



A NEW CLINICAL TEST REVEALED THAT THE FREQUENCY OF COMPLIANCE OF THE GLUTEN FREE DIET IS HIGHLY DEPENDENT ON THE AGE AND SEX OF THE CELIAC PATIENTS

- *A study involving 13 clinical centers coordinated by the University of Seville have tested a new technology for detection of ingested gluten developed by a Spanish Biotech company, Biomedal*
- *The direct detection of gluten in human feces revealed that at least 40% of celiac patients fail to fulfill the gluten free diet*

A research group of the University of Seville and Biomedal, a Spanish biotechnology company located in Seville, Spain, have studied the level of compliance of the Gluten Free Diet (GFD) among celiac patients. The results of this first clinical trial showed the high frequency of failure of the current methods to determine the adherence to a GFD: more than 40% of celiac patients fail to adhere to this diet, at least once every 2-4 days.

The research, published by the *American Journal of Gastroenterology*, has been carried out by 13 Spanish health centers with 188 celiac patients and 84 control volunteers. The Spanish researcher team concluded that the traditional methods used to control gluten ingestion by celiac patients are hardly reliable. This way, researchers demonstrated that 75 % of patients with negative blood results had indeed ingested gluten.

The fulfillment rates of the GFD are higher in men (60%) than in women (31%). The younger the patient is, the higher are the levels of compliance of the GFD: only 12% of preschoolers fail to adhere to this diet, which is not surprising because the food they ingested is under parent control.

Problems with the traditional methods of detection and control of the GFD

Nowadays, the most frequent method to detect and monitor the GFD in celiac patients is through blood tests, that measure the presence of antibodies, and dietetic questionnaires. These methods are neither sensitive nor specific enough. They showed many “false negatives”: results point out that the person has not eaten gluten but in fact, the ingestion has occurred. So far, the biopsy is the only reliable method to study successful GFD adherence. The problem of biopsies is, besides that it is an invasive and unpleasant technique for patients, they have a very high cost for the national health system all over the world.

New technique iVYLISA GIP Stool

Biomedal's CEO has explained in BioSpain the advantages of this new technology that offers a useful tool to identify the origin of either the clinical symptoms or the lack of recovery of celiac patients. iVYLISA GIP Stool, developed by Biomedal's iVYDAL In Vitro Diagnostics division. According to Dr. Cebolla, "the iVYLISA GIP Stool test allows direct detection of gluten traces in stool samples in the last 2-7 days. This new test will reduce consistently the number of biopsies, which is an advantage for the patient and also for any national health system or private insurances".

Biomedal Diagnostics' iVYDAL division has three lines of products for the detection of gluten intake through urine and stool samples. Both iVYLISA GIP Stool and iVYCHECK GIP Stool are laboratory tests. Biomedal is developing a self-monitoring test for home use.

Celiac Disease (CD) context

Research indicates that the frequency of the CD in America, North Africa, the Middle East and India is the same as in Europe: around 1%. According to the study, 90% of celiac patients suffer similar symptoms to gluten intake every week. If the origin of the symptoms is not clear, the patients might experience many frustrating and expensive tests. Also, it is known that 45% of gluten intolerants do not get over the intestinal damage caused by the CD before at least one year following the GFD, probably due to the unfulfillments of this diet. Celiac patients have more risk of fractures, lymphoma and other autoimmune diseases if they do not follow a correct GFD.

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