European Respiratory Society
Annual Congress 2012

Abstract Number: 189

Publication Number: 3281

Abstract Group: 7.2. Paediatric Asthma and Allergy

Keyword 1: Asthma - management **Keyword 2:** Biomarkers **Keyword 3:** Children

Title: Pulmonary immunoglobulin E levels and the response to anti-immunoglobulin E antibody therapy in paediatric severe therapy resistant asthma

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Body: Background: Omalizumab is used in children with atopic, moderate to severe persistent asthma, but predictors of response are unknown. Broncho-alveolar lavage (BAL) or endobronchial biopsy (EB) immunoglobulin E (IgE) has not been reported. It has been proposed that pulmonary IgE levels may predict response to therapy. Hypothesis: there is no relationship between serum and pulmonary IgE; and pulmonary IgE levels predict response to omalizumab. Methods: We measured IgE levels in serum, induced sputum (IS), BAL and EB in 70 children (6-16 yr) with severe asthma. 15 underwent an omalizumab trial. IgE expression was determined in EB by immunohistochemistry and levels in IS and BAL were quantified using ELISA. Haematoxylin and eosin stained EB were used to quantify airway remodelling and eosinophilic inflammation was quantified using the congo red stain. Results: 54 subjects had at least one evaluable biopsy. There was no relationship between total serum IgE and EB IgE+ cells, Spearman r=0.4739. Non-responders had higher serum IgE (failed trial: median 1582 IU/ml, range [1324 - 11355] vs. successful trial: 386 IU/ml, range [105-2438], $p<0.05$). EB IgE+ cells did not predict omalizumab response. There was no association between EB IgE expression and airway remodelling or eosinophilic inflammation. Conclusions: There was no relationship between serum and pulmonary IgE. Very high serum IgE levels predicted a failed response to omalizumab, but EB IgE expression was not useful in predicting a response. There was no relationship between airway remodeling, eosinophilic inflammation and EB IgE+ cells.
Funding: Asthma UK.