

GENDER DIFFERENCE IN ADVERSE DRUG REACTIONS: ANALYSIS OF SPONTANEOUS REPORTS OF AN ITALIAN INTERREGIONAL DATABASE (GIF)

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Aim: to investigate the influence of gender on adverse drug reaction (ADRs) occurrence.

Methods: Data were obtained from an Italian Interregional database (GIF) which collects all spontaneous reports of suspected ADRs from 8 Italian regions: Veneto and Provincia Autonoma di Trento (since 1988), Lombardia (since 1993), Sicilia (since 1996), Emilia Romagna (since 2000) Friuli Venezia Giulia (since 2003), Campania (since 2005), Toscana (since 2006). This area represents a population of about 34 millions inhabitants (59,6% of the total Italian population); however, in 2006, more than 78% of all Italian reports come from these regions. The reporting rate of these regions is 14,8/100.000 inhabitants, compared to 6,2/100.000 inhabitants for other Italian regions.

Results: Overall, there were 26448 reports, 56,2% of which (14864) occurred in women and 42,2% (11172) in men. The annual ADR reporting rate was higher in women (16,1/100.000 inhabitants) than in men (11,2/100.000 inhabitants). Looking at reporters category, suspected ADR in women are more frequently reported by nurses (73,3% vs 26,0%), while paediatricians tend to report more frequently ADR occurred in male babies (51,3% vs 48,7%). No statistical difference was observed in gender distribution for ADR associated to vaccines administration (50,6% vs 49,4%). As regards the age of patients, men were more represented than women only in the range between 0-14 year [RR: 1,28 (1,25-1,32)], with the highest prevalence of women for the patients over 75 years old (25,1% vs 17,6%).

Focusing on serious ADR, our data shows a slight prevalence for men [46,1% vs 42,8%; RR 1,08 (1,05 – 1,11) $p < 0,001$], homogeneously distributed between age groups (the highest was for the range between 65-74 years, 54,0% vs 44,4%). Significant gender differences in system organ involved by ADR have been observed. Skin, gastro-intestinal, respiratory, cardiovascular and vascular (extracardiac), central and peripheral nervous system disorders were more frequent in women, while general, application site, musculo-skeletal, liver, metabolic and endocrine disorders were more frequent in men. ADR occurred more frequently in women for the following drug classes: musculo-skeletal, central nervous system, gastrointestinal and metabolic, while antimicrobials and haematological drugs were more frequently involved in ADR occurred in men.

Conclusion: These result indicate that female gender is a risk factor for the development of ADR; furthermore, several gender-based differences in terms of drug classes involved and of features and severity of symptoms have been observed.