

The use of biomarkers in asthma clinical trials:

:A potential of EDN as a marker for eosinophilic phenotype

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Asthma is a syndrome that consists of various subgroups with different clinical characteristics, called as phenotypes. However, phenotypes are often overlap and change with time and do not have direct relationships to distinct pathogenic mechanisms, called as endotypes. Although endotypes of asthma have not been fully elucidated, the eosinophil is one of the most important pathogenic player in asthma and markers that reflect the activation status of the cell can be important endotypic biomarkers for “eosinophilic” asthma or Th2^{high} asthma.

We focused on serum EDN as an eosinophil activation marker. EDN has advantage over ECP in terms of its reproducibility in assays, performance in discrimination of asthma from allergic rhinitis and correlation with exhaled NO. We then employed serum EDN as a possible endotypic biomarker for preschool children with recurrent wheezing and compared efficacy of inhaled corticosteroid (ICS) and montelukast for a biomarker-defined subgroup, the HDM-sensitized and high serum EDN patients. On the contrary to our initial hypothesis that ICS would be the choice for the group, there was no difference in primary outcome, asthma control days, between the randomized 2 groups. Interestingly, however, serum EDN significantly decreased in montelukast treated group, not in ICS group. Although decreased EDN did not reflect clinical outcome after the short term treatment, we suspected that it may have a link to a long term outcome such as remodeling.