#45 - THE EFFECTIVENESS OF A QUALITATIVE LATERAL FLOW IMMUNOASSAY TOOL FOR DETECTING STOOL GLUTEN IMMUNOGENIC PEPTIDES IN THE REAL LIFE OF CELIAC DISEASE PATIENTS.

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Background: Detection of Gluten Immunogenic Peptides (GIP) in stool is a reliable, sensitive, and specific method for exploring gluten exposure and monitoring gluten-free (GFD) diet compliance in celiac disease (CeD) patients.

AIM: To assess the statistical performance of a stool lateral flow immunoassay (LFIA) test compared with the quantitative determination of stool GIP by ELISA, as the gold standard, in a series of samples from treated CeD patients.

Methods: 53 patients collected stool samples over four consecutive weeks. To measure stool GIP excretion (µg/g of stool) a sandwich ELISA kit (iVYLISA GIP S®, Biomedal SL) was used and positive tests were categorized as ≥0.156 µg/g (lowest limit of detection), ≥0.32, and ≥0.64. For the qualitative evaluation of stool GIP, we employed an LFIA test (GlutenDetect®; Biomedal S.L).

Results: A total of 299 stool samples were collected during the study period. The ELISA test for stool GIP was >0.156 µg/g in 40.6%, ≥0.32 in 39.1%, and ≥0.64 in 23.4% of samples. (Table 1) The sensitivity of LFIA for detecting positive samples at the three different cut-offs varied from 43.9 to 53.3%. In contrast, specificities were high (varied from 83.7% to 88.8%). Agreement between the ELISA and LFIA tests varied from 70.9% and 76.7%. Finally, Cohen's kappa statistics evidenced a weak concordance between tests.

Conclusion: Our study found that the LFIA test has a lower sensitivity but adequate specificity and a good concordance when compared to the quantitative ELISA. Among other potential factors, the different combination of monoclonal antibodies employed between the immune methods and different extraction procedures for stool samples seems to be relevant. Furthermore, the higher detection limit and the requirement of higher levels of gluten exposure for a positive LFIA test seem to be factors contributing to its low sensitivity.