in real-life

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Introduction: Foslevodopa-Foscarbidopa has been recently approved for treatment of motor fluctuation in advanced Parkinson's disease (PD)[1]. Three different daily dosages can be implemented (low, basal and high). Little is known on the implementation of Foslevodopa-foscarbidopa in real-life settings.

Objectives: To describe our single-center experience with Foslevodopa-Foscarbidopa in patients with advanced PD.

Methods: Foslevodopa-Foscarbidopa was initiated in 21 patients; three discontinued treatment (two withdrew consent, one developed a subcutaneous abscess). All patients underwent motor and non-motor evaluations at baseline and after a mean follow-up of 6.44 months. Assessments included the Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) parts I-II-III-IV and the Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease Rating Scale (QUIP-RS). MDS-UPDRS part III was recorded during best-ON both pre- and post-implementation. To date, 13 of the 21 patients completed the follow-up. Data normality was assessed with the Shapiro-Wilk test. Paired sample t-tests and Wilcoxon signed-rank tests were used for statistical comparisons.

Demographics at baseline	Mean	Standard deviation
Age	66.7	9.60
Disease duration (years)	14.35	5.87
Total LEDD	1125.84	331.73
Rating scales	**Median difference (baseline– follow up)**	**p-value**
MDS-UPDRS 1	2	0.19
MDS-UPDRS 2	-6.5	0.37
MDS-UPDRS 3	-3	0.46
MDS-UPDRS 4	-2	0.24
MDS-UPDRS 4.1	-1	**0.038**
MDS-UPDRS 4.2	0	**0.048**
QUIP-RS	2	0.19

Table 1. Demographic clinical feature and rating scales of the enrolled sample. Data are expressed as mean ± st.deviation. Legend:; MDS-UPDR 1-2-3-4-4.1-4.2 = section of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale; LEDD = levodopa equivalent daily dose. QUIP-RS= Questionnaire for Impulsive-Compulsive Disorder in Parkinson's disease – Rating Scale.

Results: Eighteen out of 21 patients remained on Foslevodopa-Foscarbidopa. Mean age (standard deviation) and disease duration at implementation were 66.7 (9.60) and 14.35 (5.87) years, respectively (Table 1). Before the implementation, Total Levodopa Daily Dosage was 1125.84 (331.73) mg. The median MDS-UPDRS part I-II-III-IV total score at baseline and at 6.44 months follow-up was: [11 (IQR: 5) and 13 (IQR:10) p=0.19], [17.5 (IQR:13.5) and 11 (IQR: 15.05) p=0.37], [24.50 (IQR: 15.25) and 27.50 (IQR: 19.25) p=0.46] and [9.5 (IQR:3.0) and 7.5 (IQR: 6.25) p=0.24] remained stable over time. The median MDS-UPDRS 4.1 score showed a significant reduction from baseline to 6.44 months follow-up, decreasing from 2 to 1 (p=0.038), whereas the median MDS-UPDRS 4.2 score remained significantly stable at 1 (p=0.048). The QUIP-RS presented a trend towards significance for an increase over time [11 (IQR: 5) and 13 (IQR 10) p=0.19]. Over the follow up, the low dosage showed a 7.02% decrease (p = 0.31), the basal dosage showed a 9.63% increase (p = 0.063), while the high dosage exhibited a statistically significant 7.72% increase (p = 0.028) (Figure 1).

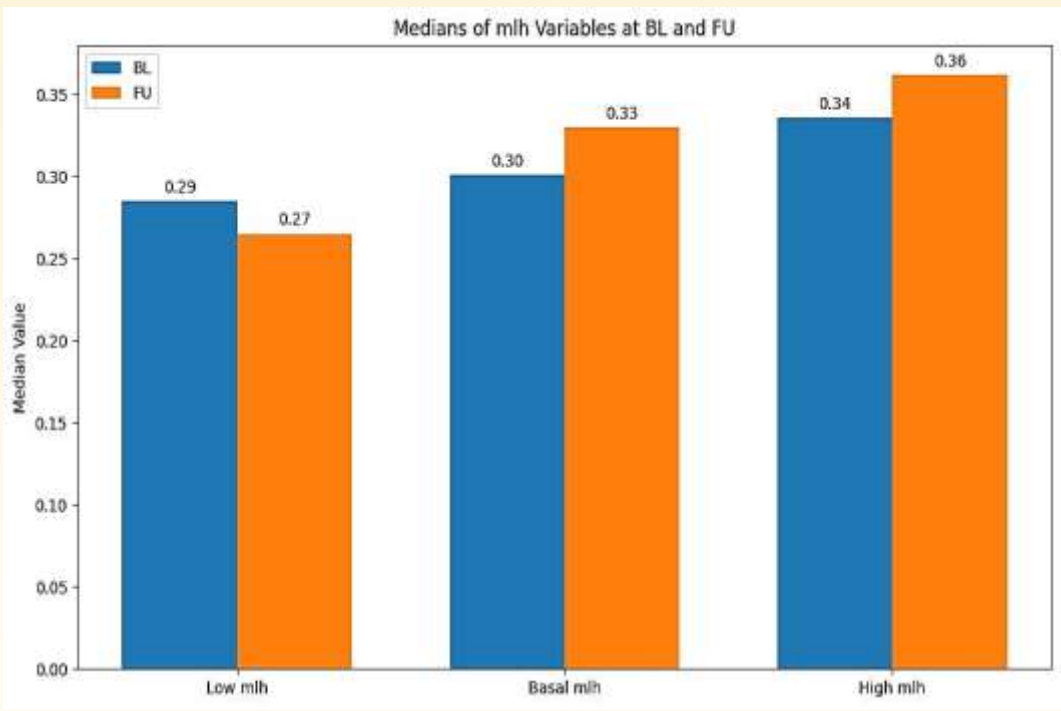

Figure 1. Histogram depicting the change in daily dosage rate from baseline to follow up

Conclusion: Our preliminary real-world data support the beneficial effect of Foslevodopa-Foscarbidopa on dyskinesia impact (MDS-UPDRS 4.1), along with a tendency toward dosage increase over time. Follow-up of the remaining patients is ongoing.

References: Soileau MJ et Al. Safety and efficacy of continuous subcutaneous foslevodopa-foscarbidopa in patients with advanced Parkinson's disease: a randomised, double-blind, active-controlled, phase 3 trial. Lancet Neurol. 2022 Dec;21(12):1099-1109. doi: 10.1016/S1474-4422(22)00400-8. Erratum in: Lancet Neurol. 2023 Mar;22(3):e5. doi: 10.1016/S1474-4422(23)00048-0. PMID: 36402160.