

Is the rapid whole blood test useful for diagnosis and monitoring celiac disease in children?

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Est ce que le test rapide sur sang total est utile pour le diagnostic et la surveillance de la maladie coeliaque chez l'enfant?

Is the rapid whole blood test useful for diagnosis and monitoring celiac disease in children?

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R É S U M É

But : Evaluer un nouveau test rapide pour la détection des IgA anti-transglutaminase (ATG) pour le diagnostic et le suivi de la maladie coeliaque.

Méthodes : Nous avons recruté 57 enfants parmi lesquels, 20 étaient des patients cœliaques sous régime sans gluten et 37 étaient adressés pour suspicion de la maladie coeliaque. Les IgA ATG été détectés par le test ELISA conventionnel et par le nouveau test rapide.

Résultats : La concordance entre les 2 tests était de 96,4%. Tous les patients positifs avec le test ELISA, l'étaient aussi avec le test rapide. Seuls 2 patients étaient faiblement positifs par le test rapide et négatifs par ELISA.

Conclusion : Le test rapide semble aussi performant que le test ELISA pour la détection des IgA ATG.

S U M M A R Y

Aim: To evaluate a new whole blood rapid test for the detection of IgA anti-transglutaminase (ATG) for diagnosis and diet survey of celiac disease (CD).

Methods: 57 children, 20 of them were CD patients on a gluten-free diet and 37 were under suspicion of CD were enrolled. IgA ATG was detected by the conventional ELISA test and the new rapid whole blood test.

Results: Concordance between the 2 tests was 96.4%. All patients positive with ELISA were also positive by the rapid test. Only 2 patients were slightly positive by the rapid test and negative by ELISA.

Conclusion: Whole blood rapid test seems to be as performant as ELISA test for IgA ATG detection.

M o t s - c l é s

Maladie coeliaque, transglutaminase tissulaire, test rapide

Key - words

Celiac disease, tissue transglutaminase, whole blood, rapid test

In celiac disease (CD), endomysial and transglutaminase antibodies are directed against the human auto-antigen: transglutaminase (1). The conventional CD antibody tests require patient's sera and are laborious and time-consuming. Recently, a new rapid test was performed for the detection of IgA anti-tissue transglutaminase antibodies (ATG) (2).

The aim of this study was to evaluate this new test and its usefulness for diagnosis and diet survey of CD children.

PATIENTS AND METHODS

We enrolled 57 subjects (27 boys and 30 girls, aged from 6 months to 16 years) attending La Rabta hospital immunology department for the detection of CD antibodies. Twenty of them were diagnosed according to the ESPGHAN criteria (confirmed by small-intestinal mucosal biopsy with villous atrophy) and were on a gluten-free diet. Thirty seven children were suspected to be suffering from CD and enrolled before histological confirmation.

For all children, IgA ATG was detected by 2 methods: the conventional ELISA test (The Binding site®, UK) using purified human red cells tissue transglutaminase and the new rapid whole blood test (Biocard™ Celiac Test, AniBiotech®, Finland) using self transglutaminase. The two tests were performed with an interval time under 4 days.

RESULTS

Fourteen patients were positive and 41 negative by both tests thus concordance between the 2 tests was 96.4%. If we consider ELISA as a reference test, the rapid test showed 100% sensitivity, 96.4% specificity, 100% negative predictive value and 86.6% positive predictive value. Only 2 patients were slightly positive by the rapid test and negative by ELISA. These 2 patients were confirmed CD and on gluten-free diet (for more than 2 years). One of them had IgA deficiency with positive IgG anti-endomysium antibodies.

DISCUSSION

Few studies have evaluated this new whole blood rapid test, but all of them showed an excellent concordance with ELISA test and high sensitivity (65-97%) and specificity (79-98%) for the detection of ATG in CD diagnosis (3-7) (table 1).

Références

- 1- Dieterich W, Ehnis T, Bauer M, et al. Identification of tissue transglutaminase as the autoantigen of celiac disease. *Nat Med* 1997; 3:797-801.
- 2- Maki M, Korponay-Szabo IR. Methods and means for detecting gluten-induced disease. Patent application PCT/FI02/00340, international publication number W002/086509 A19.
- 3- Korponay-Szabo IR, Raivio T, et al. Celiac disease case finding and diet monitoring by point of care testing. *Aliment Pharmacol Ther* 2005; 22:729-37.
- 4- Raivio T, Kaukinen K, Nemes E, et al. Self transglutaminase-based rapid celiac disease antibody detection by a lateral flow method.

Tableau 1 : Comparison between the whole blood rapid test and ELISA for the detection of ATG in the literature

| | Population | Sensitivity | Specificity | Concordance |
|----------------------------|--------------------|-------------|-------------|-------------|
| T Raivio et al (4) | 378 (0.9-72 years) | 94.1% | 97.5% | 96% |
| G Nemec et al (5) | 151 (1-43 years) | 95.8% | 97.9% | 94.7% |
| T Raivio et al (6) | 45 adults | 95.6% | 78.9% | 83% |
| I Korponay-Szabo et al (7) | 2690 children | 65.1% | 100% | 99.4% |
| Our study | 57 children | 100% | 95.3% | 96.4% |

The usefulness of this test was assessed in diet survey by the first study using this test (254 CD patients) (3) and then by a prospective study (15 CD patients) (4). In these studies the authors reported a high concordance between this rapid test and conventional tests (94% and 86% respectively).

This test showed comparable sensitivity to detect untreated CD as the currently widely employed conventional ELISA. It's easier to perform since there is no need for purified or recombinant transglutaminase or for serum separation and the test result is easy to interpret visually. In addition, the relative simplicity of this test makes it more suitable for mass screening studies.

Nevertheless, this test remains expensive (15 Tunisian Dinars ~10 US Dollars) and may give some false results. It's also inappropriate in the case of CD associated with IgA deficiency. This limit has been recently corrected in the second generation of the test that can detect this deficiency.

CONCLUSION

Whole blood rapid test seems to be as preferment as ELISA test for IgA ATG detection. This test could be useful for CD diagnosis since it's easy and fast. Nevertheless its suitability for diet survey should be assessed in prospective studies on larger cohorts.

Alim Pharmacol Ther 2006; 24: 147-54.

- 5- Nemec G, Ventura A, Stefano M, et al. Looking for celiac disease: diagnostic accuracy of two rapid commercial assays. *Am J Gastroenterol* 2006; 101:1597-600.
- 6- Raivio T, Korponay-Szabo I, Collin P, et al. Performance of a new rapid whole blood celiac test in adult patients with low prevalence of endomysial antibodies. *Dig Liv Dis* 2007; 39:1057-63.
- 7- Korponay-Szabo IR, Szabados K, Pusztai J, et al. Population screening for celiac disease in primary care by district nurses using a rapid antibody test: diagnostic accuracy and feasibility study. *BMJ* 2007; 335:1244-7.