

# Case #1471: A Case Study Evaluating the Effects of an Anti-Inflammatory Medical Food Program and an Immune Support Supplement in a Patient with Inflammatory Immuno Syndrome

Jacob Kornberg, MD

---

## PURPOSE

*The purpose of this study was to assess the effectiveness of an anti-inflammatory medical food and dietary supplement for immune function support—along with dietary modifications—in a patient with inflammatory immuno syndrome (IIS).*

---

## PATIENT'S PRESENTATION AND HISTORY

A 62-year-old Caucasian female presented with complaints of joint, muscle, and soft tissue pain with tissue breakdown in her fingers and toes. Lesions on her fingers started about 15 years earlier, along with finger joint pain. Fatigue started several years later and the lack of energy affected her daily living. A year after the condition spread to her legs and toes, and tissue breakdown caused the loss of most of her toenails. The patient had been on and off prednisone starting 10 years prior to presentation, but had weaned off about 2 years earlier due to intolerance and was placed on azathioprine. The patient had suffered with Raynaud's phenomenon since her late 20s with feet that were either blue/purple and cold or hot and painful. She currently had occasional foot flare-ups, difficulty wearing shoes, and pain when walking.

Other current complaints included environmental allergies causing rhinitis, congestion, and occasional sinusitis; hypertension; hypercholesterolemia; pernio (an inflammatory response to cold temperatures); heat and cold intolerance; tinnitus and hearing loss; headaches; sleep disturbances; binge eating; and abdominal bloating and further GI symptoms.

The patient's past history included exposure to pesticides as a child and young adult. She had a family history of emphysema, cancer, hypertension, kidney problems, Alzheimer's disease, diabetes, and rheumatoid arthritis.

### *Patient's Objective Information*

- HT: 66.5"; WT: 159.5 lb; BP: 130/81
- Prescriptive medications: losartan, 25 mg 3 times/week and hydrochlorothiazide, 4 times/week for hypertension; azathioprine, 100 mg daily and celecoxib, 400 mg daily for joint pain; atorvastatin, 20 mg daily for hypercholesterolemia; aspirin/dipyridamole, 25/200 mg daily for cardiovascular protection; alendronate, 70 mg/week for bone resorption; zolpidem, 5 mg as needed for sleep; estrogen, 0.6 mg daily for hormone replacement.
- Non-prescriptive medications/supplements: ibuprofen, 400 mg twice daily; niacin;

magnesium; glucosamine/chondroitin and calcium/vitamin D

- Significant laboratory findings: elevated sedimentation rate, homocysteine, hs-CRP, TSH, and antigliadin IgG antibody; positive antinuclear antibody (ANA); slightly depressed 25 (OH) vitamin D; depressed progesterone; elevated estrone and estradiol

## ASSESSMENT AND PLAN

Initial assessment indicated IIS, joint and soft tissue pain, tissue breakdown, Raynaud's phenomenon, erythromelalgia, hypertension, hypercholesterolemia, and allergies. The patient was placed on the following protocol:

- Anti-inflammatory medical food, 2 scoops twice daily
- Combination supplement containing reduced iso-alpha acids (RIAA, from hops), vitamin D, zinc, and selenium, 2 tablets twice daily
- EPA & DHA supplement (600 mg/400 mg), 2 softgels twice daily
- Vitamin D and soy isoflavone combination supplement, 1 tablet daily
- Indole-3-carbinol (I3C) with rosemary extract supplement, 1 capsule twice daily with food
- Botanical supplement for sinus support, 2 tablets 3 times daily

## RESULTS

### *4 Weeks After Starting the Program*

The patient reported 50% improvement of abdominal complaints. She had a few painful flare-ups in her feet, but of shorter duration than usual and pain was less severe. Her overall pain had decreased to the point where she wanted to discontinue the celecoxib. She noted sleeping well, but still did not have a lot of stamina. Stool analysis indicated elevated antigliadin IgA antibodies, elevated transglutaminase IgA, low intestinal beneficial bacteria, and imbalanced metabolites. The patient was instructed to:

- Continue the protocol
- Begin a gluten-free diet
- Add combination *Lactobacillus acidophilus* and *Bifidobacterium lactis* probiotic (30 billion organisms each), 1 capsule twice daily
- Add nutritional support for the upper GI tract (including green tea, cinnamon, plantain fruit, and arabinogalactans), 1 Tbsp twice daily
- Add 1:1 blend of soluble/ insoluble fiber, 1 scoop 1 to 2 times daily for constipation

### 8 Weeks After Starting the Program

The patient reported doing much better with fewer flare-ups and just one area of tissue breakdown on her toe. The patient was instructed to:

- Continue current therapeutic protocol
- Decrease upper GI support formula and fiber supplement to manage bloating
- Add combination niacinamide/NAC supplement to promote PARS inhibition, 1 tablet 3 times daily for hip pain

### 10 and 13 Weeks After Starting the Program

After 10 weeks, the patient reported healthier looking hands and feet and a lot less pain. At the 13-week visit, she reported that others had commented on the improved appearance of her hands. She could wear shoes comfortably and had good circulation, rating her discomfort as 3 to 4 on a 10-point scale. Her GI issues had abated with normal BMs. The sedimentation rate decreased significantly.

### 20 Weeks After Starting the Program

The patient estimated a 90% improvement in foot pain and was able to walk in sand with no discomfort. Her hip pain was reduced and she noted great improvement in leg varicosities. She had been able to discontinue the azathioprine and aspirin/dipyridamole. She reported increased energy and was able to enjoy vacationing. Her protocol was adjusted to:

- Replace RIAA/vitamin D/zinc/selenium supplement with new formulation of tetrahydro-iso-alpha acids (THIAA, from hops)/vitamin D/zinc/selenium combination supplement, 1 tablet 3 times daily

### 24 Weeks After Starting the Program

The patient continued to feel good with no new sores. Her hs-CRP had decreased to 1.2 mg/L. She was instructed to:

- Continue on the protocol
- Add a digestive support formula (containing betaine HCl, pepsin, and gentian root), 1 to 2 tablets with meals
- Add a combination supplement for healthy homocysteine metabolism (containing B<sub>6</sub>, B<sub>12</sub>, folate, trimethylglycine, and choline), 1 tablet twice daily

### 30 and 35 Weeks After Starting the Program

The patient continued to do well, exercising more and enjoying the way she felt. She was avoiding gluten in her diet and was advised to continue the nutritional protocol.

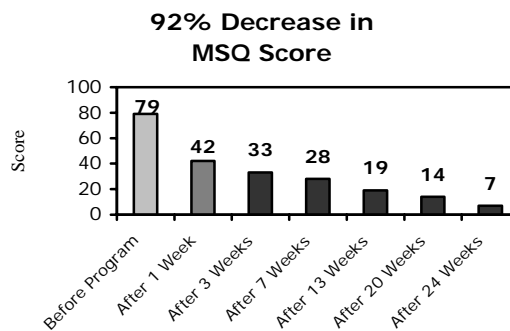


Figure 1. After 24 weeks, the patient's MSQ<sup>†</sup> score decreased from 79 to 7. This result suggests a substantial improvement in general well-being.

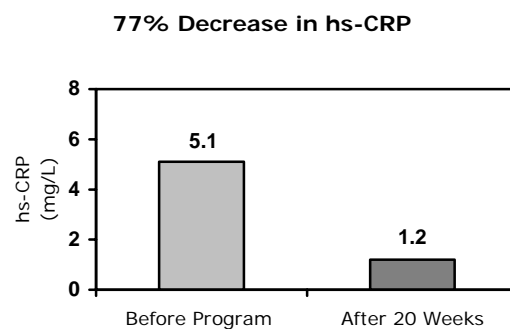


Figure 2. The patient's hs-CRP level, a marker of inflammation also associated with cardiovascular disease risk, was reduced after 20 weeks to 1.2 mg/L (ref. range <0.7 mg/L). This result suggests a substantial reduction in inflammation.

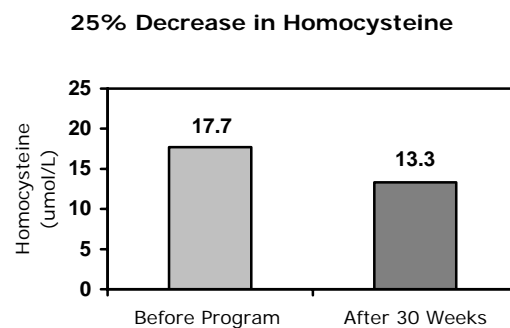
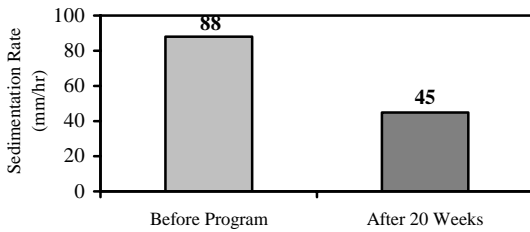


Figure 3. The patient's homocysteine level was reduced after 30 weeks (ref. range <9.0 umol/L). Elevated homocysteine levels have been associated with autoimmune and inflammatory conditions and cardiovascular disease (CVD). This result suggests a notable reduction in inflammation and risk for issues related to CVD.

### 49% Reduction in Erythrocyte Sedimentation Rate



*Figure 4.* After 20 weeks, the patient's ESR was reduced to 45 (ref. range for women over 50: <30 mm/hr). This result suggests a noteworthy improvement in inflammation related to immune system dysfunction.

#### SUMMARY

This case study demonstrates that a targeted nutritional support program that incorporates an anti-inflammatory medical food and dietary supplement to support immune function improves symptoms in a patient with an immune-inflammatory condition.

#### 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. The anti-inflammatory medical food discussed in this study is to be used under the supervision of a physician or other licensed healthcare practitioner.

Financial support for this study was provided by Metagenics, Inc. This study was performed in collaboration with the Functional Medicine Research Center (FMRC), the clinical research arm of Metagenics, Inc.

<sup>†</sup>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.

©2007 Functional Medicine Research Center

Case Study: A Case Study Evaluating the Effects of an Anti-Inflammatory Medical Food Program and an RIAA/Vitamin D/Selenium/Zinc Dietary Supplement in a Patient with Inflammatory Immuno Syndrome. Metagenics, Inc; 11011S806.

MET1471 3/07