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Review Article

A Review on Asthma Related Adverse Drug Reaction

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This study evaluated the safety of biological medicines used for severe asthma by analysing suspected adverse drug reactions (ADRs) reported in the WHO VigiBase pharmacovigilance database. Five biologic medicines—omalizumab, mepolizumab, reslizumab, benralizumab and dupilumab—were studied using individual case safety reports up to August 2022. A total of 48,440 reports were related to asthma. Commonly reported suspected ADRs included asthma, breathing difficulty, cough, headache, fatigue and wheezing. Some possible safety signals, such as malignancies, cardiovascular events, hair loss and autoimmune conditions, were also identified. Overall, the study found that most reported ADRs were already known, but some less-known events require further investigation to better understand the long-term safety of biologic therapies in severe asthma.

Keywords: Asthma, Adverse Drug Reaction, omalizumab, mepolizumab, reslizumab, benralizumab and dupilumab.

INTRODUCTION

Asthma is a common long-term respiratory disease that affects millions of people worldwide. The response to asthma medicines can vary from one person to another because of factors such as disease severity, treatment adherence, environment, and genetic differences. Asthma medicines can also cause adverse drug reactions (ADRs), which may affect the patient's health and quality of life. Pharmacogenomics helps to understand how genetic differences may influence the effects and side effects of medicines. Therefore, studying the relationship between genetic variations and ADRs can help identify patients who may be at greater risk of harmful effects and support more personalised and safer asthma treatment.

MATERIALS AND METHOD

Data Source

VigiBase, the WHO global database of adverse drug reaction reports, was used as the data source. Data were extracted using VigiLyze from Uppsala Monitoring Centre (UMC). Duplicate reports were removed using vigiMatch. Drugs were identified using WHO Drug Global, and adverse drug reactions were coded using MedDRA version 25.0.

Study Drugs and Drug Analysis

The study included five biologic medicines used for asthma: omalizumab, mepolizumab, reslizumab, benralizumab, and dupilumab. All unique individual case safety reports (ICSRs) from VigiBase up to 31 August 2022 were analyzed. Reports related to asthma were identified using specific MedDRA terms. Patient age, sex, seriousness of adverse reactions, reporting trends, reporter type, and patient outcomes were examined. The asthma-related reports

were also compared with reports for other therapeutic uses, and the Chi-square test was used to assess categorical variables, with $p < 0.05$ considered statistically significant. Serious adverse reactions were identified according to standard regulatory definitions, including death, life-threatening events, hospitalization, disability, or other medically important events. Unexpected reactions were identified by comparing reported events with information in approved product labels and regulatory documents. Reporting Odds Ratios (RORs) were used to detect disproportionate reporting of adverse reactions. An event was considered a potential safety signal when the lower limit of the 95% confidence interval was above 1 and at least three reports were available. Two comparison groups were used: all other medicines in VigiBase and asthma medicines containing inhaled corticosteroids with or without long-acting beta-agonists. A sensitivity analysis was also performed after excluding vaccine-related reports, mainly COVID-19 vaccine reports.

RESULT

The study analyzed 31.7 million de-duplicated safety reports in VigiBase up to August 2022, including 167,282 reports related to the five asthma biologics: dupilumab, omalizumab, mepolizumab, benralizumab, and reslizumab. Among these, 48,440 reports were related to asthma, with omalizumab being the most frequently reported drug. Most asthma-related reports were from females, and serious adverse drug reactions were more common in asthma patients than in patients treated for other conditions. The most commonly reported reactions included asthma, breathing difficulty, product-use problems, lack of drug effect, cough, headache, fatigue, and wheezing. Different biologics showed different patterns of adverse reactions, involving respiratory, immune, infection-related, eye, nervous-system, and other organ-system disorders.

CONCLUSION

Overall, the study showed that biologic medicines used for severe asthma have a generally good safety profile. Commonly reported side effects included injection-site reactions, general disorders, nasopharyngitis, headache, and hypersensitivity. Some reports of asthma worsening or treatment failure may be related to the underlying disease rather than the medicines themselves. Anaphylaxis was reported as a potential safety concern with most of the studied biologics except dupilumab. The study also identified possible signals such as cancer, heart rhythm problems, pulmonary embolism, and hair loss, but further research is needed to confirm whether these are truly related to the biologic treatments.

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