

Case #1271: A Case Study Evaluating the Effects of an Inflammatory-Modulating Medical Food and a Nutritional Supplement Containing a Proprietary Blend of RIAA, Vitamin D₃, Selenium, and Zinc in a Patient with Crohn's Disease

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Patient's Objective Information

PURPOSE

This study was designed to assess the effectiveness of an anti-inflammatory medical food, an anti-inflammatory nutritional supplement (featuring a proprietary blend of reduced iso-alpha acids, vitamin D₃, selenium, and zinc), and a complementary diet in a patient with Crohn's disease.

PATIENT'S PRESENTATION AND HISTORY

A 57-year-old female presented in July 2005 with a previous diagnosis of Crohn's disease. She was currently having 3-5 loose bowel movements (BMs) with narrow stools in the morning, associated with gas, cramps, and urgency of evacuation. She had been diagnosed with anemia 8 years earlier and with Crohn's disease 2 years later. A colonoscopy revealed ulcers in the terminal ileum. She was placed on sulfasalazine, but later discontinued it due to stomach cramping. After return of symptoms and worsening of anemia 2 years later, a repeat colonoscopy revealed new ulcerations in her ileum. The patient was started on mesalamine with improvement of symptoms, and budesonide was added later. She felt better but her stool frequency was never less than 2-3 times/day. Four months before presentation, the patient began a high fiber diet and she promptly became very sick with vomiting, diarrhea, and blood in stool. She was hospitalized, given IV steroids and antibiotics, and was started on azathioprine, and a 3-month course of budesonide.

Other current medical conditions included: exophthalmia due to Graves' disease (diagnosed 2001); hot flashes since April 2003 after discontinuing a combination of estrogens and progestin; osteopenia of the hip and spine (diagnosed 1992); arthritic joint pain (hands, right knee, right toes) since onset of Crohn's disease; and hyperlipidemia. She also suffered environmental allergies and was intolerant to dairy products.

Her past medical conditions included pneumonia (1950); anemia off and on since 1997; and mitral valve prolapse. Surgeries included endarterectomy for almost complete occlusion of carotid artery (2003).

The patient had a family history of osteoporosis on the maternal side and osteopenia in 3 sisters. Her mother died at age 64 of congestive heart failure and had a history of Graves' disease, type 2 diabetes, lupus, and obesity. Her father had hypertension and died at age 45 with glioblastoma.

- Ht: 63"; Wt: 118 lb; BP: 138/81
- Laboratory tests revealed depressed red blood cell count, hemoglobin, and hematocrit; elevated mean corpuscular volume (MCV) and sedimentation rate (40 mm/hr); normal hs-CRP at 1.1 mg/L; elevated IgM *Candida albicans* and IgG *E. coli*; positive gluten sensitivity test; increased intestinal permeability; elevated eosinophil protein X and calprotectin; low DHEA and female hormones
- Physical examination: essentially unremarkable except for mild right lower quadrant abdominal tenderness
- Prescription medications and supplements: mesalamine (1,600 mg three times daily) and azathioprine (100 mg daily) for Crohn's disease; venlafaxine HCl (112.5 mg daily) for hot flashes; alendronat (70 mg weekly) for osteopenia; atorvastatin (10 mg daily) for hypercholesterolemia; propoxyphene and acetaminophen combination drug for joint pain (as needed); ibuprofen or aspirin (as needed, but she had taken aspirin daily for many years); multivitamin (1 tablet daily); calcium citrate (630 mg) and vitamin D (400 IU) supplement (twice daily); and lactase enzyme (as needed)

PLAN AND RESULTS

The patient was instructed to stop all current supplements and to begin an inflammatory-modulating medical food in powdered beverage form, including reduced iso-alpha acids from hops (RIAA) and Vitamin D₃, working up to 2 scoops twice daily.

3 and 5 Week Results

After 3 weeks, the patient reported that immediately after starting the medical food she started having normal BMs (formed, large caliber stools) 1-2 times/day "for the first time in my life." Stools then became softer and more frequent and she was currently having 4-5 soft BMs per day with a little gas and no discomfort. Her sleeping was disturbed by hot flashes. A stool test for gluten sensitivity was positive and she was instructed to:

- Continue inflammatory-modulating medical food
- Begin a combination isoflavone supplement (containing vitamins, folate, kudzu and clover isoflavones, turmeric, rosemary, and resveratrol), 3 tablets daily
- Begin a gluten-free diet

After 5 weeks, the patient's BMs had normalized, much to her amazement. She was asked to take:

- Consume an inflammatory-modulating medical food, 2 scoops twice daily
- Consume a supplement containing 200 mg RIAA, 1 tablet twice daily
- Add a nutritional supplement containing 2,000 IU vitamin D₃ with soy isoflavones, 1 tablet daily
- Start an elimination diet

7 Week Results

After 7 weeks, her hot flashes had improved from the previous 20 strong ones per day to the current 10-14 milder ones per day. The patient rated her overall improvement at 25% from the start of the program. She was instructed to:

- Continue on prescribed doses of the medical food and vitamin D₃/isoflavone supplement
- Begin a supplement containing a combination of RIAA (225 mg), vitamin D₃ (500 IU), zinc (5 mg), and selenium (50 mcg), 1 tablet twice daily
- Add a supplement containing a combination of EPA (300 mg) and DHA (400 mg) essential fatty acids and vitamin E (10 IU), 2 softgels three times daily
- Start a dairy-free probiotic supplement containing an ultra-concentrated combination of *Lactobacillus acidophilus* NCFM[®] strain and *Bifidobacterium lactis* BI-07 strain (60 billion organisms per capsule), 1 capsule twice daily
- Add a hematinic formula containing highly absorbable iron, vitamins B₆ and B₁₂, thiamin, folate, succinic acid, and glycine, 1 tablet twice daily (for anemia)

9, 13 and 16 Week Results

At both the 9- and 13-week visits, the patient reported feeling well, with normalized BMs and less intense hot flashes. At the 9-week visit, she noted that she had played golf the day before and for the first time she had not taken the ibuprofen for her arthritic pain. She had continued the elimination diet and food reintroduction.

After 16 weeks, patient commented that she had not felt this well as far as she could remember. She was having 1 formed BM/day, and no diarrhea or other abnormalities. She reported an excellent level of energy and no joint pain. Laboratory results indicated normalization of fecal calprotectin and eosinophil protein X, IgM *Candida albicans*, and IgG *E. coli*. She was instructed to continue on prescribed plan.

Figure 1. The patient's MSQ* score decreased from 39 to 21 in 13 weeks. This result suggests a noteworthy improvement in general physical symptoms.

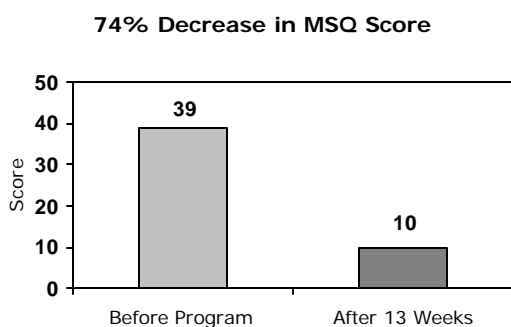
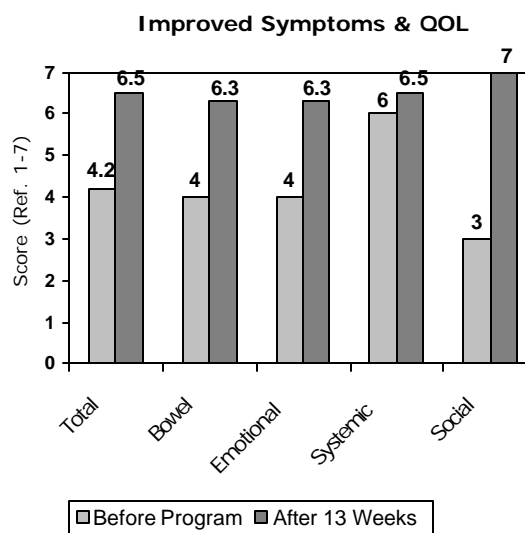


Figure 2. The patient's overall SIBDQ[†] scores improved within 13 weeks of the program, suggesting an improvement in Crohn's disease symptoms and quality of life (QOL).



SUMMARY

This case study suggests that a protocol combining an inflammatory-modulating medical food and a nutraceutical—featuring a combination of RIAA, vitamin D₃, selenium, and zinc—along with a prescribed diet may be beneficial for patients with Crohn's disease and symptoms relating to other immune-inflammatory conditions.

NOTE

The information provided in this case study describes the results of one patient under the care of a licensed healthcare practitioner and may not be a typical response.

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*The Medical Symptoms Questionnaire (MSQ) is a clinical tool for the evaluation of general physical symptoms. Total scores above 75 are generally associated with substantial symptomatology and disability; scores below 30 generally indicate few or low-intensity symptoms.

†The SIBDQ is a shortened version of the Inflammatory Bowel Disease Questionnaire (IBDQ), valuable in assessing important clinical changes in the health and outcomes of patients with IBD. The 10 items in the SIBDQ provide information in 4 categorical scores: bowel, systemic, social, and emotional. A higher score indicates a better quality of life, while a lower score indicates a poorer quality of life.

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