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Study of more than one million patients adds to evidence of SABA overuse

New findings, announced by AstraZeneca, from the largest real-world observational data analysis of asthma inhaler therapy, demonstrated that short-acting beta₂-agonist (SABA) reliever overuse adversely impacts asthma outcomes and is a global concern.

Results from the SABINA program were published in the *European Respiratory Journal* and in the *Journal of Allergy and Clinical Immunology: In Practice*.

Studying more than one million patients globally

An AstraZeneca news release described the SABA Use IN Asthma (SABINA) program as the largest real-world data analysis of clinical outcomes related to SABA use and maintenance therapy in asthma. Funded by the company, it consists of harmonized, large-scale, observational studies across 40 countries.

The SABINA program is used to examine patterns of prescribing and receiving SABA and inhaled corticosteroid (ICS)-containing medications as a surrogate measure of medication use. The studies evaluate diverse asthma populations, healthcare systems and asthma management strategies on data collected between 2007 and 2017.

More than one million patients globally are included in the program, which has four main pillars:

- SABINA I: a retrospective observational database study in the United Kingdom



- SABINA II: a retrospective observational database study in eight countries (France, Germany, Italy, Netherlands, Spain, Sweden, Canada and Israel)
- SABINA III: a cross-sectional study conducted in 24 countries across five continents
- SABINA +: a multi-design extended pillar for countries that joined after initiation of the program (China, Hong Kong, Morocco, Poland, Portugal, Romania, Switzerland and the United States)

Comparing SABA and ICS medications

The SABINA study published in the *Journal of Allergy and Clinical Immunology: In Practice* provided the following brief descriptions of the benefits and limitations of the SABA and ICS-containing medications being evaluated:

“When used acutely, short-acting beta₂-agonists (SABAs) provide rapid symptom relief and can be life-saving. However, beta₂-agonists have no inherent anti-inflammatory activity, and their use without concomitant inhaled corticosteroids (ICS) may be proinflammatory.”

“Budesonide-formoterol (ICS and a fast-acting bronchodilator fixed-dose combination) used as a rescue/reliever or as maintenance and rescue/reliever reduces exacerbation risk in patients with asthma aged 12 years or older of all severities compared with as-needed SABA, budesonide maintenance plus as-needed SABA, or budesonide-formoterol maintenance plus as-needed SABA.”

At risk of severe exacerbations

AstraZeneca noted there are as many as 339 million adults and

children, worldwide, who have asthma and are at risk of severe exacerbations, regardless of their disease severity, adherence to treatment or level of control. Further, an estimated 176 million asthma exacerbations occur globally per year, which are physically threatening and emotionally significant for many patients and can be fatal.

Consistent findings, regardless of country or asthma severity

AstraZeneca discussed the overall results noting the multi-country analyses of more than one million patients with asthma showed use of three or more SABA inhalers per year was associated with an increased risk of severe exacerbations and a lower likelihood of controlled asthma. The findings were consistent regardless of country and asthma severity. In addition, the risk of exacerbation was independent of maintenance therapy containing inhaled corticosteroids, which they stated further highlighted the need for continued efforts to improve asthma management.

In the *European Respiratory Journal*

SABINA data from 24 countries across five continents demonstrated that 38% of patients were prescribed three or more SABA relievers a year. This was associated with an increasing rate of severe exacerbations and a lower likelihood of satisfactory symptom control. Patients prescribed three to five SABA relievers a year had 40% more severe exacerbations compared to patients receiving one or two inhalers per year. This percentage rose further in conjunction with increasing numbers of SABA prescriptions.

“The SABINA Program shows that the overuse of SABA is a global problem of considerable magnitude, associated with negative outcomes of asthma treatment,” said Eric D. Bateman, Division of Pulmonology, Department of Medicine, University of Cape Town, Cape Town, South Africa, and lead author of the *European Respiratory Journal* article. “It brings into focus the need for renewed efforts to reduce over-reliance on SABAs and the adoption of treatment strategies that provide both quick symptom relief and an anti-inflammatory effect.”

In the *Journal of Allergy and Clinical Immunology: In Practice*

SABINA data from Europe and North America, published in the *Journal of Allergy and Clinical Immunology: In Practice* showed that approximately 40% of patients across all asthma severities were prescribed or received three or more SABA inhalers per year. This was associated with a 32% increase in risk of severe asthma exacerbations compared to patients receiving one or two inhalers per year, independent of ICS-containing medications used.

Adding to the body of evidence

“Results from SABINA across diverse patient populations and healthcare systems add to the body of evidence demonstrating SABA overuse is associated with an increased risk of exacerbations in patients with asthma,” commented Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca. “With more than 176 million asthma attacks experienced globally each year, there is a clear need

for asthma management that addresses the inflammatory nature of the disease and reduces exacerbation risk to improve outcomes for patients.”

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Study of SABA over-prescribing suggests improvements and support tools

According to *Science Daily*, SABA inhaler prescribing was also evaluated in a large study conducted in East London, UK. In that section of the city, hospitalizations for acute asthma are 14% above the London average. Due to “that impact on the community,” researchers from Queen Mary University of London’s Clinical Effectiveness Group (CEG) studied SABA inhaler prescribing by general practitioners.

Overprescribing SABAs and underutilizing preventive inhalers

In analyzing more than 700,000 patient records (which had been made anonymous) from 117 general practitioner (GP) practices in East London, the researchers found that 26% of patients with asthma were overprescribed SABA inhalers (defined as more than 6 inhalers per year). Further, within that group, a quarter of the patients were found to be underutilizing preventative (corticosteroid) inhalers. That finding raised concerns about inadequate asthma prevention for patients who had significant asthma.

In addition, the study demonstrated that prescribing varied significantly among GP practices. Some overprescribed to 6% of their asthma patients while others overprescribed to as many as 60% of their asthma patients. Further analysis of that variation showed overprescribing was strongly linked to repeat dispensing (in which prescriptions are issued automatically by community pharmacists).

Next: Providing tools to support GPs and pharmacists

Anna De Simoni, lead author and GP and Clinical Lecturer in Primary Care at Queen Mary University of London, told *Science Daily* that, “Working with patients to improve regular use of preventative inhalers should be central to reducing asthma-related hospital admissions” and noted, “There is still significant room for improvement.” She explained the researchers had determined if patients who use more than 12 SABA inhalers per year could reduce their usage to 4-12 inhalers per year, the reduction could result in 70% fewer asthma-related hospital admissions in that patient group.

“There is also a need to provide GPs and pharmacists with the right tools to support patients to do this,” she added. In the next phase of the Queen Mary program, the researchers plan to provide practices with tools to support the identification and management of high-risk patients, based on prescribing records.

References

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