Assessment of tolerability and efficacy of opicapone in daily clinical practice

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Background

There are several adjunct therapies for the treatment of motor fluctuations after optimal modification of L-dopa dosage and frequency of administration including dopamine agonist, monoamine oxidase type B inhibitor or catechol-O-methyl transferase (COMT) inhibitors. Opicapone is a peripherally selective, once-daily COMT inhibitor recently approved as adjunctive therapy to L-dopa/DOPA decarboxylase inhibitors in patients with Parkinson's disease (PD) and end-of-dose motor fluctuations.

Objectives

To analyse the tolerability and efficacy of opicapone added as adjunctive therapy in a group of patients with PD in daily clinical practice.

Methods

Eighty-five patients with PD were included in the study, 56% males with a mean age of 69,8 years. The mean disease duration was 11,4 years and mean Hoehn & Yahr staging was 3. Further clinical and demographic data are shown in *table 1*. Mean L-dopa equivalent daily dose was 897 ± 415. Forty one per cent of patients were on an oral or transdermal dopamine agonist and 19% were on advanced therapies for PD. Further data regarding previous treatment are shown in *table 2*. Tolerability and response to treatment were recorded at months 6 and 12.

CLINICAL AND DEMOGRAPHIC DATA (n=85)			
Age (years) *	69,8 ± 10,6 (40-92)		
Gender (F:M)	37:48		
Age of onset (years)*	58,3 ± 10,5 (35-83)		
Duration of disease (years)*	11,4 ± 5,0 (3-24)		
Phenotype			
• Akinetic-rigid (%)	38 (45%)		
• Tremulous (%)	39 (46%)		
• Mixed (%)	8 (9%)		
Hoehn & Yahr			
1	2 (2%)	**2,5**	5 (6%)
1,5	6 (7%)	**3**	40 (47%)
2	17 (20%)	**4**	15 (18%)
Fluctuations	82%		
Dyskinesia	60%		
*Mean ± standard deviation (range)			

Table 1

TREATMENT WHEN OPICAPONE WAS ADDED	
Levodopa equivalent daily dose (mg/day) *	897 ± 415 (150-2230)
Number of levodopa doses a day *	4 ± 1 (1-10)
COMT-I previously	1
Dopamine agonists (%)	35 (41%)
Rotigotine (%)	23 (27%)
• Dose(mg)#	10 (4-16)
Ropinirole (%)	3 (4%)
• Dose (mg)#	9 (4-16)
Pramipexole (%)	9 (11%)
• Dose (mg)#	2,1 (0,56-3,15)
Amantadine	21 (25%)
Trihexyphenidyl	2 (2%)
AChEI	13 (15%)
Rasagiline	15 (18%)
Safinamide	33 (39%)
Advanced therapies	16 (19%)
• Apomorfine	2
• DBS	13
• Duodopa	1
*Mean ± standard deviation (range); #Mean (range)	

Table 2

Results

Forty five per cent of patients improved during follow up, 40% remained stable and just 15% deteriorated. Response to fluctuations, dyskinesia and non-motor symptoms was recorded, as shown in *figure 1*. No serious adverse events were recorded. Treatment had to be withdrawn in 27 patients due to different causes. The most frequently identified reason for discontinuation was behavioural or cognitive deterioration (30%), followed by aggravation of dyskinesia (22%). *Figure 2* details causes of withdrawal. Of note, 85% of the discontinuation of treatment occurred during the first 6 months of drug use. There were no significant differences in demographic or clinical features between the responder group and neither the non-responder group nor the discontinuation group. The rigid-akinetic subtype was significantly more common in the group of patients that had to discontinue the drug.

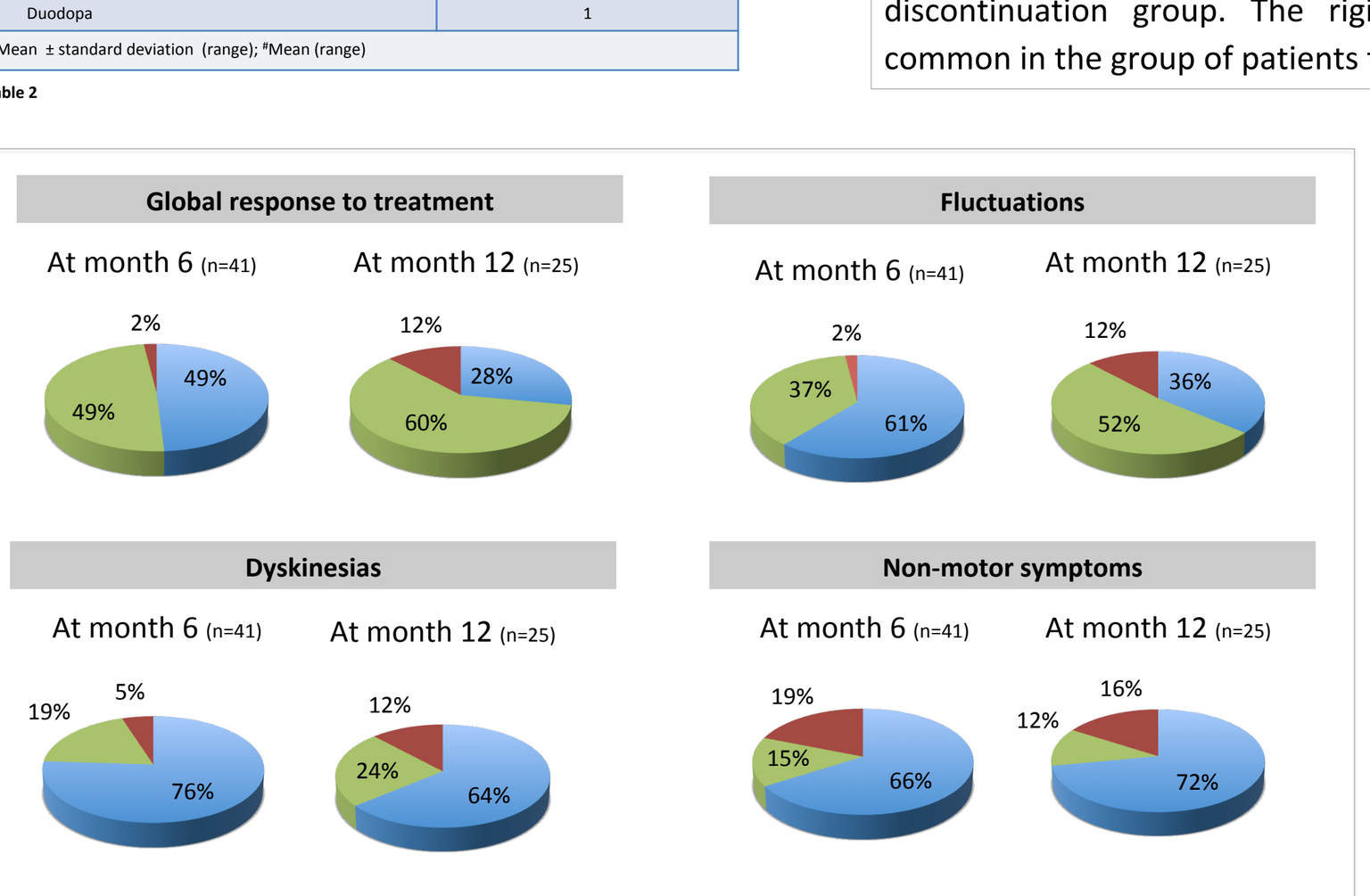

Figure 1

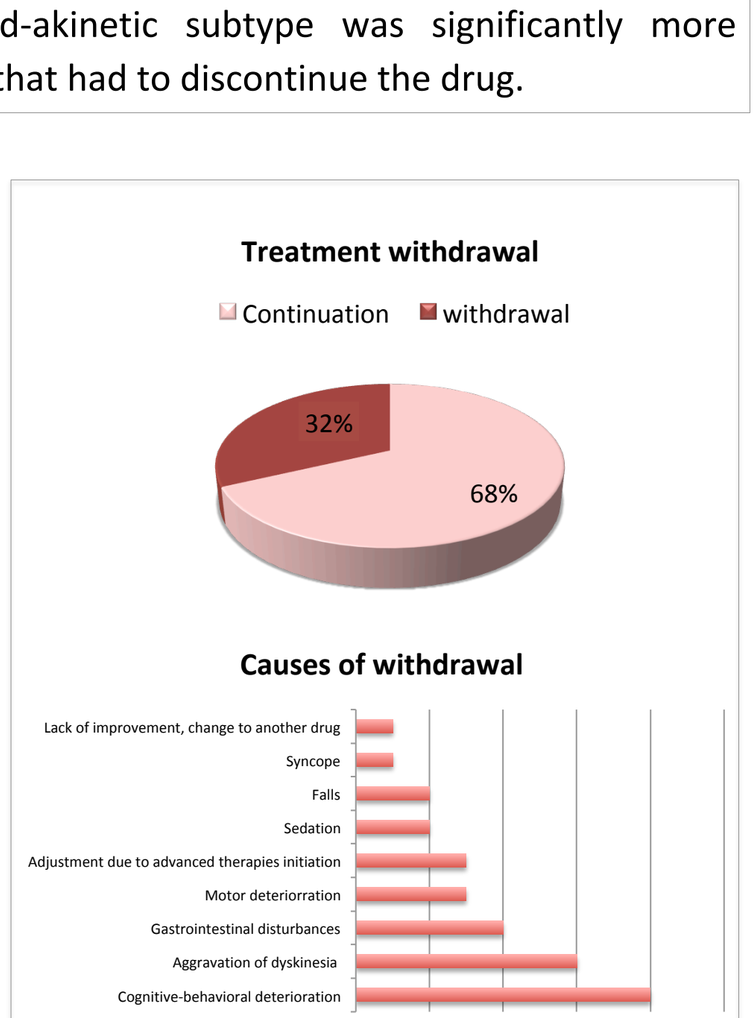

Figure 2

Conclusion

Opicapone has a good tolerability profile in patients with PD despite polytherapy or advanced state. Most of our patients exhibited a good response to treatment by improving or remaining stable while on opicapone. The incidence of discontinuation may be explained by an initial limited experience using the drug and selecting adequate candidates.

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