EFFECTIVENESS OF THE OMALIZUMAB TREATMENT FOR SEVERE ALLERGIC ASTHMA: A SINGLE-CENTER EXPERIENCE IN CROATIA

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INTRODUCTION: Omalizumab (OMA) is a subcutaneously administrated recombinant humanized monoclonal anti-IgE antibody indicated in adults, adolescents and children six years of age and older. In Croatia, patients must fulfill strict qualification criteria: severe allergic asthma uncontrolled by conventional pharmacological treatments, including oral steroids, with frequent exacerbations, and low lung function values.

METHODS: This is an observational, single-center study obtained in Clinical hospital centre Zagreb, Clinical Department for lung diseases Jordanovac. The patients were diagnosed and treated according to the best clinical practice. From October 2015, fourteen patients were enrolled. Patients were evaluated at the baseline and after 12 weeks for number of asthma exacerbations, Asthma Control Test (ACT), spirometry, eosinophil count and modified Medical Research Council (mMRC) Dyspnea Scale. Statistical analysis was carried out using the methods of descriptive statistics. The effectiveness of the intervention was analysed using paired simple t-test. A P<0.05 was considered statistically significant.

RESULTS: In total, 3 men and 11 women, with a mean age of 56 years, were included in the OMA program. The average duration of severe asthma in patients enrolled for the program was 20 years. Allergies revealed that the
house dust mite was the most frequently sensitizing allergen (10 of 14 patients, 71.4%) followed by pollen allergen (8 of 14 patients, 57.14%). In the year preceding enrolment, the mean number of exacerbations in the group was 8.4/year.

When evaluating for clinically significant improvement, we found that all patients 10/10 (100%) treated with OMA had a decrease in asthma exacerbations (p<0.006). In 5 of 10 (50%) ACT score was significantly reduced (P <0.0026). 8 of 10 (80%) patients showed improvement in mMRC scale with no statistical significance (p<0.19). Also 5 of 10 (50%) patients had a statistically non-significant reduction in absolute eosinophilic count (p<0.68).

Finally, 5 of 10 (50 %) patients achieved a clinical improvement in lung function, i.e., showed a ≥ 200 ml improvement in the forced expiratory volume in first second (FEV1), although for the whole group the increase in FEV1 was not statistically significant (p<0.1).

CONCLUSION: Omalizumab is the key therapeutic option for the management of patients with uncontrolled moderate/severe allergic asthma. Our study has shown significant reduction in the asthma exacerbation rate and improvement in quality of life among other advantages listed before.