PERFORMANCE OF THREE NEW CHEMILUMINESCENT ASSAYS FOR CELIAC DISEASE IN PEDIATRIC PATIENTS SHOWING DIFFICULT CLINICAL AND SEROLOGIC PRESENTATION

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Introduction

The tissue transglutaminase antibody (tTG-IgA) immunoassay is the universally recommended screening test for CD. In IgA deficiency cases, testing with tTG-IgG is recommended. Because of the inferior accuracy of the antigliadin assay, this test is refused. The use of deamidated gliadin peptides (DPG) to improve specificity awaits confirmation by large-scale validation. The clinical of CD is very unspecific, from asymptomatic to classical symptoms. Small bowel biopsy is the confirmatory cornerstone test. Clinical suspicion and/or positive serological test are necessary to recommend intestinal study. The histological (serological and/or clinical) response to gluten free diet (GFD) confirms CD diagnosis.

Objetive

Determine if the new serological tests can aid in the diagnosis of CD in paediatric patients with difficult clinical and serologic presentation.

Material and methods

Samples were chosen from four groups of patients:

1 – Specificity: 29 supposed non-CD paediatric patients from 1 to 2 years old with digestive symptoms but negative serological markers.

2 – Sensitivity: 27 asymptomatic CD patients (Marsh III) detected by positive serological markers obtained in an at risk population.

3 – Border zone: 27 CD patients on GFD with low levels of serological markers.

4 – And finally, 3 CD patients (Marsh III) displaying classical CD symptoms in spite of negative serological markers.

All serum samples were tested on 3 new automated chemiluminiscent immuno-assays in the BIO-FLASH™ Analyzer for: IgA anti-tTG antibodies, IgG anti-tTG antibodies and IgA/IgG anti-DPG antibodies (DGP-screen).

(Samples were previously analyzed by the established IgA anti-tTG EIA ImmunoCAP250 from PHADIA)

Results

1 - Specificity: all 29 supposed non-CD paediatric patients were negative for both IgA anti-tTG and IgG anti-tTG antibodies, while one patient was positive on the DGP-screen on the BIO-FLASH™.

2 - Sensitivity: all 27 asymptomatic CD patients were positive on the IgA anti-tTG, 12/27 on the IgG anti-tTG and 25/27 on the DGP-screen.

3 - Border zone: 10 of 27 CD patients on GFD were low positive on IgA anti-tTG, all were negative on the IgG anti-tTG and 5/27 were low positive on the DGP-screen.

4 - All 3 clinical CD patients diagnosed in spite of their negative serological markers were also negative in the new IgA anti-tTG and IgG anti-tTG assays. One of them (1/3) was positive on the DGP-screen.

We highlight the extended linearity of IgA anti-tTG on the chemiluminescent BIO-FLASH™assay that allows quantitation of a wide concentrations range.

Figure 1 and 2 illustrate the good correlation between the new IgA anti-tTG run on the BIO-FLASH™ and the established IgA anti-tTG EIA run on the ImmunoCAP250 PHADIA in all patients (Figure 1) and only in border zone (Figure 2). Positive value of BIO-FLASH™ ≥ 20 U/ml. Positive value of PHADIA ≥ 3.8 U/ml.

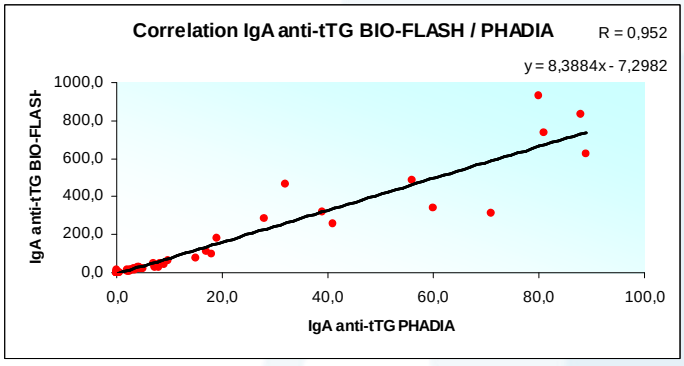

Figure 1. **Correlation IgA anti-tTG BIO-FLASH™ and PHADIA.** These results include non-CD patients, asymptomatic CD patients and CD patients on GFD.

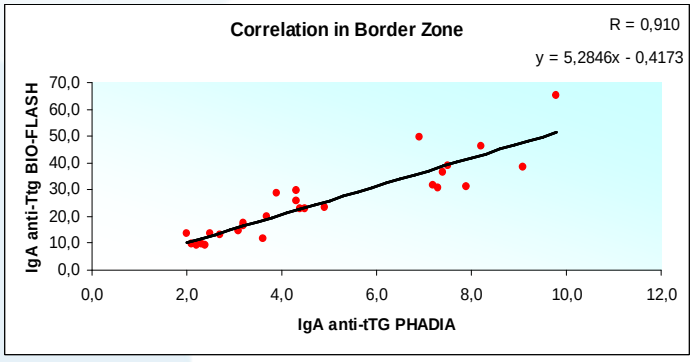

Figure 2. **Correlation of IgA anti-tTG BIO-FLASH™ and PHADIA in border zone.** The border zone includes 27 CD patients on a gluten free diet.

Conclusions

1. Both the new IgA anti-tTG and DGP-screen chemiluminescent immuno-assay methods run on the automated BIO-FLASH™ Analyzer are useful to detect antibodies in CD patients.

2.The IgA anti-tTG on the BIO-FLASH™ is equal to the results from the IgA anti-tTG on the EIA ImmunoCAP250 PHADIA.

3. The IgA anti-tTG on the BIO-FLASH™ is more efficient than the DGP-screen on the BIO-FLASH™ to detect asymptomatic CD patients in at risk populations because it detects 27 of 27 patients, while the DGP-screen finds 25 of 27 patients.

4. In CD patients on GFD treatment, the DGP-screen yields less positive results than IgA anti-tTG, suggesting that the anti-DGP antibodies disappeared more quickly than IgA anti-tTG in GFD patients of our series.

5. In our criteria, IgG anti-tTG analysis is only recommended in IgA deficient patients.

6. The DGP-screen result was positive in 1 of 3 diagnosed CD patients who were negative for the conventional IgA anti-tTG autoantibodies