

deliveries, 1 (<1%) very preterm delivery with no congenital anomaly, 2 (<1%) elective abortions, 16 (3%) spontaneous abortions, 123 (26%) lost to follow-up, and 238 (50%) awaiting pregnancy outcome. Among the retrospective reports, there were 8 (80%) term deliveries (7 infants with no congenital anomaly and 1 infant with patent foramen ovale and peripheral pulmonic stenosis), and 2 (20%) spontaneous abortions.

Conclusions: The data from this Adacel vaccine pregnancy registry do not raise concern for maternal or infant health and they should be reassuring to women vaccinated during pregnancy.

141. Withdrawn by Author

142. Inhaled and Intranasal Corticosteroids and Behavioral and Psychiatric Problems: A Pharmacovigilance Analysis Using AERS Data

Ayad K Ali, Abraham G Hartzema. *Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, FL, United States.*

Background: Analysis of spontaneous reporting systems in the European Union resulted in a concern regarding the association between inhaled and intranasal corticosteroids (CS) and behavioral or psychiatric (BP) adverse events.

Objectives: We conducted an analysis using the United States Adverse Event Reporting System (AERS) to assess BP safety signals associated with inhaled and intranasal CS.

Methods: The AERS database is used to conduct a retrospective pharmacovigilance analysis of adverse event reports received between January 1, 2004 and March 31, 2010. Proportional Reporting Ratios (PRR) as a data mining algorithm and corresponding 95% Confidence Intervals (95%CI) are used to estimate the association between specific corticosteroids (CS) and BP adverse events. These events are identified using defined Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PT). The PRR and 95%CI are reported for individual CS by route of administration (systemic, intranasal, and orally inhaled). The reporting ratios for individual CS are compared with all CS in the drug class by route of administration.

Results: A total of 2,245,691 reports for the specified exposure are identified in AERS during the study period. 68,101 reports were for CS; 78%, 11.3%, and 10.7% of the CS reports were for systemic, inhaled, and intranasal CS, respectively. Compared to all CS, inhaled and intranasal CS had higher PRR values of BP than systemic CS (1.40 95% CI 1.20–1.63; 1.71 95%CI 1.48–1.97; and 0.48 95%CI 0.43–0.54; respectively). PRR values higher than 1 are found for inhaled mometasone (2.50 95%CI 0.38–16.8); inhaled budesonide (1.20 95%CI 0.93–1.54); intranasal triamcinolone (1.24 95%CI 0.79–1.97); intranasal mometasone (1.13 95%CI 0.83–1.54); and intranasal beclomethasone (1.13 95%CI 0.79–1.61). However, all the estimates are statistically not significant.

Conclusions: Compared to systemic CS, inhaled and intranasal CS are associated with higher than expected reporting of behavioral and psychiatric events, however; -except for inhaled mometasone—the PRR data mining algorithm failed to detect a safety signal (PRR \geq 2).

143. Epidemiology of Pneumoconioses in the U.K. General Population

Rajeev K Amar,¹ Susan S Jick,² Daniel Rosenberg,³ Toby M Maher,⁴ Christoph R Meier.¹ ¹Basel Pharmacoepidemiology Unit, Division of Clinical Pharmacy and Epidemiology, Department of Pharmaceutical Sciences, University of Basel & University Hospital Basel, Basel, Switzerland; ²Boston Collaborative Drug Surveillance Program, Boston University School of Medicine, Lexington, MA, United States; ³Epidemiology & Observational Studies, Actelion Pharmaceuticals Ltd., Allschwil, Switzerland; ⁴Interstitial Lung Disease Unit, Department of Respiratory Medicine, Royal Brompton Hospital, London, United Kingdom.

Background: Incidence of the pneumoconioses in the UK has primarily been estimated using occupational registries and disability pension schemes. These sources indicate a downward trend in pneumoconiosis incidence from 1995 onward. Published, population-based studies quantifying incidence of the pneumococinoses in the UK are lacking.

Objectives: To estimate the incidence of the pneumococinoses in the UK general population during 1997–2008 using data from electronic primary care records and to compare prescription drug use prior to the first pneumococinosis diagnosis (index date) in cases and controls.

Methods: We selected from the UK General Practice Research Database (GPRD) all patients with a first-time pneumoconiosis diagnosis between 1997–2008, and a control group of the same size matched on age, gender, general practice, and index date. We characterized the study population at baseline with respect to demographics, comorbidities, and prescription drug use, and we assessed incidence density stratified by gender, age group, and time period. Poisson regression was used to model disease incidence and conditional logistic regression was used to compare prescription drug use prior to index date in cases and controls.

Results: A total of 1,843 patients with an incident diagnosis of any type of pneumoconiosis were identified during the study period. The highest incidence rate was observed in men and in the age group 60–79 years. The overall crude incidence density during the study period was 5.9 (95% CI: 5.7 to 6.2) per 100,000 person-years. Relative to the period 1997–1999, the incidence density increased by a factor of 1.7 during 2000–2002 and more than doubled during 2003–2005. After adjusting for gender and age group there was evidence of statistically significant heterogeneity of rate ratios across time periods ($p < 0.001$). A case-control comparison of comorbidities and prescription drug use is currently under investigation.