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Title: Characterisation of patients with difficult-to-treat and treatment-resistant severe asthma

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Body: Background: A recent World Health Organization (WHO) meeting proposed a uniform classification of severe asthma (SA) into 3 groups: untreated SA, difficult-to-treat SA, and treatment-resistant SA (JACI 2010). Aim: To characterize and compare the demographic, functional and inflammatory parameters and the level of control of patients with difficult-to-treat and treatment-resistant SA. Method: 12 patients with treatment-resistant SA and 24 patients with difficult-to-treat SA (defined according to WHO document) were enrolled in this study (mean age: 59 yrs). All patients underwent spirometry and methacholine test. Asthma control was evaluated according to GINA guidelines and also by ACT questionnaire, ACQ questionnaire and PEF diary. Sputum eosinophils percentage and exhaled nitric oxide (eNO) were measured as markers of airway inflammation. Furthermore, all patients underwent ENT visit to evaluate the presence of pathology of the upper airways (in particular rhinosinusitis and/or polyps). Results: Patients with treatment-resistant SA had a higher sputum eosinophilia (57.1% (3.7-86.2) Vs 12.5 (0-95.6), $p < 0.01$) and a shorter asthma duration (11.5 (3-40) vs 25 (8-50), $p < 0.01$) than patients with difficult-to-treat SA. The indices of asthma control, as well as FEV₁, PD₂₀ methacholine, eNO, and the level of treatment were similar in the two groups. Conclusions: Patients with treatment-resistant SA have a greater eosinophilic inflammation of lower airway than patients with difficult-to-treat SA, but a similar level of control and pharmacologic therapy, suggesting the need for different treatment strategies in the two groups of patients.