51. Allergen immunotherapy and anti-immunoglobulin E

P262

Sublinguial allergen extract immunotherapy in a rush pattern to reach the maintainance faster

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Introduction: Slit (sub lingual immunotherapy Rush immunotherapy was tried on some patients to evolve some faster and affordable immunotherapy modality to make the patient achieve the maintenance pleatu within a very short time. Conventional method of immunotherapy is administered with long durations; rush immunotherapy is super fast methodology in attaining the maintenance/boosting module, which requires hospitalization and other precautionary methods, and multiple allergen vaccines to be administered within short span of time. But in this method, it was found that within 15-20 days the relief of the immunotherapy was reached.

Material & method: 186 patients out of which 48 with urticaria allergy and 138 with allergic Rhinitis & Bronchial Asthma were selected. The therapy consists of administration of four vials of allergen extracts, 1st vial: 1:25,00, 2nd vial 1:25, 3nd vial 1:25, and 4th vial 1:10 dil. The 1st & the 2nd concs were administered in daily 6 hourly schedules in a graphically rising manner. The patients had been given pre-medication. Blood examination and IgG & IgE level estimation were done before & after 8 weeks.

Results: Some of the patients showed local skin reactions which subsided without drugs and no systemic reaction was noted. There was substantial decrease in IgE & increased IgG level, significant & marked satisfactory relief was observed in the patients symptomatology, thus the procedure was graded as a very fast & affordable & SAFE immunotherapy.

P263

Adherence to sublingual immunotherapy in patients allergic to mites

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Background: Adherence is essential for effective treatment. Specific allergen immunotherapy (SIT) should be continued until the patient has had substantially reduced symptom free for 3 or 5 years. Sublingual immunotherapy (SLIT) is referred to improve adherence to SIT. The aim of this study was to identify factors that may influence adherence to SLIT.

Methods: We evaluated 610 patients (15-45 years), 54.4% male, monosensitised to house dust mites with moderate persistent rhinitis and mild persistent asthma, submitted to SLIT in the last 5 years. We analysed factors related to non adherence to SLIT.

Results: 81 patients (13%) suspended SLIT based on different motives:

For 28 patients (35%), main reason for discontinuation of SLIT is inability to take medication according to schedule. 21 patients (26%) withdrew in the first 4 months because of local side effects. 14 patients (17%) due to symptoms resolution: they began to show a 30% improvement of their symptoms compared to the basal score, already 6 months after the start of the the therapy. 10 patients (12%) "get bored" after 6 months of maintenance treatment. 5 patients (6%) stopped because they went to holidays or working habits, 3 patients (4%) due to respiratory recurrent infections. After quitting SLIT, 14 patients (17%) preferred subcutaneous specific immunotherapy.

Conclusions: The main cause of SLIT cessation was desertion, suggesting a need of a greater number of clinical appointments, at least during the first six months of treatment. Candidates to SLIT should be well selected to improve adherence to treatment. The ineffectiveness of SLIT could not be explained by non-adherence.

P264

Maintenance schedule of subcutaneous allergoid immunotherapy more efficacious than pre-seasonal

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Pre-seasonal (PS) and maintenance (M) schedules of specific subcutaneous immunotherapy (SCIT) with allergoids are used to treat patients suffering from seasonal allergic rhinitis. Which of them is more profitable? The aim of the study was to compare an efficacy of two schedules of SCIT, PS vs. M.

Fifty seven patients included into the study randomly divided into two groups: PS group (n=28) and M group (n=29). Allergovit[®] 006 – grass pollen (Allergopharma, Germany) was chosen to treat of them. SCIT lasted 3 years. Every year since 1st May-31st August diary cards were fulfilled. Intensity of symptoms (sneezing, nose itching, rhinorrhea, nasal obstruction, eyes itching, lacrymation, eyes reddening, cough and shortness of breath) and concomitant drug consumption were evaluated. Serum total and sIgE were evaluated before and after stopping SCIT. Intensity of a pollination was evaluated every year.

Each individual from PS group was injected 30 times and obtained cumulative dose of 86862 SBU, whereas the one from M group - 41injections and 172892 SBU. In 2006 the highest concentration of grass pollen in the air was 197/m³, in 2007 much higher – $475/m^3$, and in 2008 – $247/m^3$. The highest intensity of the symptoms in both group were registered in the first season of SCIT (2006). No significant differences between PS and M were found. The intensity of the symptoms decreased in successive years of SCIT, and in M group was more evident. After SCIT the concentration of tgE and sIgE decreased significantly. **Conclusion:** Both schedules, PS and M of SCIT with allergoid vaccine are effective

in pollinosis patients, but M is more profitable.

P265

Pollen asthma treatment: Comparative efficacy study

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Background: Airborne pollen has always been one of the most common triggers of asthma, so there is vital need in efficient specific hyposensibilisation.

Aims and objectives: Principal aim was to check efficacy of different combinations of inhaled corticosteroid/long-acting β_2 -agonist upheld by specific immunotherapy and/or montelukast.

Methods: In open-label, randomized, parallel group, one-year panel study were involved 468 patients with pollen asthma (moderate-to-severe airflow limitations, bronchitis symptoms, and a history of exacerbations). All participants had completed allergy examination (prick skin test), immunologic, and functional assessment corroborating their asthma status. Participants were randomized in three equal groups, 156 patients each. First group got specific immunotherapy, second - montelukast (Singulair), and third – both treatments. Entire population received budesonide/formoterol (Symbicort Turbuhaler) as well.

Results: After 52-week treatment first group exhibited strong remission in 68% patients assigned, second group – in 61% patients, and third group – in 79% patients. These changes were statistically independent of patient's age, sex, and smoking status (P<0.01).

Conclusions: Budesonide/formoterol in conjunction with allergen-specific immunotherapy and montelukast proved to be the most successful combination for curing pollen asthma.

P266

Omalizumab in asthmatics with IgE levels > 700 IU/ml

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Introduction: Omalizumab, a monoclonal antibody against IgE, has been effectively used to control symptoms and reduce steroid requirements in asthmatics with serum IgE levels between 30-700 IU/ml and positive testing for perennial allergens. Its use when IgE levels are > 700 IU/ml is unclear.

Aim: To evaluate the response of asthmatics treated with omalizumab with IgE levels > 700 IU/ml.

Methods: A retrospective, case-controlled study was performed in an allergy referral clinic. Consecutive asthmatics treated with omalizumab \geq 6 months with elevated IgE levels were identified, and demographic variables recorded. Systemic corticosteroid requirements, emergency room visits, hospitalizations, FEV1, Asthma Control Test (ACT) scores, medications and allergen responses were recorded for a period of 6 months pre and post treatment.

Results: Twenty-six patients with an IgE >700 IU/ml (Group 1) and 26 with an IgE of 30 to 700 IU/ml (Group 2) were identified. The mean IgE level was 2371 IU/ml (786-10979) vs. 221 IU/ml (30-578) respectively (p<0.001). Age, gender, and weight were similar in both groups. Both, Group 1 and Group 2, had an improvement in asthma control based on the mean ACT pre and post treatment (15.6 vs. 18.9 [p=0.016] and 15.4 vs. 19 [p=0.006]) respectively. There was also a significant reduction in the frequency of systemic corticosteroid use during the 6 months pre and post treatment (2.58 vs. 0.96 and 2.62 vs. 1.23/steroid bursts) respectively (p<0.001).

Conclusions: Omalizumab was effective in controlling asthma symptoms and reducing the need for systemic corticosteroids in patients with IgE levels > 700 IU/ml and produced clinical improvement similar to patients with IgE levels between 30-700 IU/ml.

P267

Effects of add-on omalizumab therapy on airway wall thickening in severe persistent asthma

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Background: Omalizumab has an important role in inhibiting the allergic inflammation, and it could possibly contribute to decreased airway remodeling in patients with asthma.

Aims and objectives: The aim of the study is to assess the effects of omalizumab on airway wall thickening using computed tomography (CT).

Methods: Twenty-eight patients with severe asthma were randomized to treat with conventional therapy with (n = 13) or without omalizumab (n = 15) for 16 weeks. Airway dimensions were assessed by CT, and wall area corrected for body surface area (WA/BSA), percentage wall area (WA%), wall thickness (T)/ \sqrt{BSA} at the right apical segmental bronchus were measured before and after treatment. The percentage of eosinophils in induced sputum, pulmonary function, and Asthma Quality of Life Questionnaire (AQLQ) were also measured.

Results: Treatment with omalizumab significantly decreased WA/BSA, WA% and T/ \sqrt{BSA} (p<0.01, each) whereas conventional therapy had no change. In the omalizumab group, there were significant decrease in the sputum eosinophils (p<0.01), and improved forced expiratory volume in 1s (FEV₁), morning expiratory peak flow and the AQLQ score. The changes in FEV₁% predicted and sputum eosinophils were significantly correlated with changes in WA% (r=0.88, p<0.001, and r=072, p<0.01, respectively).

Conclusions: These findings suggest that omalizumab reduced wall thickness and airway inflammation.

P268

Decreasing dose protocol for omalizumab treatment in oral corticosteroid allergic asthma patients

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Purpose: To evaluate the viability of a protocol for the progressive decrease of omalizumab dose in allergic GINA step V asthma patients.

Methods: To enter the protocol, the patients had to be receiving treatment with omalizumab for a minimum of one year; oral corticosteroid dose had to have reached its lowest level and spirometry had to be \geq than at entry. Intervention: a) The omalizumab dose was reduced by half; b) If patients were clinically stable after 6 months, the dose was reduced by half again; c) If needed, oral corticosteroid boosters were administered; d) When repeated boosters were needed and/or spirometry worsened, omalizumab dose was increased to the previous figure until the patient stabilized.

Results: The protocol started in July 2006 until December 2010. Forty-five adult patients (31 female) were included; three females were lost during follow-up. The omalizumab dose was decreased in 12 patients (26.6%); it was stopped in three and has not been re-introduced after 4, 12 and 21 months. These patients had been treated for 45, 34 and 18 months respectively. Of the nine remaining patients, in six the dose was reduced and did not need to be re-increased; in three the omalizumab dose had to be increased to the initial dose at months 10, 15 and 32.

Conclusion: 1) A progressive decrease in the dose of omalizumab was feasible and safe in 26% of the patients. 2) A treatment-free window period is possible, and in one patient lasted up to 21 months.

P269

The APEX study: Retrospective review of oral corticosteroid use in omalizumab-treated severe allergic asthma patients in UK clinical practice

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Treatments that reduce oral corticosteroid (OCS) use can help reduce the burden of asthma. We retrospectively reviewed OCS-sparing in 136 omalizumab recipients (age \geq 12 years) with severe persistent allergic asthma. The primary endpoint was the difference in OCS quantity given during 12 months pre- and post-omalizumab initiation. Secondary endpoints included changes in lung function, asthma exacerbations and healthcare resource utilization and OCS use in patients on continuous OCS at baseline. Mean (±SD) total quantity of OCS prescribed per year decreased by 34% (p<0.001) between the 12 months pre- (5.5±4.21 g) and post-omalizumab initiation (3.6±3.73 g). During 12 months post-omalizumab initiation 87 patients (64%) stopped/reduced OCS use and 66 (49%) completely stopped. Mean percent predicted FEV₁ increased from 66.0±17.63% at baseline to 75.2±21.79% at Week 16 of omalizumab therapy (p=0.001). The number of asthma exacerba

tions decreased from 3.7 ± 2.69 during 12 months pre-omalizumab to 1.7 ± 1.93 during 12 months post-initiation (-53%; p<0.001). Between the 12 months preand post-omalizumab initiation there were reductions in accident/emergency visits (from 1.52±2.19 to 0.46 ± 1.42 ; -70%) and hospitalizations (from 1.30±1.73 to 0.51 ± 1.10 ; -61%) (both p<0.001). In 90 patients on continuous OCS at baseline, total quantity of OCS per year decreased from 6.8 ± 4.34 g to 4.4 ± 3.78 g (-36%; p<0.001). In conclusion: in routine UK clinical practice, omalizumab was associated with lower OCS use, improved lung function, and reduced exacerbation frequency and use of healthcare resources, versus the year pre-initiation.

P270

OPURIT: <u>O</u>malizumab-protected <u>ultra rush specific immunotherapy</u> in severe asthmatic patients with house dust mite allergy

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Severe uncontrolled asthma is a contraindication against allergen-specific immunotherapy due to increased risks of side effects and asthma exacerbations. Omalizumab (Xolair[®]) has been shown to be an effective treatment for patients suffering from severe allergic asthma and to increased safety of allergen SpecificImmunoTherapy SIT. We describe 3 patients (males, 28, 31 and 42years) with severe asthma GINA III-IV and total serum IgE ranging from 181 to 680 IU/ml undergoing a combination of Omalizumab and house dust mite-SIT. House dust mite (HDM) allergy was confirmed by clinical history, positive skin prick tests, elevated specific serum IgE and positive conjunctival challenge tests.

In all 3 patients Omalizumab was initiated according to manufacturer's recommendation. After 3 months in all patients asthma improved requiring less inhaled drugs and an improved quality of life. The felt effect of HDM exposure was also reduced but still somehow present. Thus we added an allergen-specific immunotherapy with HDM as the asthma situation was stable now. We opted for an ultra-rush induction regimen with a total of 6 injections over 4 hours and a cumulative dose of 100'000 SQU. Patients were closely monitored. All patients tolerated the ultra rush induction very well. The maintenance regimen of the HDM extract was then injected on a monthly base. Also Omalizumab was continued on the initial dose. Omalizumab may enable induction of allergen-specific immunotherapy with HDM in severe asthma patients otherwise not accessible to this approach. The long term effect of this combined treatment will have to be further evaluated to judge clinical and pharmacoeconomical aspects.

P271

Biological monitoring of cellular effects of omalizumab with basophil degranulation test (BAT) in severe asthma

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The use of anti-IgE antibodies (Omalizumab) for the treatment of severe asthma is the first approach with biological drugs in this setting. IgE bound to receptor on responsive cells induce both mast cell and basophil degranulation with release of new mediators responsible of clinical features. There aren't objective tests to dimonstrate the biological effects to this treatment. We evaluated basophil degranulation during treatment with Omalizumab using a basophil degranulation test based on a one-step method of basophil staining after exposure to a specific allergen with flow citometry that shows basophilic reactivity in vitro and their degranulation after contact with specific allergens. This method is based on recognition of peripheric blood cells positive to marking with monoclonal antibody CD123 that together with citophluorimetric caratheristic by Forward and Side Scatter and the contemporary negativity of expression of superficial antigen HLA-DR,identify basophil granocyte subset. In these cells after specific stimulation in vitro, is possible to identify IgE degranulation for the expression on the citoplasmatic surface of the antigen with monoclonal antibody CD63.

Seven patients were examined with the test baseline and after 12 and 24 months of OMA treatment. After 24 months of treatment degranulated basophil cells were 0.7% in comparison 53.9% at 12 months and 53.5% at baseline and this decrease was associated both to clinical improvements and reduction in oral corticosteroid daily dosage.Basophil degranulation test may be an appropriate method to evaluate Omalizumab biologic therapy in severe asthma where response and treatment duration are important aims.

P272

The APEX study: A retrospective review of responses of severe allergic asthma patients to omalizumab on continuous or non-continuous oral corticosteroids in UK clinical practice

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Omalizumab is an effective add-on option for patients with severe allergic asthma (who remain uncontrolled despite inhaled corticosteroid therapy), many of whom are receiving oral corticosteroids (OCS). We retrospectively reviewed records from 12 months pre- and post-omalizumab initiation in patients (age \geq 12 years) with

	Patients receiving continuous OCS at baseline (n=90)	Patients not receiving continuous OCS at baseline (n=46)	
OCS use over 1 year pre-omalizumab, g	6.8±4.34	3.0±2.44	
OCS reduction [†] (%)	36	26	
Patients reducing/stopping OCS [‡] , n (%)	59 (65.6)	28 (60.9)	
Responders [#] , n (%)	71 (78.9)	41 (89.1)	
Change in exacerbations [†] (%)	-54.6***	-49.3***	
Change in hospitalizations [†] (%)	-60.6***	-61.9***	
Change in A&E visits [†] (%)	-68.1***	-73.6***	
Change in % predicted FEV_1 at week 16^{\dagger} , (%)	$+8.7 \pm 15.08 **$	$+14.7\pm26.15$	

Values are mean \pm SD unless otherwise stated. *p<0.05, **p<0.01, ***p<0.001 vs preomalizumab; [†]year pre- vs year post-omalizumab initiation; [‡]during year post-omalizumab initiation; [#]significant improvement on physician's assessment at 16 weeks.

severe persistent allergic asthma who were or were not receiving continuous OCS. Percentages of patients reducing/stopping OCS use, changes in exacerbation rates, hospitalization and accident/emergency visit rates, overall responder rates and FEV₁ all improved post-omalizumab (table).

Responses were similar when comparing those who were and those who were not on continuous OCS at baseline. In conclusion, the benefits of omalizumab in patients not receiving continuous OCS at baseline were at least as great as those in patients receiving continuous OCS at baseline.

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Real-life effectiveness of omalizumab in patients with severe persistent allergic (IgE-mediated) asthma: Pooled data from 3 UK centres

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Omalizumab is approved as add-on therapy for patients (age ≥ 6 years; European Union) with uncontrolled severe persistent allergic (IgE-mediated) asthma. Few studies have reported on omalizumab's effectiveness on real-life outcomes in UK clinical settings.

We report clinical outcomes in severe allergic asthma patients receiving omalizumab (150–600 mg q4wk or q2wk) at 3 UK centres (St Peter's Hospital, Chertsey; Bradford Royal Infirmary; Colchester Hospital). Data were compared for 2-years pre-omalizumab and for the most recent assessment following omalizumab initiation.

Patients (n=52; age 18–74 years) received omalizumab for an average of 982 days (range: 112–3839). 86.4% patients responded to treatment at 16 weeks. Following omalizumab, hospital admissions/bed days, A&E and GP visits decreased compared with pre-omalizumab (Table). Oral corticosteroid (OCS) use was also reduced post-omalizumab; mean maintenance dose of OCS pre- and post-omalizumab was 12.6 and 5.7 mg/day (n=43). Overall, mean [SD] improvement in AQLQ score was +1.39 [1.80]. Asthma control also improved post-omalizumab, as shown by an overall increase in mean [SD] ACT of +7.29 [4.64]. Patients not receiving OCS at baseline (n=24) achieved higher mean [SD] AQLQ scores compared with those on OCS at baseline (n=29); 2.29 [1.23] vs 1.36 [1.77].

	Hospital admissions	Hospital bed days	A&E visits	GP visits
Pre-omalizumab (n=52) Post-omalizumab (n=52)	165* 12*	259^{\dagger} 12^{\dagger}	164 [‡] 27 [‡]	474 ^{\$} 115 ^{\$}
*n-42: †n-28: ‡n-51: \$n-	.42			

*n=43; 'n=28; *n=51; *n=42.

Results from this pooled analysis demonstrate the real-life effectiveness of omalizumab in a clinical setting, further supporting the efficacy of omalizumab shown in clinical trials.

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ROMA (registry omalizumab in Malaga): Study of 84 patients

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Purpose: Our objective is to describe the patients profile and the results observed in the patients treated with omalizumab in the three main hospitals of Malaga. **Methods:** Retrospective study of clinical records. All the patients including are adult with not controlled severe allergic asthma condition. A data base has been created using software SPSS 15.0.

Results: 84 patients were included (70% women), with an average age of 51 years and FEV₁ $64.7\pm18\%$. The 100% of the patients had some exarcebations and 20% needed hospitalization in the previous year. 9 patients were steroids-

dependents. The average time of treatment is of 10.3 months with a mean dose of 306mg/month. When comparing the parameters of control and quality of life (ACT and MINI-AQLQ) and pulmonary function parameters before the treatment and 16 weeks after treatment, we found statistically significant differences (SSD). Also found SSD in the reduction of inhaled and oral steroids, number of exarcebations and hospitalizations.

Conclusions: Omalizumab is able to improve the pulmonary function, the control of the asthma and health-related quality of life, decreasing the number of hospitalization and exarcebations, and reducing the use of corticoids (oral and inhaled).

P275

Long-term treatment with monoclonal antibodies anti-IgE in severe asthma: Follow-up of ten patients

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Omalizumab is a monoclonal anti-IgE antibody suggested for the treatment of very severe asthma. Duration of therapy remains an open question.

We tried to evaluate the long-term response to omalizumab in a population of patients who extended the treatment beyond the 12 months period suggested by EMEA, with the aim of contributing to establish the ideal duration of the therapy. 10 patients (8 females, 2 males, mean age:45 yrs), with severe allergic asthma, uncontrolled despite GINA Step 4 therapy, received optimized asthma therapy and omalizumab up to 36 months. They underwent complete clinical evaluation, spirometry tests and Asthma Control Test questionnaire every month.

Patients showed, after 24 months of treatment, persistency of good clinical and functional response: medium ACT score was 20, with a 19,2% improvement compared to basal value, FEV1 and MMEF showed an increase of 21% and 26%, with best values registered after 18 months. No side-effects were reported.

Long-term therapy with omalizumab in our patients was well tolerated with significant improvement of both symptoms and function, and absence of side-effects, suggesting that administration of omalizumab for longer than 12 months could be beneficial for some responders patients, despite costs.

P276

Omalizumab and voriconazole in allergic broncopulmonary aspergillosis (A case series)

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Allergic bronchopulmonary aspergillosis (ABPA) in immunocompetent patients may represent a cause of severe, difficult to control asthma associated with recurrent exacerbations and dependence to systemic steroid. We describe of 5 F patients, age mean 62.6 y (range 50 - 74) with ABPA who were treated with combined anti-IgE omalizumab and Voriconazole. They have skin prick test positive to different pollens (Parietaria, grass) and perennial allergens such as mites and Aspergillus fumigatus, but also high levels of total (732 \pm 228 UI/mL) and specific IgE towards Aspergillus f. (>25 Ku/L) in the absence of invasive aspergillosis. Their treatment consisted of ICS and LABA daily and orally steroids during exacerbations (about 6-7/y).

All of the patients have CT- rhinosinusitis and 1of 5 pts has radiological signs of bronchiectasis. The PFR showed obstructive ventilatory pattern with FEV1% th = 66 ± 6 ; FVC% th = 77 ± 11 and ACT score was 17. Voriconazole 200mg bid was admistrated for two months before treatment with biological therapy with Omalizumab even if the serum levels of galactomannan were negative. 3 months later treatment with voriconazole, the specific Aspergillus f. IgE levels returned normal.

After 1 year of treatment with Omalizumab, the exacerbations rate (8 vs 3) and the ACT score were reduced (21 vs 17); FEV1% th 75 improved and total IgE levels were lower (363±173 UI/mL). Second year of treatment: the specific aspergillus IgE levels returned to be high but no exacerbation was registred and ACT remained stable. In APBA patients with severe allergic asthma the combined therapy with omalizumab and voriconazole in burst might offer a longer and safer approach in this setting.

P277

Eligibility for treatment with omalizumab in Italy and Germany

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Omalizumab is an add-on therapy for patients with uncontrolled severe allergic asthma. In Europe, patients must fulfil a number of additional criteria to become eligible for omalizumab therapy, creating a challenge for epidemiology studies to quantify the potential patient pool. Thus, and in the absence of robust data, the number of omalizumab-eligible patients has remained unclear. To assess eligible patient numbers, the team employed an innovative chart-audit

design approach to measure epidemiology variables based on patient-level data. 770 patient charts were reviewed in designated towns in Germany/Italy, in collaboration with >200 primary care physicians (PCPs) and respiratory specialists (RS). This study sample represents >50% and >70% of local RS in these designated towns of Germany and Italy, respectively.

Of patient charts evaluated, 4 patients were currently receiving omalizumab. A further 31 patients (12 PCP; 19 RS) were evaluated as omalizumab-eligible (i.e. fulfilled all product label criteria) but were not receiving the drug. Extrapolating to a national level, this yields >6500 eligible patients in Germany, >3200 in Italy. Furthermore, this study sample revealed a significant number of PCPs treating uncontrolled severe asthma patients without referral to RS; these patients are not consistently evaluated for FEV1, aeroallergen sensitivity as well as a qualitative understanding of severe exacerbations, and day and night-time symptoms.

This study suggests that significant numbers of omalizumab-naïve severe allergic asthma patients in Germany/Italy are eligible for omalizumab therapy; if treated, these patients may benefit from reduction in asthma exacerbations and improved asthma control and quality of life.

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Cytokine production profile of T-lymphocytes and frequence of regulatory T-cells in patients with allergic asthma receiving anti-IgE therapy

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Omalizumab is a recombinant anti-IgE antibody with proven efficacy in severe allergic asthma. Little is known about immunological changes affected by decreasing free IgE during omalizumab therapy. In the present study T-lymphocyte cytokine profiles and frequency of regulatory T-cells before and during omalizumab therapy in patients with severe allergic asthma were examined.

Twenty patients with severe allergic asthma (14 female) who met the criteria for omalizumab therapy were enrolled. Before and after 16 weeks of therapy peripheral blood mononuclear cells were isolated and activated with anti-CD3/anti-CD28 antibodies. Cells were processed for intracellular cytokine staining and frequency of CD3+ CD4+ interleukin (IL) 4, 5, 10, 17, interferon γ (IFN- γ) positive cells was assessed. The frequency of CD4+ CD25+FOX-P3+CD127- regulatory T-cells was assessed.

Anti-IgE treatment did not lead to a significant change of intracellular IL 4, 5, 10 and IFN- γ in CD3+ CD4+ T-lymphocytes (mean at baseline: IL-4 5,9±3,8%; IL-5 1,1±1,1%; IL-10 4,5±3,2%; IL-17 2,0±2,0%; IFN- γ 9,2±5,6%, intraindividual difference in week +16: IL-4 1,3±3,8% p=0,164; IL-5 0,2±1,2% p=0,474; IL-10 0,3±5,0% p=0,774; IL-17 -1,4±6,4% p=0,376; IFN- γ 2,0±4,5% p=0,056). Additionally, there was no significant change in frequency of regulatory T-cells (mean at baseline: Treg 11,4±5,7%, intraindividual difference in week +16 Treg 0,4±5,5% p=0,730).

In this study there was no significant difference of the tested intracellular cytokines before and after anti-IgE therapy. Frequency of regulatory T-cells did not change significantly 16 weeks after initiation of anti-IgE therapy.