Impact of Initiating Biologics In Patients with Severe Asthma on Long-Term OCS or Frequent Rescue Steroids (The GLITTER Study)

Poster 5700

Wenjia Chen[1], Trung N. Tran[2], Mohsen Sadatsafavi[3], Nigel Chong Boon Wong[1], Lakmini Bulathsinhala[4,5], Esther Garcia Gil[6], J. Mark FitzGerald[7], Ruth Murray[5] and David Price[4,5,8], on behalf of the ISAR GLITTER Working Group

[1]Saw Swee Hock School of Public Health, National University of Singapore, Singapore; [2]AstraZeneca, Gaithersburg, MD, USA; [3]Respiratory Evaluation Sciences Program, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, British Columbia, Canada; [4]Observational and Pragmatic Research Institute, Singapore; [5]Optimum Patient Care, Cambridge, UK; [6]AstraZeneca, Barcelona, Spain; [7]sDepartment of Medicine, The University of British Columbia, Vancouver, Canada; [8]Centre of Academic Primary Care, Division of Applied Health Sciences, University of Aberdeen, Aberdeen, UK.

Introduction

- Real-world evidence on the effectiveness of biologic treatment among severe asthma (SA) patients is limited.

Aim(s)

- To assess the comparative effectiveness of initiating versus non-initiation of biologics in a large, international, real-world cohort of adult SA patients with high oral corticosteroid (OCS) exposure.

Methods

Study Design and Population

Propensity matched cohort study using the International Severe Asthma Registry (ISAR; http://isaregistries.org/). Data was collected between Jan 2015 and Feb 2021 from 19 countries:

- Argentina, Australia, Bulgaria, Canada, Colombia, Denmark, Greece, India, Ireland, Italy, Japan, Kuwait, Mexico, Saudi Arabia, South Korea, Spain, Taiwan, United Arab Emirates, and the United Kingdom

Patient Criteria

- ≥18 years of age, with SA and history of high OCS exposure (long-term use of OCS and/or ≥4 courses of rescue steroid bursts during the 12-month pre-index period, HOCS)
- Exclusions criteria: patients with bronchial thermoplasty, a prior history of biologic use, or missing baseline data at the index date
- Index date: date of biologic initiation for biologic initiators, and date of study entry for non-initiators).

Analysis

- To ensure comparability between groups, 1:1 propensity score matching with replacement was used to match biologic initiators (N=996) and non-initiators (N=416) (Table 1).
- Multiple imputations (4 iterations) to impute missing data within matching variables.
- Generalized linear models and estimating equations to account for clustered time-series data in matched pairs.
- The impact of biologic initiation on outcomes was estimated as marginal effects by the first 365 days of follow up, controlling for unbalanced matching variables and outcome history.

Table 1: Post-matching baseline characteristics

	Bx initiated (n=996)	Bx not initiated (n=996)	SMD
Age, years			
Mean (SD)	51.7 (13.9)	51.1 (14.6)	-0.04
Gender, n (%)			
Male	387 (38.9)	296 (29.7)	0.19
Female	609 (61.1)	700 (70.3)	
Ethnicity, n (%)			
Caucasian	689 (69.2)	682 (68.5)	
Asian	62 (6.2)	65 (6.5)	
African	36 (3.6)	42 (4.2)	0.34
Mixed	17 (1.7)	55 (5.5)	
Other	83 (8.3)	108 (10.8)	
Unknown	109 (10.9)	46 (4.6)	
Age of asthma onset, years			
Mean (SD)	28.4 (18.7)	28.2 (18.8)	-0.01
BMI (kg/M^2),			
mean (SD)	29.3 (6.8)	28.5 (7.4)	-0.11
BEC (n/ml)			
Mean (SD)	479.8 (469.7)	527.4 (471.3)	0.10
Smoking status, n (%)			
Current smoker	25 (2.5)	70 (7.0)	
Ex-smoker	285 (28.6)	210 (21.1)	0.27
Non-smoker	686 (68.9)	716 (71.9)	
Invasive ventilation, n (%)	69 (6.9)	138 (13.9)	0.23
Positive allergen test, n (%)	618 (62.0)	623 (62.6)	0.04
Allergic rhinitis, n (%)	313 (31.4)	302 (30.3)	0.08
Chronic rhinosinusitis, n (%)	246 (24.7)	167 (16.8)	0.20
Eczema, n (%)	98 (9.8)	61 (6.1)	0.14
Nasal polyps, n (%)	351 (35.2)	266 (26.7)	0.19
Atopic sensibilization, n (%)	819 (82.2)	866 (86.9)	0.13
Country			0.22
Asthma exacerbations			
Mean (SD)	5.1 (4.1)	5.0 (3.8)	-0.02
Asthma-related emergency department visits			
Mean (SD)	1.7 (4.3)	1.8 (3.7)	0.02
Asthma-related hospitalizations			
Mean (SD)	0.9 (2.0)	0.9 (1.6)	0.00

SMD: Standardized mean difference
SD: Standard deviation

Results

Figure 1A. Impact of biologic initiation on annualized rates of exacerbations, emergency department visits and hospitalizations in SA HOCS patients in the first 365 days of follow up

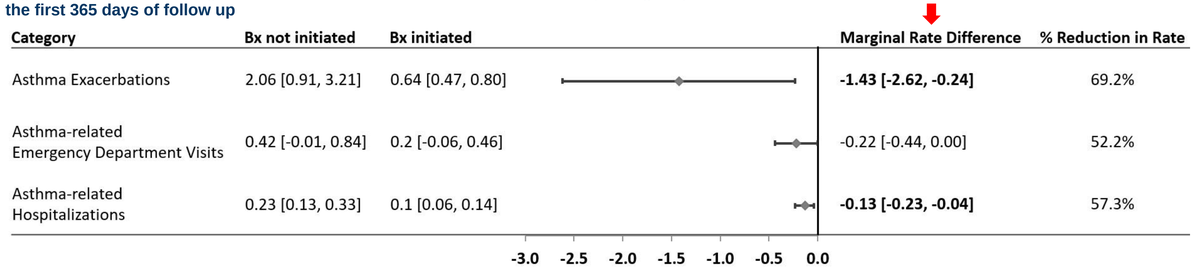
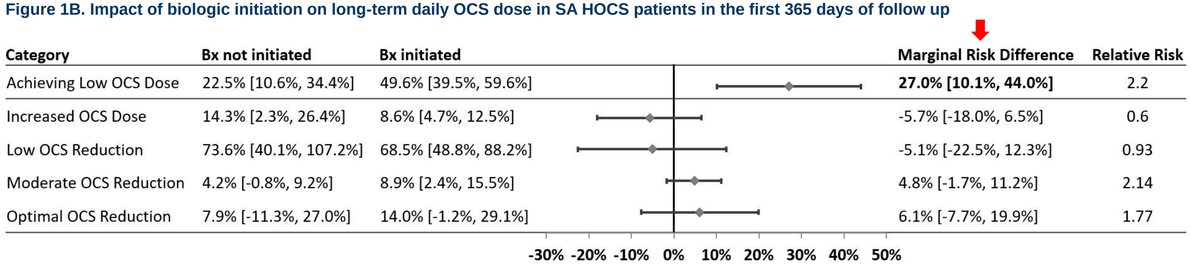


Figure 1B. Impact of biologic initiation on long-term daily OCS dose in SA HOCS patients in the first 365 days of follow up



Low Daily OCS Dose < 5 mg/day

Low Reduction: R ≤ 50%
Moderate Reduction: 50% < R ≤ 75%
Optimal Reduction: 75% < R ≤ 100%
where R = Reduction (in percentage) of dose at follow-up relative to baseline

Asthma Exacerbations

- Biologic initiation was associated with an average reduction of 70% relative to non-initiators in the first year (p=0.019).

Healthcare Resource Utilization

- Initiation of biologics was associated with lower rates of asthma-related emergency department (ED) visits (52.2% rate reduction; p=0.054) and hospitalizations (57.3% rate reduction; p=0.006).

Long-Term OCS Use

- Patients who started a biologic were more likely to achieve a low daily OCS dose below 5 mg (p=0.002).
- There was also an overall trend of achieving better long-term OCS reduction for biologics initiators.

Asthma control & Comorbidities

- No significantly greater improvement within the first year was seen in biologic initiators for asthma control (risk of uncontrolled asthma: 20.5% vs 30.2%; p=0.142), or incidence of any OCS-related comorbidities (2.31% vs 0.18%; p=0.294).

Conclusions

- In a real-world setting, although both groups showed improvements in outcomes from baseline, ***initiation of biologics was associated with significant improvements in exacerbation rate, healthcare resource utilization and OCS exposure among patients with severe asthma on high OCS***.
- The impact of biologics on OCS-related comorbidities needs to be followed over a longer duration.

Abbreviations

BEC, Blood eosinophil count; BMI, Body Mass Index; ED, Emergency department; OCS, Oral corticosteroid; R, reduction; SA, Severe asthma; SD, Standard deviation; SMD, Standardized mean difference.

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COI disclosures

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