Adverse Drug Reactions induced by Multiple Sclerosis medications

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Objective: To assess nature and frequency of adverse drug reactions (ADRs) induced by multiple sclerosis (MS) medications.

Method: In an observational cross-sectional study, ADRs of all outpatients referred to a neurologist office who have been received at least one drug modifying therapy (DMT) of MS, for a duration of at least 3 months, were evaluated.

Results: A total number of 250 patients including 185 (74%) women and 65(26 %) men were enrolled in the study. Out of 250 patients, 191 (76.4%) including 42 males and 149 females developed at least one ADR. The total number 484 ADRs were detected in these patients. ADR occurrence was higher in females than males (80.5% vs. 64.4%). The highest number of ADRs occurred with interferon beta 1a (IFN β1a) (141, 72%).Among different brands of IFN β1a, Rebif® was the most frequent cause of ADRs(47, 85.5 %).Among 484 detected ADRs, 0.61%was recognized as serious, and 5.9%as preventable ADRs. Flu-like symptoms in 96 patients (38.4%), headache in 66 patients, (26.4%), hair loss in 51 patients, (20.4%), and injection sitepain (ISP) in 50 patients (20%) had the highest rate of detected ADRs. The causality assessment of ADRs revealed that 65.2%of ADRs were detected as possible, followed by 22.9% as certain, 11.5%asunlikely, and 0.2 %as probable. There was one case offulminant hepatitis induced by Rebif® and one seizure induced by Cinnovex®that lead to medication withdrawal.

Conclusion: All DMTs are associated with ADRs, as noted in present study.The high frequency of ADRs detected shows that there is a need for planning a strong program including patient education and encourage health

professionals to report ADRs related to MS medications over a prolonged period of time to reduce these ADRs and to increase the adherence of patients to DMTs .

Keywords : Adverse Drug Reactions; Multiple Sclerosis; Drug Modifying Therapy; Beta interferons ;Biosimilars.