

Publication

A methodological comparison of two European primary care databases and replication in a US claims database: inhaled long-acting beta-2-agonists and the risk of acute myocardial infarction

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Results from observational studies on inhaled long-acting beta-2-agonists (LABA) and acute myocardial infarction (AMI) risk are conflicting, presumably due to variation in methodology. We aimed to evaluate the impact of applying a common study protocol on consistency of results in three databases.; In the primary analysis, we included patients from two GP databases (Dutch-Mondriaan, UK-CPRD GOLD) with a diagnosis of asthma and/or COPD and at least one inhaled LABA or a "non-LABA inhaled bronchodilator medication" (short-acting beta-2-agonist or short-/long-acting muscarinic antagonist) prescription between 2002 and 2009. A claims database (USA-Clinformatics) was used for replication. LABA use was divided into current, recent (first 91 days following the end of a treatment episode), and past use (after more than 91 days following the end of a treatment episode). Adjusted hazard ratios (AMI-aHR) and 95 % confidence intervals (95 % CI) were estimated using time-dependent multivariable Cox regression models stratified by recorded diagnoses (asthma, COPD, or both asthma and COPD).; For asthma or COPD patients, no statistically significant AMI-aHRs (age- and sex-adjusted) were found in the primary analysis. For patients with both diagnoses, a decreased AMI-aHR was found for current vs. recent LABA use in the CPRD GOLD (0.78; 95 % CI 0.68-0.90) and in Mondriaan (0.55; 95 % CI 0.28-1.08), too. The replication study yielded similar results. Adjusting for concomitant medication use and comorbidities, in addition to age and sex, had little impact on the results.; By using a common protocol, we observed similar results in the primary analysis performed in two GP databases and in the replication study in a claims database. Regarding differences between databases, a common protocol facilitates interpreting results due to minimized methodological variations. However, results of multinational comparative observational studies might be affected by bias not fully addressed by a common protocol.

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