

## NON-CELIAC WHEAT SENSITIVITY DIAGNOSED BY DOUBLE-BLIND PLACEBO-CONTROLLED CHALLENGE: EXPLORING A NEW CLINICAL ENTITY

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### ABSTRACT

**Background and Aims:** Non-celiac wheat sensitivity (WS) is considered a new clinical entity. An increasing percentage of the general population avoids gluten ingestion. However, the real existence of this entity is debated and markers for this condition are lacking. We aimed to demonstrate the existence of WS and define its clinical, serologic and histological markers.

**Methods:** We reviewed the clinical charts of all subjects who had been diagnosed with wheat sensitivity (WS) using a double-blind placebo-controlled challenge (DBPCC) from 2001-2010. One hundred CD patients served as controls.

**Results:** Four hundred and seven patients with WS were included, as diagnosed by DBPCC. Two groups showing distinct clinical characteristics were identified: wheat sensitivity alone (Group 1) and wheat sensitivity associated with multiple food hypersensitivity (Group 2). Group 1 WS was characterized by clinical features very similar to those found in CD patients: all subjects showed the HLA DQ2 and/or DQ8 haplotypes, EmA assay in the culture medium of the intestinal biopsies was positive in 27% and duodenal lymphocytosis was seen in 94% of cases. Group 2 WS was characterized by a high frequency of IBS, the presence of HLA DQ2 or DQ8 haplotype in 50% of cases, a high frequency of positive serum anti-gliadin IgG (60%) and basophil *in vitro* activation with wheat antigen stimulation (80%), as well as eosinophil infiltration of the duodenal (47%) and colon (67%) mucosa.

**Conclusions:** Our data confirm the existence of not-celiac WS as a distinct clinical condition. We also suggest the existence of two distinct populations of subjects with WS: one with characteristics more similar to CD and the other with characteristics pointing to food allergy.