

Influence of gender on side effects' incidence in plaque psoriasis patients treated with cyclosporine: final results from the Italian observational GENDER ATTENTION study

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Introduction and Objectives: Response to pharmacologic treatment usually differs between men and women. Sex hormones influence drug absorption, distribution, metabolism, pharmacodynamics and adverse effects. Due to the increasing interest in gender medicine, the primary aim of the GENDER ATTENTION study is to describe the side effects' incidence rate between genders and in relation to the estrogenic status (fertile or menopause) on a sample of Italian patients with psoriasis treated with cyclosporine.

Materials and Methods: GENDER ATTENTION is an Italian observational cohort prospective, multicenter study, involving 50 dermatology public sites across Italy, recruiting plaque psoriasis patients aged ≥ 18 years who started any cyclosporine cycle. Enrollment started on May 2011 and ended on December 2012. Patients were followed up to cycle end (max 6 months) until June 2013. Exposure period was defined as number of months elapsed from the start to the end of cyclosporine cycle or to the follow-up visit/withdrawal from the study whichever came first.

Results: 969 patients were enrolled in the study, 889 (92%) of whom were evaluable considering inclusion criteria fulfillment and the availability of the exposure period. Four patient cohorts were defined: 336 fertile women (FW) and 253 age-matched men, 182 menopausal women (MW) and 118 age-matched men. Mean (SD) age of FW and MW was 35.6 (9.0) and 57.1 (5.7) years, respectively. Mean (SD) Psoriasis Area and Severity Index (PASI) was 14.7 (6.7) and 3.1 (4.5) at the beginning of the cycle and at the end of observation, respectively. Side effects were experienced by 30.9% of patients: 27% for both FW and age-matched men, 41% of MW and 36% of age-matched men. FW incidence rate was 0.20/person-month vs 0.14 in corresponding men. In MW and matched men, incidence rates were 0.30 and 0.26, respectively. Side effects mostly affected nervous system (15% and 13% in FW and corresponding men, 20% and 17% in MW and age-matched men), gastrointestinal tract (11% and 6% in FW and corresponding men, 13% and 12% in MW and age-matched men) and musculoskeletal system and connective tissue (7% of FW and 7% of corresponding men, 17% of MW and 14% of age-matched men). Interestingly, headache was complained by 11% and 8% vs 12% and 11% of FW/MW and corresponding men.

Conclusions: Final results of the GENDER ATTENTION study confirm the good safety profile of cyclosporine in a large sample of Italian patients with psoriasis. The proportion of patients with at least one side effect was higher in MW than in FW, while no differences were observed between men and women, also considering the estrogenic status. Nevertheless, side effects' incidence was higher in FW than in corresponding men, while lower differences were observed between MW and related men.