Publication of the Month

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Parizade M, Bujanover Y, Weiss B, Nachmias V, Shainberg B

Performance of Serology Assays for Diagnosing Celiac Disease in a Clinical Setting

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Introduction: The prevalence of celiac disease (CD) is very high with approximately 1% in Europe and the USA. According to the current iceberg concept, the majority of affected individuals are still undiagnosed. Serological tests for celiac disease are sensitive and specific and are becoming the obligatory tool for correctly referring patients for biopsies. Anti-tissue transglutaminase IgA antibodies are widely accepted as the best assays to perform a reliable screening for celiac disease. Antibodies to deamidated gliadin peptides (DGP) were shown to be of higher diagnostic value than the well known gliadin antibodies.

Aim of the study: Parizade et al examined a group of children presenting with symptoms giving rise to a clinical suspicion for developing CD. The authors examined the diagnostic value of several serological kits, calculated the correlations between antibody titer and severity of mucosal damage, and assessed the possibility that high antibody titers have a predictive value for the level of mucosal damage.

Materials and Methods: 5 serology tests were performed with samples of 116 children at the age of 1 to 17 years: tTG-IgA Celikey (Phadia), tTG-IgA Immulite 2000 (Siemens), tTG-IgG Celikey (Phadia), DGP (IgG + IgA) Screen Quantalite (Inova), and EMA with dual anti-IgG/anti-IgA conjugate (Immco). All children underwent small bowel biopsies. 31 were biopsy-negative and 85 were positive.

Results:

	EMA	tTG-IgA Celikey	tTG IgA Immulite 2000	Inova DGP IgA + IgG screen	tTG-IgG Celikey
Sensitivity	95.3	94.1	92.9	95.3	67.7
Specificity	74.2	87.1	74.2	64.5	93.5
PPV	91.0	95.2	90.8	83.3	96.5
NPV	85.2	84.4	79.3	88.0	49.2
Test efficiency	89.6	91.4	87.9	87.0	72.4
Test efficiency 2*	92.2	92.2	89.7	87.9	81.9

*Table: Statistical performance of serology assays using cutoff values recommended by the manufacturers. *Test efficiency 2 is calculated with cutoff determined by logic regression analysis.*

Conclusion: Biopsy-proven CD is found in a large proportion of children with a wide range of classical and atypical symptoms. The five serological assays varied in their performance levels and appeared to exhibit lower specificities in the clinical setting than those previously reported. The tTG-IgA Celikey kit demonstrated the best test efficiency for the studied population.

Comment: Our own (Phadia's) experience with tTG IgA assays is that the specificity is lowest when the control group consists of children with gastrointestinal manifestations. Possibly, the antibody titer present indicates a latent or developing CD which is not yet expressed as mucosal damage. These cases are sometimes called non-celiac gluten-sensitive enteropathy and may also respond to a gluten-free diet.