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Title: Burden of illness in a cohort of Italian patients eligible for biologics for asthma but not treated: a sub analysis of the real-world ISAR EVEREST study [152/205]

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Background: Eligibility for biologic treatment in severe asthma (SA) is mainly based on clinical history, biomarkers and previous occurrence of exacerbations. Despite biologics are available to treat uncontrolled SA, a significant amount of patients in Italy still lack access to novel therapies. This study describes the characteristics and burden of SA patients who are eligible for biologic treatment but not treated.

Method: ISAR EVEREST is a multi-country, observational study aiming to describe clinical characteristics and outcomes of SA population. Eligibility for biologics was assessed according to history of allergy, blood eosinophils count (BEC), FeNO, exacerbation rates and OCS dependency. Patients' characteristics and disease burden were described in the 12 months prior to the ISAR visit when biologic eligibility was identified. Biologics use was captured between December 2017 to May 2022.

Results: 1424 patients were included in the Italian cohort. 1224 were evaluated as bio-eligible, of which 1076 (87.9%) were treated with a biologic for SA, 134 (10.9%) did not receive treatment with any biologic drug despite fulfilling the criteria to bio-eligibility and for 14 patients (1.1%) information were missing. Of the 134 bio-eligible untreated patients, 79 (59%) were classified as GINA Step 4 and 55 (41%) as GINA Step 5. Mean duration of asthma was 20.5 (± 14.3) years. Of the 106 patients having a record of BEC, 88 (83%) had ≥ 300 cells/mcL and 18 (17.0%) had <300 cells/mcL. Only 16 patients (12.4%) were well controlled, while 113 (87.8%) reported partial or poor control. 87 (74.3%) patients had ≥ 2 exacerbations and 20 (15.5%) had at least 1 hospital admission. Most frequent comorbidities included: chronic rhinosinusitis (49 pts, 36.6%), nasal polyps (43 pts, 32.1%) and hypertension (20 pts, 18.5%). The number of patients with long-term OCS use was 20 (24.6%), with 239.4 (± 132.5) days of mean duration of use. OCS-related side effects affected 42 patients (38.2%), most of which experienced osteoporosis (21 pts, 50%) and diabetes (6 pts, 7%).

Conclusion: Among bio-eligible patients, approximately 1 out 10 does not receive treatment with any biologics. Since these patients experience a high burden of illness in terms of exacerbation rate, hospital admission, lack of control and OCS-related conditions, a better evaluation and optimized management of SA patients is warranted.

This abstract is written on behalf of the SANI and ISAR EVEREST Study Groups.

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