

myositis was investigated, IC delta scores of 1.662 and 1.39 were seen for Simvastatin and Cerivastatin but negative scores of -1.907, -0.848, -1.233 and -1.668 were seen for Pravastatin, Fluvastatin, Atorvastatin and Rosuvastatin.

Conclusions: Statins and the term rhabdomyolysis were not highlighted with TPD. Low counts could reflect a rare and/or serious outcome not captured frequently in UK GPD. The more frequently recorded term myalgia-myositis was highlighted for some, but not all, statins, possibly reflecting complex statin switching patterns accentuated by NICE guidelines, but this is to be confirmed. Hypothesis-free signal detection in EMRs is no panacea; more work is needed to determine optimal granularity level for signal detection and whether data sets more reflective of specialist/hospital care are preferred for some DME surveillance.

762. The Impact of Age and Gender on Reporting of Cough and Angioedema with RAS Inhibitors: A Case/Non-Case in VigiBase

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Background: Little is known about the effect of age and gender on reporting of cough/ angioedema with renin angiotensin system (RAS) inhibitors (angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs) and aliskiren, a direct renin inhibitor (DRI).

Objectives: To assess the impact of age and sex on the occurrence of cough/angioedema with RAS inhibitors using information reported to the World Health Organization (WHO) global individual case safety report database (VigiBase).

Methods: A case/non-case study was performed in VigiBase. Cases were defined as reports of cough/angioedema and non-cases were all reports of other adverse events. Age was divided into 6 categories: infant and childhood (0-11 years), adolescence (12-19 years), young adulthood (20-39 years), middle adulthood (40-59 years), elderly (60-79 years) and late elderly (≥ 80 years). Logistic regression analysis was

used to assess the association between reporting of cough/ angioedema with each class of RAS inhibitors stratified by age/ sex and to control for confounding.

Results: The reporting of cough with ACE inhibitors was significantly higher in women than in men (adjusted reporting odds ratio (ROR): 29.2, 95%CI (28.5-29.9) for men versus 44, 95%CI (43.2-44.8) for women). There was no difference in reporting of cough with ARBs and DRI between men and women. In contrast, the reporting of angioedema with ACE inhibitors and ARBs was significantly higher in men than women but for DRI (aliskiren), women had significantly higher ROR than men. For the effect of age, the reporting of cough with ACE inhibitors was significantly increased with age until reaching a plateau at 60 years and the reporting of angioedema with ACE inhibitors was significantly increased with age until 80 years. Age had only a slight effect on reporting of cough/angioedema with ARBs and DRI.

Conclusions: Age and sex have substantial effects on reporting of cough/angioedema with RAS inhibitors especially with ACE inhibitors. Further studies are needed to study both factors on occurrence of cough/angioedema with RAS inhibitors and to elucidate the underlying mechanism involved.

763. A Novel Approach to Study the Impact of Ethnicity on Reporting of Cough/Angioedema with RAS Inhibitors in VigiBase

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Background: Cough and angioedema are adverse events associated with especially angiotensin-converting enzyme (ACE) inhibitors but also reported with angiotensin receptor blockers (ARBs) and aliskiren, a direct renin inhibitor (DRI). Susceptibility of developing cough/angioedema with ACE inhibitors depends on ethnicity, which is not documented in spontaneous reporting systems of drug safety.

Objectives: To assess the impact of ethnicity on the occurrence of cough/angioedema with renin angiotensin system (RAS) inhibitors using information