

## **A comparison between two different in vitro basophil activation tests for gluten and cow 's milk protein sensitivity in irritable bowel syndrome-like patients**

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**Introduction:** The diagnosis of food hypersensitivity (FH) in adult patients with gastrointestinal symptoms, beyond the immediate IgE-mediated clinical manifestations, is very often difficult. The aims of our study were to: 1) evaluate the frequency of FH in patients with irritable bowel syndrome (IBS)-like clinical presentation; and 2) compare the diagnostic accuracy of two different methods of in vitro basophil activation test (BAT).

**Materials and Methods:** Three hundred and five patients, (235 females, age range 18-66 years) were included and underwent a diagnostic elimination diet and successive double-blind placebo-controlled (DBPC) challenges. Two different methods of in vitro BAT (CD63 expression after in vitro wheat or cow's milk protein stimulation) were evaluated: one was performed on separated leukocytes, and the other on whole blood.

**Results:** Ninety patients of the 305 studied (29.5%) were positive to the challenges and were diagnosed as suffering from FH. BAT on separate leukocytes showed a sensitivity of 86% and a specificity of 91% in FH diagnosis. BAT on whole blood showed a sensitivity of 15%-20% and a specificity of 73% in FH diagnosis ( $p < 0.0001$  compared to the other method).

**Conclusions:** About one third of the IBS patients included in the study were suffering from FH and were cured on the elimination diet. The BAT based on CD63 detection on whole blood samples did not work in FH diagnosis and showed a significantly lower sensitivity, specificity and diagnostic accuracy than the assay based on separated leukocytes.