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Title: Airway hyperresponsiveness to mannitol as a predictor of treatment response to ciclesonide in patients with suspected asthma: A double-blind, randomised, placebo-controlled trial

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Body: Background: Inhaled corticosteroids (ICS) are the basic treatment in patients with asthma. The aim of the study was to find predictors which detect subjects who clinically benefit from ICS using a combined endpoint (improvement in either FEV1 [$>12\%$ and $>200\text{ml}$], Juniper asthma control questionnaire [ACQ] >0.5 or asthma quality of life questionnaire [AQLQ] >0.5). Methods: 70 treatment-naïve subjects (mean age 40.3 years (range 18-70); 21 male) with suspected asthma were randomised to inhale ciclesonide (320mcg/day, n= 34) or placebo (n= 36) in a double-blind manner for 1 month. Spirometry, airway hyperresponsiveness (AHR) to mannitol and to methacholine, exhaled nitric oxide, ACQ and AQLQ were assessed before and after treatment. Results: An improvement in the combined endpoint was seen in 16 subjects (47%) in the ciclesonide group (1 FEV1, 9 ACQ, 14 AQLQ) and in 15 subjects (42%) in the placebo group (2 FEV1, 5 ACQ, 13 AQLQ). AHR to mannitol was found in 8/16 responders and only 3/18 non-responders in the ciclesonide group (sensitivity 50%, specificity 83%, PPV 72%, NPV 65%, $p=0.038$). Using a logistic regression analysis, AHR to mannitol was the only significant predictor of a response to ciclesonide with an odds ratio of 5.0 (95%CI 1.03-24.28, $p=0.046$). Conclusions: In subjects with suspected asthma, AHR to mannitol is a predictor of subsequent response to ICS treatment.