

standard deviation of Rotarod Sampler was 124.2 and 40, and 23.4 and 10.6 for the prototype. The correlation coefficient was 0.61, signifying moderate positive association between pollen counts obtained from the Rotarod Sampler and prototype.

Conclusion: Though our prototype has a larger surface area, it collected significantly less pollen than the Rotarod Sampler. A moderate correlation between the two devices was observed, though increases in the RPM of the prototype should be considered for future evaluation.

Total Pollen Collected Each Day from Rotarod Sampler Rods and Prototype Slides

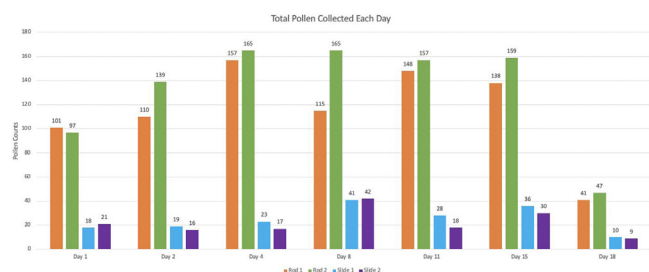


Figure Total pollen counted for each day between the Rotarod Sampler, using two I-rods, and our prototype, using two glass slides.

P034

BAYESIAN NETWORK ANALYSIS INDICATES A HIGH PROBABILITY OF SIMULTANEOUS SENSITIZATION TO MAJOR GRASS ALLERGENS

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Introduction: Grass pollen allergy impacts many patients characterized by high allergen cross-reactivity. The primary elicitor of grass allergy is Phl p 1. However, IgE to Phl p 5 or Phl p 2 also serve as markers of true grass pollen sensitization. Understanding the patterns of sensitization to grasses in certain population remains important for accurate prevention and treatment of allergy to Poaceae pollen.

Methods: Data obtained by multiplex allergy testing Alex² was collected from 20,333 patients. Bayesian Network analysis was used to build probabilistic patterns of patient sensitization to major grass pollen allergens.

Results: Grass pollen sensitive individuals constituted 6170 patients or 30.34 % of the entire database; 3935 (19.35 %) were sensitive to Phl p 1; 3460 (17.02 %) – to Lol p 1; 2842 (13.98 %) – to Cyn d 1; and 1772 (8.71 %) – to Phl p 2. Bayesian Network analysis indicated that sensitization to Phl p 1 was associated with sensitivity to Cyn d 1, Lol p 1, Phl p 2 and Sec c_pollen with 94.70 % probability. Sensitization to Lol p 1 was connected with sensitivity to Cyn d 1, Pas n extract, Phl p 2, Phl p 5 with 91.96 % probability. Cyn d 1 sensitization could be seen together with Cyn d, Sec c_pollen, Phr c extracts and Phl p 6 sensitization in 86.58 % of cases.

Conclusion: Bayesian Network analysis suggests that group I allergens are highly cross-reactive and can be a good target for AIT in the Ukrainian population sensitive to grass pollen.

P035

HOURLY VARIATION OF POLLEN COUNTS

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Introduction: Patients with pollen allergies need to be aware about the time of day when they are exposed to the higher pollen levels.

Methods: we first evaluated the accuracy of the pollen measurements of an automated real-time pollen imaging sensor (APS-300) to that of the Rotorod sampler with manual counting at the Atlanta

Allergy and Asthma Clinic (AAAC) located ~30 km northwest of downtown Atlanta (i.e. the Marietta site). We then investigated the diurnal variability of pollen levels at all three of our study sites (Marietta, Emory ~ 7 km northeast of downtown Atlanta, and SouthFace at downtown Atlanta) from 24 March to 31 March 2021, which measured the highest pollen levels during our study period. We also averaged the hourly pollen concentrations during this week to reduce day-to-day fluctuations due to weather conditions.

Results: Analysis of data collection knows that real-time pollen monitoring measured lower pollen levels between 4 am to noon and then a gradual increase with the peak pollen counts at approximately 2 PM to 9 pm.

Conclusions: Hourly pollen counts are difficult to measure but the automated real-time imaging sensor enables accurate hourly counts. Clinical implication is that patients with pollen allergy should plan their outdoor activities in the morning when the pollen counts are lowest.

Real-Time Pollen Monitoring

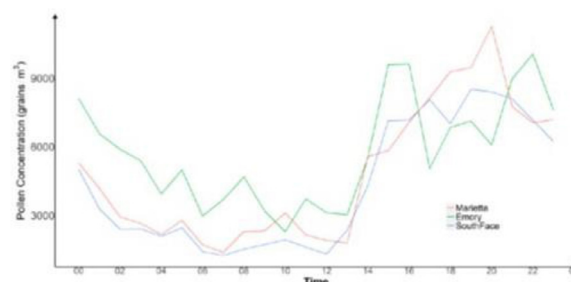


Figure Real-Time Pollen Monitoring of three devices over 24 hours on March 24, 2021.

Allergy Diagnostics and Immunotherapy

P040

HYMENOPTERA VENOM SKIN TESTING: ADOPTING AN ACCELERATED TEST METHOD

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Introduction: The standard method of hymenoptera venom intradermal skin testing (IDST) is performed at a starting concentration of 0.001 to 0.01 µg/ml and increased every 10-fold until positive or maximum concentration of 1 µg/ml. Accelerated methods such as a 1-step method utilizing only the 1 µg/ml have been reported as safe, however many institutions have not adopted this approach. Our objective is to determine and compare the outcomes and safety of standard and accelerated venom IDST.

Methods: This is a retrospective chart review of patients with suspected venom allergy who underwent IDST at three allergy clinics within a single health care system. Demographic data, test method (standard vs. accelerated), test results, and adverse reactions were reviewed.

Results: Data collection is ongoing. Two out of 119 patients (1.7%) who underwent standard venom IDST experienced adverse reactions while none of 24 patients who underwent accelerated venom IDST experienced adverse reaction. One patient, with a history of chronic urticaria, experienced urticaria. The other experienced anaphylaxis requiring epinephrine although had tested negative to all venom concentrations. Within the standard method, ≥80% of positive results occurred at concentrations of 0.1 or 1 µg/ml, and ≥60% of positive results occurred at 1 µg/ml for all species except wasp which was 45% and 40% at 0.1 and 1 µg/ml respectively.

Conclusion: The result of this study underscores the safety of venom allergy testing. As majority of positive results occurred at 0.1 or 1 µg/ml, adopting an accelerated approach would reduce time and cost associated with testing.

P041**DIAGNOSTIC PARAMETERS OF CAT EXTRACTS FOR SKIN PRICK TESTING AGAINST GOLD STANDARD NASAL PROVOCATION TESTING**

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Introduction: Cat allergen is a pervasive perennial allergen that evokes nasal symptoms in sensitive subjects. Diagnosis of IgE-mediated hypersensitivity is important for patient management. The objective of this study was to evaluate the diagnostic capabilities of 10,000 BAU/mL Cat Hair and Cat Pelt Allergen Extracts for Skin Prick Testing (SPT).

Methods: Thirty-two subjects were enrolled in a phase I single-center, double-blinded study. Subjects were assigned to one of three groups, Positive Responder (Low (11), High (11)) or Non-Responder (10), based on their responsiveness to Nasal Provocation Test (NPT) using Cat Pelt reference. Subjects underwent SPT using Cat Hair, Cat Pelt, and positive/negative controls. SPT diagnostic parameters were calculated relative to the NPT results (gold standard).

Results: Cat Hair used for SPT demonstrated high sensitivity, specificity, PPV and NPV of 95.45%, 80.00%, 91.30%, 88.89%, respectively. Cat Hair elicited a robust positive response, with a mean (SE) maximum wheal diameter of 7.8 (0.63) mm and erythema diameter of 18.7 (2.44) mm. Cat Pelt used for SPT also demonstrated high sensitivity, specificity, PPV and NPV of 95.45%, 70.00%, 87.50%, and 87.50%, respectively. Cat Pelt elicited a robust positive response, with a mean (SE) wheal diameter of 6.3 (0.54) mm. For Cat Hair and Cat Pelt, there was a discernible difference in wheal and erythema diameters for cat allergen positive subjects compared to cat allergen negative subjects.

Conclusions: The data show strong diagnostic performance for both Cat Hair and Cat Pelt when used for SPT. NPT using Cat Pelt was an appropriate gold standard for identifying cat allergy.

P042**OPEN-LABEL SAFETY TRIAL OF HOUSE DUST MITE SUBLINGUAL IMMUNOTHERAPY TABLET IN ADOLESCENTS WITH ALLERGIC RHINITIS/ RHINOCONJUNCTIVITIS**

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Introduction: The HDM sublingual immunotherapy (SLIT) tablet is a treatment option for allergic rhinitis with/without conjunctivitis (AR/C) approved in adults worldwide and in adolescents in some countries. The MT-18 trial was conducted specifically in adolescents per FDA request to supplement existing adolescent safety data of the HDM SLIT tablet.

Methods: MT-18 (EudraCT:2020-000446-34) was a phase 3, open-label, single-arm, multi-center, 28-day safety trial of daily HDM SLIT tablet (12 SQ-HDM dose) conducted in European adolescents (12-17 y; N=253) with HDM-associated AR/C, with or without asthma. The primary endpoint was at least 1 treatment-emergent adverse event (TEAE). Secondary endpoints were at least 1 solicited TEAE, at least 1 treatment-related adverse event (TRAE), and at least 1 serious TEAE.

Results: The percentage of adolescents reporting any TEAE was 88%, the percentage reporting any TRAE was 86%, and there were no serious TEAEs. Two subjects (1%) discontinued due to AEs. The most common TRAEs were local application site reactions. Most TRAEs were mild in severity and were typically experienced during the first 1-2 days of treatment. The most common TRAEs recurred for <10 days in MT-18. No treatment-related anaphylaxis, epinephrine administrations, severe local swellings, severe mouth or throat edema, or eosinophilic esophagitis occurred in the trial.

Conclusions: There were no new or unexpected safety findings in MT-18 compared with previous safety data. The HDM SLIT tablet was

well tolerated in European adolescents with HDM AR/C, similar to previous data in North American adolescents.

P043**ENVIRONMENTAL FACTORS INFLUENCING SYMPTOMS AND USE OF RELIEF MEDICATIONS IN SUBJECTS WITH SEASONAL ALLERGIC RHINOCONJUNCTIVITIS**

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Introduction: In Phase III Allergen Immunotherapy (AIT) trials, the underlying assumption is that there is a causal relation between symptoms and allergen burden. However, there is a more complex interplay of allergen exposure and environmental variables. We report on a study where the impact of environmental factors has prospectively been taken into account to evaluate their impact on AIT treatment effects.

Methods: An exploratory field study comparing the efficacy of a modified grass subcutaneous immunotherapy product using MCT and MPL as adjuvant system (PQ Grass) versus placebo in subjects with allergic rhinitis/rhinoconjunctivitis was performed. The combined symptom and medication score (CSMS) during the peak grass pollen season was the primary endpoint. The daily pollen exposure as well as daily ozone and humidity levels were also collected. An exploratory analysis was defined using a hierarchical linear mixed model to evaluate the influence of these environmental variables on the primary endpoint results using observed cases.

Results: A statistically significant influence of daily humidity ($p < 0.001$) in addition to the daily pollen burden on CSMS was demonstrated. When correcting the primary endpoint for these environmental factors the average CSMS improvement after PQ grass compared to placebo improved from 39.5% (based on the primary analysis model) without adjustment for environmental factors to 55.6% with adjustment ($p < 0.001$) (observed cases).

Conclusion: Environmental conditions have an influence on the severity of the CSMS and correcting for these influences by introducing these as covariates may improve the primary outcome of Phase III AIT field studies.

P044**IMMUNOMODULATORY MECHANISMS OF GRASS ALLERGEN IMMUNOTHERAPY ON DIFFERENTIAL T CELLS TRANSCRIPTOME POLARIZATION IN EXPLORATORY TRIAL**

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Introduction: A short pre-seasonal course of grass subcutaneous immunotherapy (SCIT) using MicroCrystalline Tyrosine (MCT) and Monophosphoryl Lipid A showed a significant improvement in combined symptom and medication scores (CSMS) in an exploratory field study (PQGrass309). Moreover, molecular mechanisms associated clinical benefit remain to be fully determined.

Methods: Peripheral blood mononuclear cells were obtained from participants, who underwent subcutaneous grass immunotherapy or placebo with MCT at baseline, end of treatment and end of grass pollen season (GPS). A panel of 58 genes was profiled. Ingenuity Pathway Analysis was deployed to elucidate molecular signature and functional relationships for observed gene expression.

Results: CSMS was significantly decreased (~33%) following grass SCIT compared to placebo with MCT. Transcriptome profiling showed