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A Glutalytic Enzyme Supplement Was Tolerated by Healthy Young Adults

Margaret Maher, Anton Breunig, Madeline De France, Gaokhia Yang, Erin Richardson, Jackie McGinley, Kendra Ruffalo

Biology Department, University of Wisconsin—La Crosse, La Crosse, WI, USA
Email: mmaher@uwlax.edu

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Abstract

Glutalytic action can be defined as digestion of intolerance- and inflammation-promoting gluten proteins and may be useful in related conditions. To determine tolerance and potential effectiveness in a healthy population, a glutalytic supplement or placebo was randomly provided to twenty-three reportedly healthy college students for 30 days of consumption with meals three times daily. Both supplement and placebo were well-tolerated and despite no expectation of improvement on metabolic and humoral indices in this healthy population, some humoral responses were observed.

Keywords

Gluten Intolerance, Gluten Sensitivity, Glutalytic, Celiac Sprue, Celiac Disease

1. Introduction

Gluten intolerance may be an immunologically-mediated disorder that affects genetically predisposed individuals. It is characterized by more or less small intestinal mucosal damage due to the ingestion of gluten, a principal protein component of common grains and grain products. Although women are more frequently diagnosed than men, some studies show that the sexes may be equally affected. This disorder manifests itself in a variety of intestinal and/or extra-intestinal symptoms including bloating, abdominal pain, constipation, dyspepsia, fatigue, iron-deficiency anemia, osteopenia, and depression [1]. The presence of these symptoms following ingestion of gluten is also associated with celiac disease. Celiac disease is inflammatory with change to the intestinal wall that results in significant malabsorption and malnutrition [2]. Many individuals with gluten intolerance have no clear markers of celiac disease but still show ad-

verse symptoms that respond well to a gluten-free diet. In a double blind randomized placebo-controlled trial of this population, gluten was found to specifically trigger symptoms including bloating, abdominal pain, fatigue, and dissatisfaction with stool consistency [3]. Reducing the gastrointestinal impact of gluten consumption with probiotics has been explored with some success [4]. In an attempt to utilize probiotic features and diminish adverse symptoms in populations with gluten intolerance, a new glutalytic enzyme supplement was engineered to assist in the breakdown of gluten with ingestion. Though persons with celiac disease are currently advised to avoid all potential sources of gluten, this supplement may be useful for eating situations where unintentional exposure may occur. For those with intolerance void of inflammation, this supplement may be useful for expanding their diet choices. The aim of this study was to assess the safety and limited efficacy parameters of this enzyme supplement in a healthy college population and determine whether further study and expansion of use of this enzyme supplement would be beneficial.

2. Materials and Methods

A convenience sample of twenty-three generally healthy college-aged participants (16 female, 7 male, ages 18 - 22 years) was recruited through print and health class advertisements to participate in this study, which spanned October through December 2015. The study protocol received approval from the Institutional Review Board for the Protection of Human Subjects at the University of Wisconsin—La Crosse. All participants provided informed consent and were compensated for their participation in this study.

Participants were randomly assigned to receive glutalytic (100 mg/capsule with 250 mg maltodextrin) or placebo (350 mg maltodextrin) capsules to be consumed with breakfast, lunch, and dinner meals. Participants' blood was collected before and after 30 days of capsule consumption from the median vein into two 3.5 mL Serum Separator Tubes, allowed to clot for 20 minutes, and centrifuged at 3000 rpm for 10 min at room temperature. Serum samples were divided and sent for analysis to Quest or frozen at −80˚C.

Each participant recorded the contents of their meals and snacks for 30 days into a Google document shared with the researchers. They recorded each item of food they ate for breakfast, lunch, dinner, and snacks, and the time they ate. Researchers periodically checked the Google documents to ensure that participants were recording their intakes daily and sent reminders to those who fell behind. To determine the number of known meals containing gluten each participant ate, meals known to contain gluten and meals possibly containing gluten were counted. Food items that were counted as potentially containing gluten included: granola, cereal, granola bar, junk food, Caesar salad, cheese curds, chips, Chinese food, soy sauce, oatmeal bar, stir-fry, dessert, Halloween candy, protein bar, protein ball, and Italian restaurant soup.

Though the participants in this study did not identify as gluten intolerant or

diagnosed with celiac disease, a validated 16 question celiac disease gastrointestinal symptom questionnaire [5] was given before and after PLAC or GLUT conditions.

Participants' serum specimens were analyzed within comprehensive metabolic panel. Glucose, BUN, creatinine, carbon dioxide, calcium, total protein, albumin, globulin, total bilirubin, alkaline phosphatase, AST and ALT were measured by spectrophotometry. Sodium, potassium and chloride were measured by ion selective electrode analysis. Proteins IgA and IgG were measured by immunoturbidometric assay, and C-reactive protein was analyzed by nephelometry.

Results were analyzed with SPSS® Version 25 (IBM Corporation, Armonk, NY). Repeated measures GLM procedures were used to assess time, condition, and gender effects and interactions.

3. Results

3.1. Gluten Containing Meals

The average number of meals containing gluten per participant consumed over 30 days was 68.3 ± 2.7 for the GLUT condition and 58.5 ± 5.1 for the PLAC condition, $p = 0.086$. The range of gluten containing meals over 30 days was 31-94 meals. The average number of additional meals that may have contained gluten was 8.7 ± 1.8 for the GLUT condition and 8.5 ± 2.2 for the PLAC condition, $p = 0.362$.

3.2. Gastrointestinal Symptoms Questionnaire

There was no effect of time or time by condition or time by condition by gender interactions with gastrointestinal symptoms reporting from before to after 30-day consumption of PLAC or GLUT. Mean score across groups was 22.2 ± 0.8 before and 22.2 ± 0.8 after out of a possible high score of 80 (counting 5 for all 16 questions). Mean score for PLAC was 21.5 ± 1.2 before and 21.8 ± 1.3 after and for GLUT was 23.0 ± 1.2 before and 22.7 ± 0.9 after.

3.3. Glucose

Serum glucose was not significantly different pre to post by time, condition, gender, or any combination. For all participants, the average serum glucose level was 89.7± 1.5 mg/dL at the initial draw and 88.8 ± 1.5 mg/dL at the final draw. For the group receiving the GLUT condition, the average serum glucose level was 90.0 ± 2.61 mg/dL at the initial draw and 87.6 ± 1.8 mg/dL at the final draw. For the group receiving the PLAC condition, the average serum glucose level was 89.3 ± 1.6 mg/dL at the initial draw and 89.8 ± 2.3 mg/dL at the final draw. The time by condition interaction was near significance with $p = 0.117$.

3.4. Liver Function

A significant time by condition interaction was observed for bilirubin ($p = 0.021$). For all participants, the average serum bilirubin level was 0.661 ± 0.078

mg/dL at the initial draw and 0.604 ± 0.081 mg/dL at the final draw. For the group receiving the GLUT condition, the average serum bilirubin level was 0.718 ± 0.148 mg/dL at the initial draw and 0.718 ± 0.157 mg/dL at the final draw. For the group receiving the PLAC condition, the average serum bilirubin level was greater (0.608 ± 0.067 mg/dL) initially than at the final draw (0.500 ± 0.051 mg/dL), $p = 0.035$.

No significant time by condition interaction was observed for serum aspartate aminotransferase (AST). For all participants, the average AST level was 26.7 ± 3.2 units/L at the initial draw and 21.3 ± 1.1 units/L at the final draw. For the group receiving the GLUT condition, the average AST level was 30.0 ± 6.4 units/L at the initial draw and 22.8 ± 1.8 units/L at the final draw. For the group receiving the PLAC condition, the average AST level was greater (23.6 ± 2.2 Units/L) initially than at the final draw (19.8 ± 1.1 Units/L), $p = 0.079$.

No significant time by condition interaction was observed for serum alanine transaminase (ALT). For all participants, the average serum ALT level was 17.1 ± 2.0 units/L at the initial draw and 14.7 ± 1.0 units/L at the final draw. For the group receiving the GLUT condition, the average serum ALT level was 19.4 ± 4.0 units/L at the initial draw and 15.0 ± 1.5 units/L at the final draw. For the group receiving the PLAC condition, the average serum ALT level was 15.1 ± 1.2 units/L at the initial draw and 14.3 ± 1.4 units/L at the final draw.

3.5. Humoral Response

For all participants, the average serum gliadin IgA level was greater (5.91 ± 0.51 Units) initially than at the final draw (4.91 ± 0.49 Units), $p < 0.001$. For the group receiving the GLUT condition, the average serum gliadin IgA level was greater (6.00 ± 0.89 Units) initially than at the final draw (5.36 ± 0.94 Units), $p = 0.011$. For the group receiving the PLAC condition, the average serum gliadin IgA level was greater (5.83 ± 0.58 Units) initially than at the final draw (4.50 ± 0.38 Units), $p = 0.002$.

For all participants, the average serum Gliadin IgG level was greater (2.74 ± 0.24 Units) initially than at the final draw (2.52 ± 0.20 Units), $p = 0.057$. For the group receiving the GLUT condition, the average serum Gliadin IgG level was 3.00 ± 0.45 units at the initial draw and 2.91 ± 0.37 units at the final draw. For the group receiving the PLAC condition, the average serum Gliadin IgG level was 2.50 ± 0.19 units at the initial draw and 2.17 ± 0.11 units at the final draw.

Of 23 participants, seven (3 GLUT; 4 PLAC) had clinically elevated CRP at the initial (pre) blood draw. Five (2 GLUT; 3 PLAC) of these had lower CRP, but still clinically elevated, at the final (post) blood draw. One (PLAC) was the same pre to post and one (GLUT) had lowered CRP to the level of no clinical relevance. Two participants (1 GLUT; 1 PLAC) had clinically elevated CRP at the final draw only.

3.6. Gender Differences

The GLUT group consisted of 5 females and 6 males, with no apparent gender

difference considering any variable. The PLAC group consisted of 11 females and 1 male. Therefore, no gender differences are detectable in this group.

4. Conclusion

The results for each tolerance and efficacy parameter are briefly discussed individually above. This healthy population was tolerant of the glutalytic supplement when considering supplement safety parameters such as bilirubin, AST, and ALT, as well as subjective measures of gastrointestinal symptoms. Improvements in tolerance parameters from pre to post across both conditions likely reflect some environmental characteristic of the participant population. Improvements in efficacy parameters, such as anti-gliadin immunoglobulin levels, across both conditions are not easily explained. However, this was not a gluten-intolerant or celiac disease population, so the low immunoglobulin levels corresponding to a reference value indicating undetectable antibody (<20 Units) may reflect more about assay condition differences pre to post than actual specific antibody differences pre to post. Though there were decreases in CRP in most persons with elevated CRP over the course of the study, the decreases were seen in both conditions and may be attributable to other environmental factors associated with the entire participant population. Limitations of the study included lack of control over dietary consistency, especially in a college study population over the course of a semester, and lack of resources to conduct assays in our own laboratory to provide more precision for effectiveness parameters. Further study and expansion of use of this enzyme supplement, especially in a gluten intolerant subject population, may be beneficial.

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