5PSQ-068

THE HOSPITAL PHARMACIST'S INTERVENTIONS IN THE POST-MARKETING PHARMACOVIGILANCE OF ANTI-ASTHMATIC BIOLOGICS: A REAL LIFE ANALYSIS

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Background and importance

Pharmacovigilance is an important tool for monitoring drug post-marketing safety. Hospital Pharmacist(HP) plays a primary role in the identification of suspected Adverse Drug Reaction(ADRs) due to his direct contact with the patient
Pharmacist, through the application of indirect pharmacovigilance tools in a real life context, can lead to the identification of hidden or underestimated ADRs.

Aim and objectives

The aim of the study was to evaluate the increase of suspected ADRs reports to biological drugs for the treatment of severe refractory hypereosinophilic asthma (Omalizumab, Dupilumab, Mepolizumab and Benralizumab) obtained following the interventions of HP

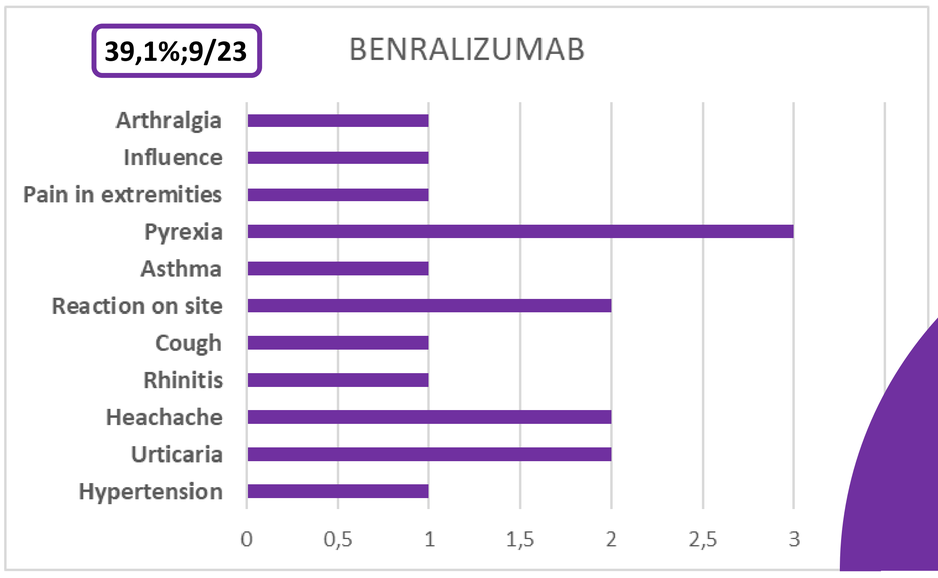
Material and methods

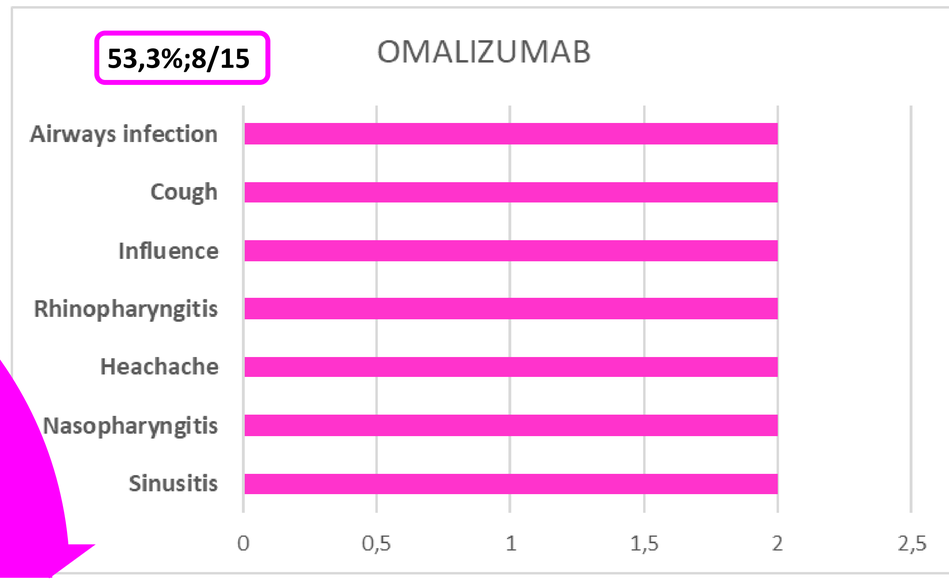
A 7-months (October 2022–May 2023) post-marketing safety study was conducted.The data were collected via a questionnaire consisting of 2 sections: general data (sex, age, comorbidities, drugs taken and start of therapy) and list reporting the most common side effects were the patient can indicate one or more suspected ADRs among those reported and/or enter any side effect that he potentially is linked to the drug. The questionnaire was illustrated and given to the patients at the time of dispensing.

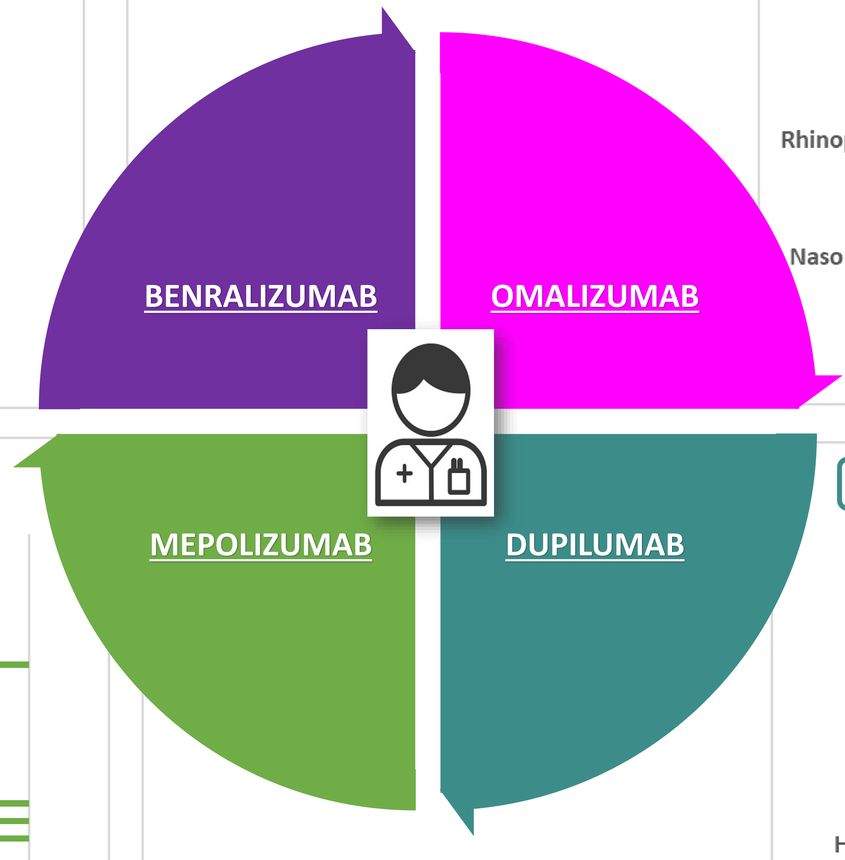
Have you ever had any of these side effects while taking Dupilumab:

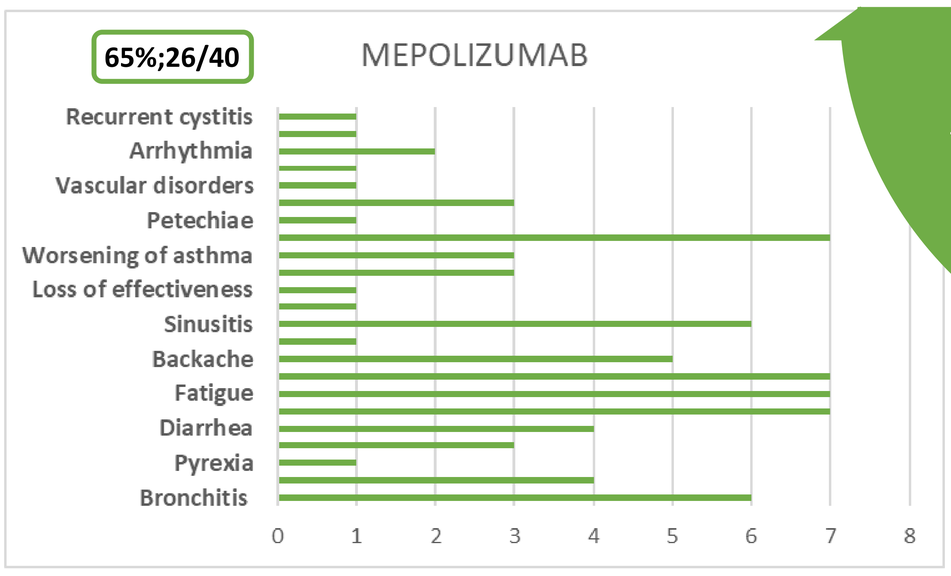
adverse drug reaction (ADR)	YES	Does the onset of the symptom coincide with taking the drug?	START date of the symptom	Symptom END date
Bronchitis				
airways infection				
heachache				

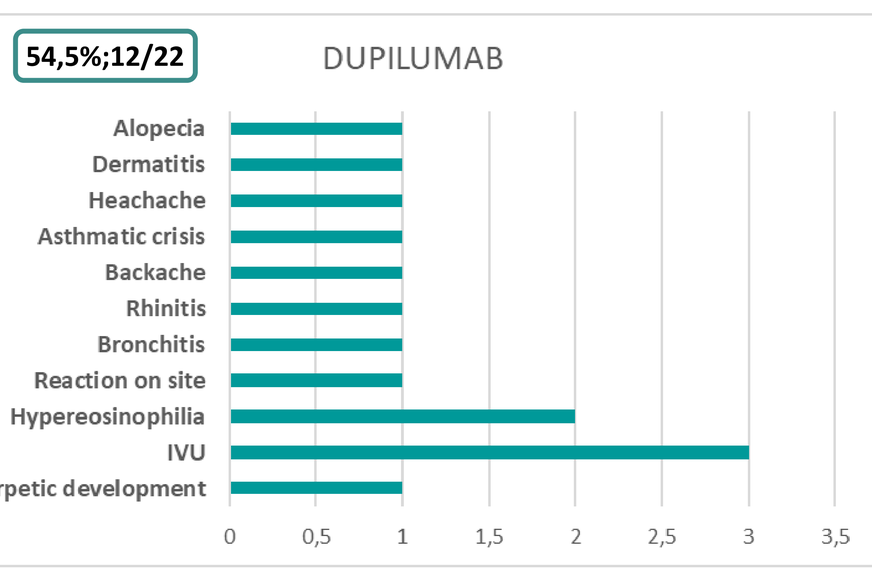
Results











- **55% (55/100) of patients reported one or more adverse reactions for a total of 122 side effect reports**
- **ADRs not reported by clinical trials: Mepolizumab petechiae, hemorrhagic cycle and frequent urination problems accompanied by recurrent cystitis(3,5%;1/26); Dupilumab herpetic development and alopecia(4,5%;1/22)**
- **pyrexia > in Benralizumab vs clinical trials (3%;12/320vs13%;3/26)**

Conclusion and relevance

The data analysis confirmed the importance of the hp role in pharmacovigilance. The investigation in a real life context characterized by a hight heterogenicity of patient caratheristics (age, comorbidity, adherence) leds to an improvement in the incidence of ADRs report's and to the highlighting of side effects not detected during the crinicals trials.