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Longitudinal analysis of stability of immune and physiological biomarkers of asthma

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Background: We reported two potential biomarkers for asthma severity, namely circulating $CD4^+$ $CRTh2^+$ T-cells and $CD14^{++}CD16^+$ $PAR2^+$. Chemoattractant receptor-homologous molecule expressed on Th2 cells (CRTh2) is a receptor for PGD2 and expressed by T cells, eosinophils, basophils and type 2 innate lymphoid cells (ILC2). Protease-Activated Receptor-2 (PAR-2) is a pro-inflammatory receptor activated by serine proteases and expressed on many cells, including monocytes and lung resident cells. Our next step to validate the utility of flowcytometric measures as biomarkers for asthma severity was to assess the stability of these markers in asthmatics over time.
Methods: Stability of "% of $CD4^+$ $CRTh2^+$T cells" and "% of $CD14^{++}CD16^+PAR\text{-}2^+$ monocytes" in peripheral blood was studied in asthmatics ($n = 19$) by flowcytometry. FEV_1 and asthma control questionnaire based on 7 (ACQ7) and 5-point scale (ACQ5) as physiological variables were collected. The stability of total numbers of ILC2 and eosinophils were analysed. Within person stability of laboratory values over 4 visits were calculated using the intraclass correlation (ICC) by R version 3.4.0.
Results: The mean age of asthmatics in our study was 45 years. The stability of % of $CD4^+CRTh2^+$ T-cells ($ICC = 0.20$) and % of $CD14^{++}CD16^+PAR\text{-}2^+$ ($ICC = 0.24$) was poor over four visits. Analysis of ICC suggested high stability over the four repeated values in FEV_1 ($ICC = 0.90$), ACQ5 ($ICC = 0.68$) and ACQ7 ($ICC = 0.75$). ICCs were moderate for % of eosinophils ($ICC = 0.44$) and ILC2 ($ICC = 0.45$). No correlations were observed between immune cell profiles, FEV_1, ACQ5 and ACQ7.
Conclusions: % $CD4^+CRTh2^+$ T-cells and % $CD14^{++}CD16^+$ $PAR\text{-}2^+$ cells varied substantially over the four visits in this asthmatic population. Variability did not correlate with physiological measures of asthma or questionnaire measures of asthma control. The reason for this variability is not known. This study also showed good stability of FEV_1, ACQ5 and ACQ7 and moderate stability of % of ILC2 and % of eosinophils.

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Observed reduction of healthcare utilization after Omalizumab initiation among patients with persistent asthma followed in clinical settings in Ontario, Canada

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Background: In Canada, it is estimated that asthma affects 8.5% of the total population. It is the leading cause of hospital admissions, the third leading cause of work loss, and results in 146,000 emergency room visits annually in the overall population. Omalizumab is indicated for the treatment of adults and adolescents with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled despite optimized standard therapy. Real world effectiveness data assessing the HCU in the Canadian context is limited.
Objective: This study was a retrospective, pre-post cohort, observational study. The primary objective was to evaluate the health care utilization (HCU) following Omalizumab initiation as assessed by the reduction in number of hospitalizations, emergency room (ER) visits, and oral corticosteroid (OCS) use in patients covered in Ontario. The number of night awakenings was an exploratory endpoint.
Results: 148 patients (mean age 57.6; female 62.2%) formed the study population. Omalizumab was associated with a 74.4% reduction in the number of hospitalization (pre vs post-Omalizumab's 12 month treatment period: 0.7 vs 0.2 $p < 0.001$). 89.9% of patients did not have any asthma related hospitalization. There was a reduction of 87.5% in ER visits (7.3 vs. 0.9 $p < 0.001$), 66.2% of patients did not have any emergency visit. A 74.7% reduction of the number of high dose OCS by (4.23 vs. 1.07 $p < 0.001$), 52.7% of patients did not need to take any courses of high dose OCS. The mean number of night awakenings/per week decreased from 6.1 (8.03) to 1.3 (2.79) following 12 month treatment with Omalizumab.
Conclusions: There was an observed reduction in the number of hospitalizations, ER visits, and high-dose OCS courses post-Omalizumab use in patients with severe uncontrolled asthma in a real-world setting. The results are consistent with outcomes observed in previous large real-world trials such as the experience registry.

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Comparative analysis of total ocular and total rhinoconjunctivitis symptom profiles in the Environmental Exposure Unit versus the Nasal Allergen Challenge model

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Background: The Environmental Exposure Unit (EEU) and Nasal Allergen Challenge (NAC) are both experimental models of Allergic rhinitis (AR). They mimic the inflammatory processes and symptom manifestations associated with exposure to sensitized aeroallergens. Previous studies demonstrated a unique Total Nasal Symptom Score (TNSS) profile following allergen challenge in each model. As AR individuals also experience ocular symptoms, we sought to compare the Total Ocular Symptom Score (TOSS) profiles following allergen challenge in both the EEU and NAC models.
Methods: 7 birch-allergic and 4 non-allergic individuals who participated in both an EEU study and a NAC study using birch pollen were included in the analysis. For both studies, TNSS, TOSS, and Total Rhinoconjunctivitis Symptom Scores (TRSS) were collected at baseline, 15 min (NAC only), 30 min, and hourly until 12 h post-challenge (every half hour during first 4 h for EEU). Data was analyzed using GraphPad Prism. Adjustments for multiplicity testing were not made.
Results: Peak increases in TOSS were observed at 3 h and 30 min post-challenge in the EEU and NAC respectively. However, they were only significant in the EEU ($p < 0.05$). In contrast, TRSS peaked at 3 h ($p < 0.05$) and 15 min ($p < 0.05$) post-challenge in the EEU and NAC respectively. Overall, a significantly higher mean TRSS ($p < 0.05$), but not TOSS ($p = 0.16$), was observed in the EEU compared to the NAC. When comparing TOSS profiles from both models by time point, significant differences were observed at 30 min, 1, 3, 4, 5, 7, and 9 h (all $p < 0.05$). Conversely, significant differences in TRSS profiles were observed at 30 min, 1 through 9 and 12 h (all $p < 0.05$) following allergen challenge.
Conclusions: Significant ocular symptoms in the EEU may be attributable to the prolonged pollen exposure period and contact with airborne pollen. Significant differences in TRSS within and between each model were primarily driven by differences in TNSS, not TOSS.