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Asthma therapy

Are long-acting bronchodilators as safe as short-acting Beta-2-Agonists?

VIENNA - The risks of death and hospitalization due to status asthmaticus are similar in asthma patients receiving long-acting β_2 -agonist (LABA) therapy and those receiving short-acting β -agonists or inhaled corticosteroid therapy, said *Frank de Vries*, PhD, PharmD, General Practice Research Database, Medicines and HealthCare Products Regulatory Agency, London, UK, during his presentation at the *19th Annual Congress of the European Respiratory Society*.

A number of studies have evaluated the risks associated with long-acting β_2 -agonist (LABA) therapy, alone or in combination with inhaled corticosteroid (ICS) treatment, for the treatment of adult asthma. However, there are many confounding factors in such analyses in asthma; for example, drug exposure is defined by asthma severity, making it very difficult to separate the effect of disease severity from treatment: the British Thoracic Society treatment guidelines recommend LABA use in asthma treatment steps 3-5, when increased rates of disease-related outcomes are expected.

The UK General Practice Research Database (GPRD) group developed a novel approach to describe the patterns of the hazard rates (i.e., the absolute risks) of asthma outcomes with changes in drug exposure. This pattern analysis focuses on convergence/divergence of hazard rates rather than estimation of relative rates. The study describes the patterns of risk of death and asthma-related adverse outcomes with LABA therapy vs. inhaled short-acting β_2 -agonists (SABA) or inhaled corticosteroids (ICS).

The study population consisted of permanently registered patients (males and females) aged ≥ 18 years who received a prescription for inhaled SABA or LABA from 1993 until March 2007.

In total, 507,966 patients who received a total of 5.5 million inhaled SABA, 4.0 million ICS, and 1.3 million LABA prescriptions were included in the analysis, explained Dr. de Vries. Higher relative rates of all outcomes were found in asthma patients who had recently started treatment or in those long-term users with very frequent prescriptions in the year before. Heavy long-term users had increased risks of asthma death with all medications, and interestingly, the patterns of risk of death were similar for LABA with or without concomitant ICS therapy.

Similarly, no major difference was found in patterns of risk of acute myocardial infarction between patients treated with inhaled long-acting β_2 -agonist, inhaled short-acting β -agonist, and inhaled corticosteroid therapies in the same study population.

The UK General Practice Research Database (GPRD) group used this novel approach to describe the patterns of hazard rates (i.e., the absolute risks) of acute myocardial infarction during exposure to inhaled long-acting β_2 -agonist (LABA), inhaled short-acting β -agonist (SABA), and inhaled corticosteroid (ICS) therapies.

In patients who recently started any asthma medication (LABA, SABA or ICS), hazard rates of myocardial infarction and hospitalizations because of myocardial infarction increased shortly after the start of asthma medication and then decreased, explained Dr. de Vries. Those patients who were heavy long-term users (≥ 13 prescriptions of the same asthma drug in the year before) had increased risks of myocardial infarction with inhaled SABA and ICS (but not with LABA) compared to short-term users (< 3 prescriptions of the same asthma drug in the year before). The pattern of risk was similar between LABA with and without concomitant ICS.

Overall, Dr. de Vries concluded that while the patterns of risks for death and hospitalization due to status asthmaticus varied considerably with exposure characteristics, these were broadly similar in patients using LABA vs. those receiving SABA or ICS. The patterns of risk of myocardial infarction were also similar between inhaled short-acting beta-agonists, long-acting beta-agonists and inhaled corticosteroids, suggesting that there were no major differences between these drugs.

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Editor's Note: There is an ongoing controversy regarding the safety of long-acting beta-agonist (LABA) treatment in asthma. Based on findings from a meta-analysis that used data from 110 trials and 60,954 patients, the FDA had concluded in December 2008 that long-acting bronchodilators (LABAs) as a group were associated with an increased risk of asthma complications and asthma-related deaths.

However, a critical stratified analysis in the FDA report involving 15,192 individuals indicates that LABA used with mandatory inhaled corticosteroids was not associated with an increased risk of asthma-related mortality, intubations, or exacerbations.

Experts currently believe that it is important to rigorously avoid LABA monotherapy in asthma, and, when long-acting beta-agonists are indicated, they should be always prescribed in combination with appropriate doses of inhaled corticosteroids.

Reference: Sears MR et al, Chest. 2009 Jun 12: Safety of Long-Acting Beta-Agonists: Are New Data Really Required?