VOLUME 117 | NUMBER 5 | SUPPLEMENT 1
November 2016 | annallergy.org

American College of Allergy, Asthma & Immunology

# Annals of Allergy, Asthma & Immunology

OFFICIAL PUBLICATION OF THE AMERICAN COLLEGE OF ALLERGY, ASTHMA & IMMUNOLOGY

## 2016 Annual Scientific Meeting of the American College of Allergy, Asthma and Immunology

Oral and Poster Abstracts

November 10-14
San Francisco, California

allergies. The biggest difference can be seen at 27 years old group with 921 vs. 334 patients. Both the female and male patients in the age group analysis of various allergic diseases demonstrated a pattern of "allergic march" from dermatologic to respiratory allergy.
**Conclusion:** Peak incidence of various allergic diseases occurred in the 5 year old age group. In early childhood the male/female ratio among allergic patients is high, this ratio being reversed in later adolescence until late adulthood. Patterns of prevalence of various childhood and adolescent allergic disease in Western Hungary demonstrated the progression from dermatologic to respiratory allergy characteristic of an allergic march.

## P076

### COMPARISON OF LONG TERM EFFICACY OF PERENNIAL VERSUS PRE-SEASONAL ALLERGEN IMMUNOTHERAPY FOR GRASS POLLEN

R. Gawlik*[1], L. DuBuske[2], *1. Warsaw, Poland; 2. Gardner, MA.*

**Background:** Allergen immunotherapy (AIT) is the only causal method of the treatment of allergic rhinitis. This study assesses the long term efficacy of perennial AIT versus pre-seasonal AIT for grass pollen induced allergic rhinitis.
**Methods:** An open comparative study was conducted in 37 allergic rhinitis patients diagnosed by clinical history, skin prick tests and asIgE serum level. Pre-seasonal subcutaneous immunotherapy (SCIT) occurred in 22 patients (mean age 24.4 ±4.6 years) and perennial treatment in 15 patients (mean age 23.8±4.3 years) using a hypoallergenic extract of grass pollen (Allergopharma, Reinbek, Germany). Symptom's medication score (sms) was recorded by all patients. The efficacy of AIT was estimated by sms after completion of therapy and 15 years later.
**Results:** Significant reductions of symptom medication scores were seen immediately after completion of AIT and 15 years later with prolonged effect more pronounced in patients treated with perennial treatment. VAS after 3 years of AIT in the perennial AIT group was reduced from 8.6 to 2.6 and in the pre-seasonal AIT group reduced from 8.2 to 3.6 ($p<0.05$). VAS after 15 years was 3.9 in the perennial AIT group and 5.1 in pre-seasonal one. There were no significant differences in number of adverse events between the 2 groups of patients. Significantly less new sensitizations and less new asthma development was seen 15 years after discontinuation of AIT in patients who had perennial treatment.
**Conclusions:** Perennial compared to pre-seasonal AIT showed greater clinical benefit and more sustained long term effects.

## P077

### EVALUATION OF LEUKOCYTE SUBSETS PRESENT IN THE IGELO AND IGEHI REGIONS ON FLOW CYTOMETRY

A. Hancharou*[1], I. Ramanava[1], L. DuBuske[2], *1. Minsk, Belarus; 2. Gardner, MA.*

**Introduction:** IgE gating strategy is used widely for the identification of basophils with flow cytometry. This study investigates cell non-uniformity of IgElo and IgEhi fractions that may affect the purity of basophil gating.
**Methods:** Blood samples from 10 healthy donors were used. Cells were stained with monoclonal antibodies (HLA-DR – Pacific Blue, CD45 – Krome Orange, IgE – FITC, CD19 + CD16 PE, CD123 PerCP-Cy5.5, CD11c – PE-Cy7, CD203c – APC, CD3 + CD14 APC-H7). The assay was performed on a BD FACSCanto II cytometer.
**Results:** The antibody panel allowed identification of basophils, monocytes, myeloid (mDC) and plasmacytoid dendritic cells (pDC), T-lymphocytes and B-lymphocytes in the IgElo and IgEhi regions. IgElo cells predominantly expressed HLA-DR (94.1%; range 90.2–98.7). HLA-DR+ cells were identified as monocytes (40.1%; range 30.2–54.8), pDC (26.0%; range 20.4–38.2), mDC (24.6%; range 15.4–39.2) and B-lymphocytes (6.0%; range 3.1–9.8). HLA-DRneg cells were predominantly T-cells and basophils (4.1%; range 1.2–5.5%). The IgEhi non-basophil fraction was composed of mDC, B-cells and very small portion of pDCs. No T-cells or monocytes were observed in the IgEhi region. Total count of cells in the contaminating basophil region was 1.9%, range 1.7 to 2.6%.
**Conclusion:** The IgElo fraction om flow cytometry contains a different cell population that indicates its non-uniformity. The contamination of IgEhi basophils with leukocyte subsets was insignificant, a finding to be considered when basophil gating using SSC/IgE strategy.

## P078

### NOVEL SACUBITRIL/VALSARTAN (ENTRESTO) DESENSITIZATION PROTOCOL: A CASE REPORT

T. Smith*, Y. Gernez, A. Tsuang, S. Muller, E. Buchbinder, *New York, NY.*

**Introduction:** Sacubitril/Valsartan (Entresto) was approved by the U.S. Food and Drug Administration (FDA) in 2015 after the Phase III PARADIGM-HF trial demonstrated 20% risk reduction of cardiovascular deaths and heart failure-related hospitalizations (NYHA II-IV) compared to enalapril. Of the adverse events reported, rates of angioedema were higher in patients treated with Entresto compared to enalapril (0.5% vs 0.2% respectively, in African Americans, 2.5%), while 9% of participants reported cough. Given the mortality benefits, the demand for Entresto on pharmacy formulary will increase and induction of drug tolerance protocols will be indicated in the event of hypersensitivity reactions. Currently, there is no available testing to assess for IgE-mediated allergy. We describe a successful desensitization protocol to Entresto in a patient with a reported hypersensitivity reaction.
**Methods:** After written consent was obtained, a novel 5-step desensitization protocol (Table 1) was performed in an intensive care unit with the use of premedication (cetirizine 10 mg, monteleukast 10 mg and solumedrol 20 mg).
**Results:** The patient completed the desensitization protocol without adverse reactions. He continued maintenance therapy for a 6-month period without recurrence of a hypersensitivity reaction, however Entresto was discontinued due to reported dizziness.
**Conclusion:** We report the first successful desensitization to Entresto.

TABLE 1. Ssacubitril/valsartan( Entresto ™) desensitization protocol

| Step | Time, min | Dilution | Dose, mg | Total dose, mg |
|---|---|---|---|---|
| 1 | 0 | (1/10,000) | 0.0024/0.0026 | 0.0024/0.0026 |
| 2 | 60 | (1/1000) | 0.024/ 0.026 | 0.0264/0.2626 |
| 3 | 120 | (1/100) | 0.24/0.26 | 0.2664/0.52 |
| 4 | 180 | (1/10) | 2.4/2.6 | 2.66/3.1 |
| 5 | 240 | (1/1) | 24/26 | 26.66/29.12 |

## P079

### EFFECT OF INFLUENZA FACT SHEET ON ACCEPTANCE AND PERCEPTION OF VACCINATION IN AN AMBULATORY CENTER

E. Abou-Jaoude*, N. Punnanithinont, N. Kataria, *Buffalo, NY.*

**Introduction:** Influenza leads to significant disease burden. Our aim was to evaluate patient acceptance of the influenza vaccine and determine factors associated with perceptions. We evaluated if a CDC Influenza Fact Sheet was associated with vaccination acceptance and perceptions.
**Methods:** Observational study involving 91 patients at an Ambulatory Center. Patients received a CDC Influenza Fact Sheet upon arrival. Patients later completed a questionnaire. Perceptions regarding influenza vaccination were scored on a 4-point scale. Patients determined if the fact sheet answered concerns and if they recommend others to read the sheet.
**Results:** There was statistically significant association between perceived effectiveness of vaccination and history of previous

## P211

### CHURG-STRAUSS SYNDROME – A CASE REPORT

K. Shah*[1], M. O'Connor[2], *1. Miami, FL; 2. Charlotte, NC.*

**Introduction:** Churg-Strauss Syndrome is a rare systemic disease primarily characterized by hypereosinophilia, asthma and vasculitis. Case(Methods/results): We present a 44 y/o male with chronic rhinosinusitis and sudden onset severe persistent asthma uncontrolled on daily high dose steroids. Patient had a history of multiple hospitalizations over the last six months for asthma exacerbation's during which he was found to have 49% eosinophils on a peripheral smear. Patient was also found to have proteinuria, splenomegaly and bronchiectasis. Physical exam revealed tachypnea and diffuse wheezing. Bronchoscopy with BAL revealed 42% eosinophils. ANCA antibodies were negative and IgE was 536 IU/ml. Diagnosis of Churg Strauss Vasculitis was made and patient was started on high dose oral steroids along with methotrexate and inhaled corticosteroids and long acting beta agonists. Patient's condition, however, hadn't improved after 6 months on therapy. Patient also had a bone marrow biopsy performed but the results were equivocal since the patient was on steroids. Patient had then started developing complications of steroids including multiple vertebral compression fractures. In an attempt to wean patient off of steroids, he was also tried on omalizumab, zileuton, leukotriene inhibitors and flunisolide inhaler with no success. After multiple failed treatments, patient was eventually started on azathioprine and umeclidinium and vilanterol ellipta and methotrexate was stopped. Patient now seems to be stabilized on azathioprine and is slowly weaning off steroids.

**Conclusion:** Azathioprine was found to be superior than methotrexate in the treatment of Churg Strauss Syndrome. Considerations will be made to initiate reslizumab in the future if needed.

## P212

### LIVER CIRRHOSIS AND WEIGHT LOSS AS PRESENTING FEATURES OF SYSTEMIC MASTOCYTOSIS

J. Bjelac*[1], D. Patil[2], C. Radojicic[3], *1. Cleveland Heights, OH; 2. Cleveland, OH; 3. Independence, OH.*

**Introduction:** Mastocytosis is a heterogeneous disease with variable clinical manifestations. Gastrointestinal involvement of systemic mastocytosis has been studied in small cohorts of patients, with cirrhosis rarely reported.

**Methods:** A 69 year old male was seen during inpatient consultation for mild eosinophilia (absolute eosinophil count of 540 k/uL) in the setting of 5 years of diarrhea, liver cirrhosis based on imaging with ascites and unintentional weight loss of 140 pounds. Evaluation at outside institutions including infectious, autoimmune, oncologic, and gastroenterological workup had failed to identify a cause.

**Results:** Exam revealed a cachectic male with dermatitis noted on chest and back. Liver biopsy demonstrated periportal fibrosis and chronic hepatitis, with mast cells within the portal tract and sinusoids highlighted by CD117 and CD25. Small bowel biopsy showed evidence of a mast cell neoplasm involving the duodenum and jejunum. Serum tryptase was found to be 151 ug/L. Bone marrow biopsy demonstrated hypercellular bone marrow with paratrabecular aggregates of spindle-shaped mast cells. Flow cytometry performed on the bone marrow aspirate showed the presence of an abnormal mast cell population positive for CD25 and CD117 and negative for CD2. KIT D816V mutation was detected. The patient was started on a high dose antihistamines with cromolyn sodium, pending additional oncologic therapy. Skin biopsy was deferred due to bone marrow confirmation.

**Conclusion:** Systemic mastocytosis is rarely associated with liver cirrhosis. However, in patients presenting with persistent GI symptoms of unknown etiology, an atypical presentation of systemic mastocytosis should be considered.

## P213

### A NON-ATOPIC CHILD WITH RECURRENT RESPIRATORY INFECTIONS SUCCESSFULLY TREATED WITH MAST CELL THERAPY

C. Cui*[1], J. Yusin[2], I. Randhawa[3], *1. Los Angeles, CA; 2. Stevenson Ranch, CA; 3. Long Beach, CA.*

**Introduction:** Mast cell activation syndrome (MCAS) has been increasingly recognized in the past few years. Its extreme heterogeneity of presentation makes the diagnosis very difficult, and often causes significant delays in diagnosis. Here we present a child with recurrent respiratory infection and reactive airway disease responding to mast cell therapy.

**Methods:** Patient was treated with comprehensive mast cell therapy including cromolyn, fexofenadine, loratidine, montelukast, and cimetidine after failing all other treatments.

**Results:** This 8-year-old male had suffered from recurrent respiratory infections and treated repeatedly with antibiotics and oral steroids. History was significant for years of reactive airway disease, frequent malaise and fevers. Patient's mother had possible Ehlers-Danlos syndrome and atypical obstructive lung disease. The patient was found to have elevated ASO titer 1266 IU/ml, anti-DNaseB titer 610 IU/ml, and positive ANA. However, workup for aeroallergen and food allergy, cystic fibrosis, rheumatic heart disease, autoimmune diseases, and immunodeficiency was all negative. Treatment with antibiotics and glucocorticoids did not help his symptoms and patient frequently missed school. Given history of recurrent airway infection, reactive airway disease, increased urinary histamine level, and concurrent hypotension, MCAS was diagnosed. Patient was placed on comprehensive mast cell therapy including cromolyn (inhaled and oral), fexofenadine, loratidine, montelukast, and cimetidine. Within one month, patient improved significantly clinically. ASO and anti-DNase B titer was normalized to 583 IU/ml and 317 IU/ml, respectively. The medications have been remained thereafter.

**Conclusions:** We believe this is the first reported case of mast cell therapy in the treatment of chronic, refractory respiratory infection.

## P214

### OPTIMIZATION OF BASOPHIL GATING STRATEGIES USING FLOW CYTOMETRY

I. Ramanava[1], A. Hancharou*[1], N. Dudarava[1], L. DuBuske[2], *1. Minsk, Belarus; 2. Gardner, MA.*

**Introduction:** The precise basophil identification with flow cytometry (FCM) is crucial for the correct interpretation of the basophil activation test (BAT) results. This study assesses gating strategies used for effective basophil identification using Flow Cytometry.

**Methods:** Blood samples from 15 patients with house dust mite allergy and 10 healthy donors were used. Basophils were activated by house dust mite allergen, stained with monoclonal antibodies (8 to 10 color panels were used). The gating strategy for basophils and identification of the cell contamination in basophil regions were performed using BD FACSCanto II cytometer.

**Results:** Seven gating strategies were analyzed: CD123hi/HLA-DRneg, CD3−/CD193+, CD193+, CD45dim/anti-IgEbright, IgEhi, CD3−/CD294+, CD203c+. The Separation Index (difference between

negative and positive peaks adjusted for the fluorochrome brightness) was the highest for IgEhi (9.1; range 4.6 to 14.9) and CD123hi/HLA-DRneg (5.9; range 5.1 to 13.0) gating strategies and the lowest for CD203+ (1.3; range 1.2 to 1.7). The IgEhi (1.9%; range 1.7 to 2.6%) and CD123+HLA-DR− (2.2%; range 1.6 to 3.2%)) regions had the lowest contamination by other cell subsets including monocytes, T-lymphocytes, B-lymphocytes, myeloid and plasmacytoid dendritic cells. The highest cell contamination was observed in the CD203c region and included B-cells and blood dendritic cells (median 3.5%; range 3.0 to 7.1%).

**Conclusion:** The most effective gating strategies for BAT were IgEhi and CD123+HLA-DR− due to the highest separation index and purity of the basophil population.

## P215

### ABNORMAL NEWBORN SCREENING FOR SCID WITH SEVERE T-CELL LYMPHOPENIA IN INFANT OF RENAL TRANSPLANT RECIPIENT

S. Patel[1], J. Bird[1], A. Yango[2], M. De La Morena[1], *1. Dallas, TX; 2. Fort Worth, TX.*

**Case Presentation:** A twenty-one day-old female born at thirty-four weeks estimated gestational age was referred after two abnormal newborn screening results for severe combined immunodeficiency (SCID). T-cell receptor excision circles (TRECs) measured were undetectable at day of life fifteen. Mother is a thirty-one year-old G1P0 living donor renal transplant recipient. Transplantation occurred three years prior to pregnancy. Maternal immunosuppression during pregnancy included azathioprine, cyclosporine (CyA) and prednisone. CyA levels were maintained between 47-121 ng/mL (goal range was 50-125 ng/mL). CyA levels were increased during the third trimester between 66-154 ng/mL. At time of delivery CyA level was 154 ng/mL. Lymphocyte subpopulations on day of life twenty-two were: ALC 660 cells/uL, CD3 T-cell count 78 cells/uL (11.9%), and normal B-cell and NK-cell counts. She had normal PHA proliferation. Infant's CyA level at day of life twenty-two was <40 ng/mL. Breast feeding was discontinued, Bactrim prophylaxis was initiated and CD3 count was >1500 by day fifty-eight of life.

**Discussion:** Lymphopenia has been observed in infants born to mothers on immunosuppression for solid organ transplant, but not reported with TREC analysis for SCID.1,2 CyA and AZA have been shown to cross the placenta and have been detected in breast milk.3,4,5 The etiology for such temporary arrest in thymic T-cell output is likely multifactorial including prematurity, stress and all three immunosuppressive drugs.

**Conclusion:** Solid organ transplant recipient mothers may deliver infants with undetectable TRECS resulting in abnormal NBS for SCID and severe T cell lymphopenia. These patients require monitoring and follow up.

## P216

### DIAGNOSIS OF SEVERE COMBINED IMMUNODEFICIENCY (SCID) IN A PATIENT WITH AUTOIMMUNITY

A. Mallapaty*[1], T. Hofmekler[1], K. Patel[2], S. Chandrakasan[1], *1. Atlanta, GA; 2. Decatur, GA.*

**Introduction:** RAG is critical in lymphocyte development and is specifically involved in VDJ rearrangement and in creating a diverse repertoire of T and B cells. Mutations in RAG classically result in SCID, but the clinical spectrum can be broad.

**Methods:** Case report Results: Our patient is a 14-year-old female with a history of neutropenia and hypothyroidism in infancy along with several non-life threatening infections. She developed extreme failure to thrive, and was diagnosed with a protein losing enteropathy at 2 years of age with presumed associated secondary hypogammaglobulinemia and lymphopenia. Shwachman Diamond syndrome was diagnosed at 4 years of age based on neutropenia, recurrent infections, presumed pancreatic insufficiency and short stature. Of note, she had only one identified mutation for this syndrome with no skeletal abnormalities. In the years following, she continued with recurrent diarrhea, multiple febrile illnesses, low grade EBV viremia, and minimal growth in weight or height. Further workup revealed that she had normal NK cells, hardly any B cells, and nearly absent CD4 and CD8 naïve cells with a predominance of memory T cells. Two different pathogenic variants of RAG1 were identified on whole exome sequencing (c.33C>T (p.R108X) & c.256_257delAA), and she was diagnosed with RAG T low B- NK+ SCID.

**Conclusions:** Phenotypic diversity can be seen with various RAG1 mutations, ranging from severe infections to autoimmunity. The severity of the phenotype has been correlated with the degree of recombination activity present and may also be influenced by external factors.

## P217

### A NOVEL MUTATION IN A PRIMARY IMMUNODEFICIENCY PATIENT REVEALING KABUKI SYNDROME

M. Mehta*, L. Kobrynski, J. Shih, *Atlanta, GA.*

**Background:** Kabuki Syndrome is a rare, congenital condition characterized by distinct facial features, intellectual disabilities, skeletal abnormalities, atypical dermatoglyphic patterns, cardiac abnormalities, and immunodeficiency. Here we report a 6-year old girl who initially presented in infancy with recurrent infections and pancytopenia who was found to have a novel, de novo mutation in the KMT2D gene.

**Case Presentation:** At 20-months of age, the patient was hospitalized for rhabdomyolysis from a viral illness. A few months later, the patient was admitted for pneumonia. She was noted to have anemia and neutropenia with a low absolute neutrophil count. Her history was remarkable for recurrent ear infections, herpangina, and skin infections. She was found to have a hypogammaglobulinemia thought to be from her acute illness. However, the patient returned shortly after discharge with persistent neutropenia for which a bone marrow aspirate was negative. She underwent an immunodeficiency work-up that was consistent with CVID (common variable immunodeficiency). She was started on IVIG infusions with improvement in immunoglobulin levels and decreased infection rates. At age 6, the patient underwent genetic testing which revealed a novel, de novo mutation (variant of unknown significance) in the KMT2D gene, which is seen in Kabuki Syndrome.

**Discussion:** This case highlights a novel, de novo mutation (VOUS) in the KMT2D gene that has not been previously reported. This mutation correlates with a unique KS phenotype of characteristic clinical abnormalities with CVID and supports the therapeutic paradigm that regular IVIG supplementation in younger ages decreases the frequency of infections.

## P218

### SEVERE COMBINED IMMUNODEFICIENCY: A CASE REPORT OF EARLY DIAGNOSIS DUE TO NEWBORN SCREENING IN TENNESSEE

S. Adams*[1], Y. Khan[2], *1. Madison, TN; 2. Nashville, TN.*

**Introduction:** Severe combined immunodeficiency (SCID) is a disorder that causes defects in the immune system. Early diagnosis of this disease is imperative to improve outcomes through early, curative treatment.

passive depictions of this common treatment. Allergy/Immunology providers and patient advocacy groups should consider increasing engagement on social media. This engagement could lead to more accurate portrayals of optimal medication use and improved health outcomes.

## P320

### A COMBINED METHOD FOR SCREENING NOVEL COMPOUNDS FOR IMMUNOMODULATORY ACTIVITY

A. Duzh[1], A. Hancharou*[1], L. DuBuske[2], *1. Minsk, Belarus; 2. Gardner, MA.*

**Introduction:** Drugs with immunomodulatory properties are widely used in Eastern Europe. Assessment of new immunomodulatory drugs is traditionally performed using freshly isolated human leukocytes or mice in animal models. This investigation assesses a new method of screening the immunomodulatory properties of novel drugs.
**Methods:** Jurkat-tat and Daudi cell lines, dendritic cells (DC), and neutrophils of blood were incubated with drugs having either microbial or synthetic origins. Expression of CD32, CD69, CD80, CD197, CD205 and HLA-DR molecules, production of reactive oxygen species (ROS) and cytokines, and cell viability and apoptosis were assessed.
**Results:** A new combined method for the screening of immunomodulatory properties of drugs was developed including: expression of CD80, HLA-DR, CD32, CD205 and CD197, interleukin-12 production and apoptosis of the DCs; production of reactive oxygen species and evaluation of phagocytosis by neutrophils; expression of CD69 and production of tumor necrosis factor-a by Jurkat-tat cells; and CD80 and HLA-DR expression, viability and apoptosis using Daudi cell line. Only immunomodulators of bacterial origin exhibited significant stimulatory effect on DC, Daudi and Jurkat-tat cells. Inosine Pranobex induced slight activation of DC. Umifenovir, Azoximer Bromide and a High Polyphenol-based compound had no effect on the functional activity of immune cells.
**Conclusion:** This study demonstrates the application of a new combined method for screening immunomodulatory activity of proposed new drugs of microbial or synthetic origin.

## P321

### EFFECT OF PROPARACAINE IN A MOUSE MODEL OF ALLERGIC RHINITIS

H. Kim*[1], Y. Chun[2], J. Yoon[1], J. Kim[3], *1. Seoul, Korea, Republic of; 2. Incheon, Korea, Republic of; 3. Uijeongbu, Korea, Republic of.*

**Introduction:** Proparacaine shows immunomodulatory properties and are able to blunt eosinophil responses to cytokines in addition to their local anesthetic or antiarrhythmic properties. In this study, we aimed to evaluate the effect following intranasal administration of proparacaine in the mouse model of allergic rhinitis.
**Methods:** BALB/c mice were sensitized with OVA and were divided into 4 groups: control group which was not sensitized (CON), allergic rhinitis group (AR), AR mice treated with ciclesonide group (Omna), AR mice treated with proparacaine group (PPC). To evaluate the effect of treatment, several parameters for allergic inflammation were compared between AR group and PPC group.
**Results:** Intranasal administration of proparacaine significantly reduced sneezing compared with AR group. Histologically, proparacaine treated group showed a significantly lower degree of eosinophil, goblet cell and mast cell infiltration in the nasal mucosa when compared with AR group.
**Conclusion:** Intranasal administration of proparacaine was effective in alleviating allergic inflammation in a mouse model of allergic rhinitis. This treatment can be considered as a new therapeutic method and agent.

## P322

### STUDY DESIGN CONSIDERATIONS TO IMPROVE PATIENT SELECTION IN CAPT STUDIES

A. Salapatek*, H. Lorentz, N. Tenorio, V. Nelson, T. Sadoway, P. Patel, *Mississauga, ON, Canada.*

**Introduction:** To determine the impact of various screening criteria on moderate to severe allergic conjunctivitis using the Conjunctival Allergen Provocation Test (CAPT) model.
**Methods:** Following informed consent, 169 subjects with an allergy history and positive SPT to grass, ragweed, or tree pollen were screened to participate in a CAPT screening study. The CAPT screening process comprised of 2-3 clinic visits: a dose finding titrating visit (tCAPT), confirmatory visit (cCAPT), and re-confirmatory visit (rCAPT), if required. CAPT responders were required to reach appropriate ocular itching (OI) and ocular redness (OR) scores. Subjects with a baseline OI score $>0$ or OR $>1$ at each initial visit were rescheduled.
**Results:** Between all visits, 14 subjects were excluded due to elevated baseline scores (86% due to elevated baseline OR), 14 subjects failed the CAPT procedure (64% due to not reaching required OR scores), and 22 subjects required the extra rCAPT visit. Between all CAPT visits, there were 73 rescheduled visits due to elevated baseline scores, with 36%, 50% and 12% of visits rescheduled due to elevated OI, OR, or both, respectively. Ragweed and grass allergic subjects responded to the complete range of all seven allergen concentrations, whereas tree allergic subjects only responded to four specific concentrations.
**Conclusion:** Controlling for ocular signs and symptoms at baseline, incorporating a rCAPT visit, and testing several allergens at various concentrations are study design elements required to ensure that the correct subject population is enrolled in a trial, and to help reduce the variability in the allergic conjunctivitis CAPT model.

## P323

### THE CORRELATION OF CHOLESTEROL LOWERING STATINS DRUGS AND WORSENING OF ALLERGIC RHINITIS IN ATOPIC PATIENTS

S. Nsouli*, *Danville, CA.*

**Introduction:** Studies have suggested that statin drugs, which are 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors, are the most effective for the lowering of cholesterol. In addition to their lipid lowering actions, statins influence allergic inflammation by immunomodulatory activities including down regulation of the T helper1 (Th1) phenotype response and up regulation of the T helper2 (Th2) allergic phenotype response. Previously we have shown that Statins treatment may worsen asthma control in mild persistent asthmatics. Clinical observations led us to believe about the worsening effects of statins in Th2 on allergic diseases such as allergic rhinitis.
**Methods:** Two groups of 40 allergic rhinitis patients were compared from baseline values. Forty patients with allergic rhinitis (group A) were prescribed statins for their lowering of their cholesterol necessity, and 40 allergic rhinitis patients (group B) were controls who did not receive statins. Written consent was obtained. The endpoints of the trial designed to compare Group A and group B included: rhinomanometry, nasal symptom score (composite score of nasal congestion, rhinorrhea, sneezing, post nasal drip and itching) and flexible fiberoptic rhinopharyngolaryngoscopy examination from baseline values.
**Results:** Mean efficacy measurements of the endpoints at the end of the 12-week trial revealed a significant worsening in all parameters examined in the statins treated allergic rhinitis patients group (A) to almost no changes in all parameters in allergic rhinitis patients group (B) none statins treated.
**Conclusion:** The results of the present study suggest that treatment with cholesterol lowering statin drugs may worsen allergy symptoms in allergic rhinitis patients.