

Self-administered Celiac Disease Testing: A Practical Approach in High Risk Individuals

Toufic A. Kabbani¹, Tarika S. Chowdhary¹, Ciaran P. Kelly¹, Kumar Pallav¹, Joshua Hansen¹, Arjun Bhansali¹, Daniel A. Leffler¹
¹Division of Gastroenterology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA

Background

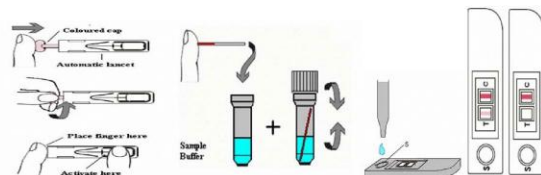
- Celiac disease (CD) continues to be under-diagnosed in the United States
- Limited awareness among primary care physicians and lack of healthcare access are two potential contributors
- Point-of-care CD tests have been used outside of the United States as reliable initial testing methods, however utility outside of clinical settings has not been assessed

Objectives

- To evaluate the utility of a self-administered finger stick CD screening test in high risk individuals

Material and Methods

- Biocard Celiac Test coeliaque kits testing for IgA-tissue transglutaminase antibodies and a short questionnaire were distributed to first or second degree relatives of CD patients (N=162)
- All participants were not previously tested or diagnosed with CD
- All participants were on a gluten containing diet within at least three months prior to enrollment



	Subject Read Positive Test*	Confirmed Positive test**	Confirmed Negative test***	P value (confirmed positive vs. confirmed negative)
Number	6	4	120	N/A
Percentage of cohort	4.5%	2.5%	74.1%	N/A
Mean age (SD)	34.2 (10.2)	39 (8.76)	43.9 (17.8)	0.6
% females	33.3%	0	60%	0.03
% males	66.7%	100%	40%	0.03
% white	100%	100%	100%	1.0
% Family history of CD	100%	100%	100%	1.0
% 1st degree relative with CD	83.3%	100%	75%	0.6
% Food intolerance (number/reported)	50%	25%	29.7% (35/118)	1.0
% Thyroid disease (number/reported)	33.3%	0	13.6% (16/118)	0.1
% Type I Diabetes (number/reported)	0	0	3.4% (4/118)	1.0
% Osteoporosis/ osteopenia (number/reported)	16.7%	25%	7.6% (9/118)	0.3
% Anemia (number/reported)	0	50%	8.5% (11/118)	1.0
% IBS (number/reported)	16.7%	25%	11.95% (14/118)	0.4
% Other autoimmune disease (number/reported)	16.7%	0	6.7% (7/104)	1.0

*One kit was not returned and one kit was read as negative by investigators.

**One of the kits reported to be negative by subjects was interpreted to be positive by the investigators.

***Some co-morbidity entries were unfilled by subjects.

Results

- 115 returned the test and reported the result
- 13 returned the test but did not report the result
- 5 did not report the result nor return the test
- 29 reported a result but did not return the test
- Six participants (3.7%, 95% CI 1.5%-8.0%) reported testing positive for CD
- Four kits (2.5%, 95% CI 0.8%-6.4% of total) were returned and confirmed to be positive by study investigators
- Five participants (3.1%) were unable to interpret the test, and of these five tests, 4 kits were returned of which 2 were un-interpretable by investigators and 2 were negative
- In the 34 kits not returned, one was read as positive (2.9%), one was un-interpretable (2.9%) and the rest were negative
- Investigator and participant readings were concordant in 95.6% of cases

Conclusions

96.6% of the participants were able to perform and report results of self-administered, point-of-care celiac testing

Reported test results were highly concordant with physician assessment

The percent positive results (2.5%) is within the expected range for this population

The majority of positive tests were in men, a population in whom celiac diagnostic rates are particularly low

Self-administered, point-of-care celiac testing is an effective strategy for evaluation of at-risk individuals who may not otherwise be tested for CD