

Safinamide use in clinical practice across Italy: a sub-analysis of SYNAPSES Study in Parkinson's disease patients

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Introduction: Safinamide modulates both dopaminergic and glutamatergic systems with positive effects on motor and nonmotor symptoms of Parkinson's disease (PD). The drug utilization study SYNAPSES was designed to investigate the use of safinamide in routine clinical practice, as recommended by the European Medicines Agency.

Objective: To describe the occurrence of adverse events in PD patients treated with safinamide in real-life conditions.

Methods: The SYNAPSES study is a multi-country, multi-center, retrospective-prospective cohort observational study, involving Belgium, Germany, Italy, Spain, Switzerland and United Kingdom. Italy enrolled 616/1610 patients in 52 centers. Patients received for the first time a treatment with safinamide at enrollment visit or in the previous 4 months, were enrolled in 24 months and were followed up for 12 months, with intermediate evaluations after 4 (+/-1) months, 8 (+/-1) months, and 12 (+/-1) months from the start of treatment with safinamide. The aim of the "global" study was to describe the occurrence of adverse events in patients treated with safinamide in a real-life setting during 1 year. Some subgroups of interest were evaluated too, such as patients >75 years, those with relevant concomitant conditions and those suffering from psychiatric conditions.

Results: Of the 616 patients enrolled, 86.0% were evaluable at 12 months, with 23.3% being >75 years, 42.4% with psychiatric conditions and 67.7% with relevant comorbidities. Safinamide was effective on fluctuations and motor symptoms measured through UPDRS III and IV, and on UPDRS total score, without safety issues in none of the subgroups considered.

Conclusion: The SYNAPSES data related to Italian patients confirms the good safety profile of safinamide even in special groups of patients. Motor complications and motor scores improved with clinically significant results in the UPDRS scale maintained in the long-term.