

Disputed asthma drugs have safe record in British Columbia

November 26 2013

A popular combination asthma therapy dogged by safety concerns has not harmed British Columbians and should remain in use, according to researchers at the University of British Columbia and Vancouver Coastal Health Research Institute.

The therapy combines an inhaled corticosteroid to reduce swelling in the airways with "long-acting beta agonists" (LABAs) to ease breathing and reduce the risk of a severe asthma attack. The U.S. Food and Drug Administration (FDA), reacting to claims that LABAs might mask conditions that leave patients vulnerable to more severe or even fatal asthma attacks, ordered the drugs' makers to conduct large-scale safety trials; with results not expected for five years, the FDA urges that LABAs be discontinued once a person's asthma is under control.

The UBC-Vancouver Coastal Health study examined hospitalization rates for patients who took [inhaled corticosteroids](#) alone and those who used the [combination therapy](#), covering 46,000 people over 15 years. Although the hospitalization rate for combination therapy users was 14 per cent higher than those who took corticosteroids alone, that difference was not statistically significant.

"By including so many patients and over such a long period, we have provided unparalleled evidence on the safety of the combination therapy," said lead author Mohsen Sadatsafavi, an assistant professor of health economics in the Division of Respiratory Medicine and a scientist at the Centre for Clinical Epidemiology and Evaluation. "Our findings

should reassure patients, doctors and policy-makers about the safety of combination therapies as we wait for the results of the trials."

This study should prompt a re-examination of the FDA's warning to restrict the use of combination therapy, said senior author Dr. Mark FitzGerald, Head of the Division of Respiratory Medicine of UBC and Vancouver General Hospital. "Patients who get relief from the combination therapy should continue using it without fear," he said.

Although corticosteroids and LABAs can be taken as two separate inhalers, most [patients](#) use a version that includes both drugs in one dose. Advair, made by GlaxoSmithKline PLC, is the fourth-highest selling drug in the world, with 2012 global sales of \$4.6 billion (U.S.). Another combination therapy, Symbicort, made by AstraZeneca Pharmaceuticals, had 2012 global sales of \$1.2 billion (U.S.). Merck & Co. has also introduced its own formulation, Zenhale.

The study confirmed that LABAs, when used without inhaled corticosteroids, do indeed pose a risk. Patients who used LABAs exclusively had an 86 per cent increased rate of hospitalization compared to those who didn't use anything at all. However, the risk of hospitalization decreased in direct proportion to the increased use of corticosteroids.

Provided by University of British Columbia

Citation: Disputed asthma drugs have safe record in British Columbia (2013, November 26) retrieved 27 December 2022 from

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