

## **Safinamide effect on bladder function in PD Patients**

*Livia Brusa*<sup>1</sup>, E. Casula<sup>2</sup>, A. Stefani<sup>3</sup>, G. Koch<sup>4</sup>, C. Iani<sup>1</sup>

<sup>1</sup>UOC Neurologia Ospedale S.Eugenio, Roma, Italia

<sup>2</sup>Dipartimento Medicina dei Sistemi Università Tor Vergata, Roma, Italia

<sup>3</sup> Clinica Neurologica Università di Tor Vergata, Rome, Italia

<sup>4</sup>Dipartim Neuroscienze e Riabilitazione Università di Ferrara, Ferrara, Italia

Among autonomic disorders, bladder dysfunction is one of the most disabling complain in patients with Parkinson's disease (PD).

Dopamine seems to play a key role in central bladder control, either in normal animals, or PD animal models or in patients affected by the disease.

Safinamide is a reversible, selective, monoamine oxidase b inhibitor (MAO-B-i) and glutamate modulator with therapeutic indication as an add-on to levodopa in fluctuating PD patients.

On these bases, this study tested safinamide effect on Lower Urinary Tract behavior in a group of moderate motor fluctuating PD patients complaining of bladder dysfunction.

Twenty-nine moderate motor fluctuating PD patients with Hoehn and Yahr score < 2.5 were included in the study.

All patients were evaluated first at baseline with IPSS questionnaire (International Prostate Symptoms Score questionnaire) and SCOPA OUT Questionnaire.

Following the first evaluating section, subjects added on their usual dopaminergic therapy a morning dose of Safinamide 50 mg for the sequent two months and at the end of this period all were re-evaluated in a second visit. A third section of evaluation with the same characteristics was administered following other two months of treatment with the same dopaminergic medication plus safinamide titrated to 100 mg per day.

Post-hoc analysis showed a significantly lower IPSS score after safinamide 50 mg ( $p < 0.001$ ) and 100 mg ( $p < 0.001$ ) compared to baseline evaluation; IPSS score was significantly lower also after Safinamide 100 mg compared to 50 mg ( $p = 0.004$ ). The evaluation of IPSS revealed a significant effect of Safinamide on the following items: urgency [EPC1] [ $\chi^2 = 39.169$ ;  $p < 0.001$ ], nicturia [EPC2] [EPC3] [ $\chi^2 = 31.871$ ;  $p < 0.001$ ] and frequency [EPC4] [ $\chi^2 = 49.854$ ;  $p < 0.001$ ][EPC5].

Analysis of total SCOPA OUT score revealed a significant effect of safinamide [ $\chi^2 = 48.713$ ;  $p < 0.001$ ]. Post-hoc analysis revealed a significantly lower SCOPA OUT score after safinamide 50 mg ( $p < 0.001$ ) and 100 mg ( $p < 0.001$ ) compared to baseline evaluation.

We performed a prospective open-label study to assess the effect of safinamide treatment on bladder function in patients with Parkinson's disease who have urinary symptoms. Our analysis showed a generalized improvement of total IPSS and SCOPA OUT score. We observed a relevant effect of safinamide on nicturia and frequency with an improvement also in motor functions.

Efficacy on nicturia is higher with safinamide 100 mg. A non dopaminergic effect of safinamide on different NMS (attention, mood, anxiety, sleep, cognitive functions and pain) suggested by different studies, could be relevant also for urinary symptoms.

In PD patients, the daily dose of 50 mg is required for reversible full inhibition of MAOB activity. The daily dose of 100 mg also inhibits glutamate release, an effect that may contribute to further efficacy on motor and NMS in fluctuating PD patients.