

**Levels of Allergy Cluster with Asthma Severity in Inner-City Children.**

Edward M. Zoratti, MD, FAAAAI, Rebecca A. Zabel, MS, Denise C. Babineau, PhD, Jacqueline A. Pongracic, MD FAAAAI, George T. O’Connor, MD, Robert A. Wood, MD FAAAAI, Gajjji K. Khurana Hershey, MD, PhD, FAAAAI, Carolyn Kercsmar, MD, Rebecca S. Gruchalla, MD, PhD, FAAAAI, Meyer Kattan, MD, Stephen J. Teach, MD, Samuel J. Arbes, Jr, Cynthia Visness, PhD, MPH, William W. Busse, MD, FAAAAI, Peter J. Jergen, MD, MPH, Alkis Togias, MD, FAAAAI, Andrew H. Liu, MD, FAAAAI, Henry W. Ford Health System, Detroit, MI, *Rho Federal Systems Division Inc., Chapel Hill, NC, *Ann and Robert H. Lurie Children’s Hospital of Chicago, Chicago, IL, *Boston University School of Medicine, Boston, MA, *Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA, *Cincinnati Children’s Hospital, Cincinnati, OH, *University of Wisconsin School of Medicine and Public Health, Madison, WI, *NIH/NIAID/NIH, Bethesda, MD, *National Jewish Health, Denver, CO, *Children’s Hospital Colorado, Aurora, CO.

**RATIONALE:** Phenotypic characterization of asthma among urban youth is lacking. Using unsupervised clustering techniques, we identified distinct asthma phenotypes in inner-city children who received one year of guideline-based asthma management.

**METHODS:** Nine sites in the NIAID-funded Inner City Asthma Consortium enrolled 717 children aged 6-17 years with mild to severe asthma. Data were collected at baseline and every 2 months for 1 year. Hierarchical cluster analysis was performed in participants completing >4 follow-up visits. Clusters were generated using 52 baseline characterization variables plus 12 longitudinal clinical variables reflecting lung function, asthma symptoms, exacerbations and controller treatment over 1 year. Univariate comparisons were used to determine distinguishing characteristics among clusters.

**RESULTS:** 616 participants were eligible for analysis (58% male, 64% Black non-Hispanic, 29% Hispanic, 7% other). Four distinct clusters were characterized by differences in indicators of asthma severity, including level of controller therapy, prednisone use, bronchial hyperresponsiveness and lung function. Laboratory and clinical indicators of airflow were increased in the phenotypes with higher asthma severity. The cluster reflecting the most severe asthma included the highest proportions of self-reported eczema (77%) and food allergy (62%), along with the highest serum total IgE levels (geometric mean 763 kU/L), number of allergic sensitizations (median 15 of 20 allergens evaluated), exhaled nitric oxide levels (geometric mean 27.4 ppb), and peripheral blood eosinophil counts (median 400/microliter).

**CONCLUSIONS:** Severe asthma phenotypes among inner-city children exhibit high levels of allergy. Treatment and environmental control of allergy may be particularly important for optimal management of asthma in this population.

**The Identification and Description of Severe Asthma Patients in a Cross-Sectional Study the Ideal Study.**

Robert Y. Suruki, Sc.D.1, Necdet Gunesy, PhD2, Ji-Yeon Shin3, Jonas Daugherty4, Linda Nelsen5, Eric Bradford, MD6, Frank C. Albers, MD, PhD7, GlaxoSmithKline, Worldwide Epidemiology, Research Triangle Park, NC, 2GlaxoSmithKline, Clinical Statistics, Stockley Park, United Kingdom, 3GlaxoSmithKline, South Korea, 4PAREXEL and Epidemiology, Research Triangle Park, NC, 5GlaxoSmithKline, King of Prussia, PA, 6GlaxoSmithKline, Respiratory R&D, Research Triangle Park, NC, 7GlaxoSmithKline, Respiratory Medical Franchise, Research Triangle Park, NC.

**RATIONALE:** Studies have shown that mepolizumab (anti-IL5), reslizumab (anti-IL5), and omalizumab (anti-IgE) are effective treatments for asthma in patients with overlapping phenotypic characteristics. The IDEAL study described the eligibility for treatment with these biologics for asthma according to label criteria or study protocols that will form the basis for approved labeling.

**METHODS:** This cross-sectional, single-visit, non-drug intervention study in 6 countries included subjects aged ≥12 years with severe asthma defined according to ATS/ERS guidelines by treatment with high-dose ICS plus additional controller(s) for ≥12 months. Assessments included a blood sample, spirometry, and symptom/burden of illness questionnaires.

**RESULTS:** 748 subjects were enrolled, of which 670 met analysis criteria (mean age 50.5 years; 62% female). After exclusion of patients currently treated with omalizumab, 502 subjects were included in this analysis. 101 (20.1% [95% Exact CI: 16.7-23.9]) were eligible for mepolizumab and 107 (21.3% [17.8-25.2]) were eligible for omalizumab by US label criteria. 28 subjects (5.6% [3.7-8.0]) were eligible for reslizumab. Among 101 mepolizumab eligible subjects, 37 (36.6% [27.3-46.8]) were also eligible for omalizumab and 18 (17.8% [10.9-26.7]) for reslizumab.

**CONCLUSIONS:** In this severe asthma population defined by high-dose ICS use plus a controller(s) not currently taking omalizumab, one-fifth are mepolizumab-eligible (i.e., uncontrolled with eosinophilic inflammation). In those mepolizumab eligible subjects, about one-third may also be eligible for omalizumab; this is equivalent to 7.4% of the severe asthma patient population not currently treated with omalizumab. These data highlight a high unmet need in this uncontrolled population that is currently underserved by existing therapies. (Supported by GSK, 201722/NCT02293265).