Identifying Predictors of Response to Suplatast Tosilate among Patients with Moderate to Severe Bronchial Asthma Receiving Inhaled Steroid Therapy

Background: The aim of this study was to identify the predictive factors, among laboratory test data and patient background variables, of an efficient response to the anti-allergic agent suplatast tosilate in patients with moderate to severe bronchial asthma.

Methods: The subjects were 44 patients with moderate to severe bronchial asthma on inhaled steroid therapy who were enrolled in a phase II clinical trial of suplatast (300 and 600 mg/day). Improvements in respiratory function parameters and symptom scores during the first 4 weeks of administration of suplatast were assessed to evaluate the response to the drug. Logistic regression analysis was used to relate the response to the independent variables. Secondly, to test whether these results were applicable to clinical practice, we examined the data from a phase III clinical trial of suplatast.

Results: Twenty-two patients were assessed as responders according to our criteria. The percentage of blood eosinophil (%EOS, P = 0.015) and basophil (%BASO, P = 0.019) counts were identified as significant variables to predict responders. When cut-off levels for %EOS and %BASO were set at 7.5 and 1.2, respectively, the sensitivity for prediction of responders with lower %EOS and %BASO was 81.8% (18/22). Furthermore, when we applied the same cut-off levels to subjects of a phase III clinical trial of suplatast, the sensitivity of prediction was found to be as high as 75.0% (6/8).

Conclusions: These results indicate that %EOS and %BASO are good candidates to predict the response to suplatast among patients with moderate to severe bronchial asthma on inhaled steroid therapy. These predictors may contribute, in combination with genomic information, to stratified medical treatment tailored to the individual needs of patients.

存档文本