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Worldwide Characterization of Severe Asthma Patients Eligible for both anti–IL-5 and anti-IgE Biologic Therapy: data from the International Severe Asthma Registry (ISAR)

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Rationale: Approximately one-third of severe asthma patients are eligible for both anti-IgE and anti-IL-5/5R therapy. However, it is not clear whether one class of biologic works better than the other amongst patients eligible for both. Our aim was to describe the demographic and clinical characteristics of anti-IgE or anti-IL-5/5R users who were eligible for both, and subsequently started either modality, using data from the International Severe Asthma Registry (ISAR; http;//isaregistries.org/). ISAR includes patients aged ≥18 years old at GINA Step 5 treatment, or with uncontrolled asthma at GINA Step 4.

Methods: Patients eligible for both anti-IgE and anti-IL-5/5R, who subsequently started either modality from 19 ISAR participating countries, recruited between January 2015 and September 2020, were included. They must have had ≥1 year of data prior to the biologic initiation date for study inclusion. Eligibility for both biologics was ascertained universally across all countries using frequent biologic-specific criteria: elevated blood eosinophil count, serum IgE, allergic-mediated asthma, and history of exacerbations at baseline. Pre-biologic-initiation demographic and clinical variables were described for both anti-IgE and anti-IL-5/5R groups using data from 2015 onwards, when both therapies were available. Groups were compared using Pearson's chi-square tests and t-tests.

Results: Amongst 8826 patients, 1868 (21.2%) were considered eligible for both anti-IgE and anti-IL-5/5R. Of these, 659 started anti-IgE and 570 started anti-IL-5/5R after 2015, comprising the study cohort. 33.2% of anti-IgE and 45.7% of anti-IL-5/5R patients were also on long-term oral corticosteroids (LT-OCS) at the time of biologic initiation. Although differences were small, anti-IL-5/5R patients were slightly older, had later asthma onset, and were more likely to have uncontrolled asthma, ≥2 exacerbations, and FeNO >50 ppb (**Table**). Patients who received anti-IgE were more likely to be female, had a slightly higher mean BMI, and a higher prevalence of osteoporosis. These demographic, clinical, and co-morbidity patterns were similar irrespective of LT-OCS use, with the exception of osteoporosis prevalence, which was more elevated in the anti-IgE group versus anti-IL-5/5R for those on LT-OCS (45.0% [n=68/151] versus 15.2% [n=27/178]).

Conclusion: Approximately one-fifth of severe asthma patients in ISAR were eligible for both anti-IgE and anti-IL-5/5R therapy. Most of these patients initiated biologic treatment. Anti-IL-5/5R eligible patients tended to have more severe disease pre-biologic initiation than their anti-IgE counterparts, which has implications when comparing effectiveness of these biologics.

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Variable	Biologic initiation (2015 onwards)		
	Anti-IgE (n=659)	Anti-IL-5/5R (n=570)	p-value
Gender Female, N (%)	607 (64.8)	329 (57.6)	0.005
Age at initiation of Bx- years Mean (SD)	N=653 50.7 (15.0)	N=564 53.3 (14.2)	0.002
Age of asthma onset -years Mean (SD)	N=378 26.8 (17.6)	N=469 30.2 (18.2)	0.005
BMI – kg/m^2 Mean (SD)	N=439 30.7 (6.6)	N=399 29.6 (6.2)	0.008
Asthma control Uncontrolled, N (%)	N=265 133 (50.2)	N=352 247 (70.2)	<0.0001
Exacerbations 2+, N (%)	N=262 162 (61.8)	N=398 285 (71.6)	0.0006
FeNO >50 ppb, N (%)	N=227 85 (37.4)	N=329 158 (48.0)	0.01
OCS related Co-morbidities Osteoporosis, N (%)	N=442 157 (35.5)	N=344 64 (18.6)	<0.0001
Type 2 Diabetes, N (%)	N=191 20 (10.5)	N=91 13 (14.3)	0.352
BMI: body mass index; Bx: biologic; FeNO: fractional exhaled nitric oxide; OCS: oral corticosteroid; SD: standard deviation;			

Word count: 393 (limit 400)