Re: “Advances in Treating Crohn’s Disease, Rheumatoid Arthritis, and Ankylosing Spondylitis: The ‘Dark Side’ of Anti–Tumor Necrosis Factor Therapy”

The following is being reprinted with permission from the reader, who lives in the Chicago area, and from the author of the original article.

Dear Dr. Goldenberg,

My family physician gave me a copy of your article in the January 2004 issue of P&T regarding advances in treating Crohn’s disease and rheumatoid arthritis. I am a 50-year-old male with severe rheumatoid arthritis. Since February 2003, I have been taking Humira® [adalimumab], which was prescribed by my rheumatologist. Recently, I was diagnosed with congestive heart failure. I had not experienced any previous heart problems, and the cardiologists were unable to determine a cause.

Since Humira® is a drug related to infliximab [Remicade®] and etanercept [Enbrel®], I was wondering if you knew of any research on Humira® which has shown any risk factors related to the heart.

Thank you in advance. I hope to hear from you.

Sincerely,

Jim Barrett

Author’s Response

Dear Mr. Barrett,

I have done some in-depth exploration in attempting to answer your query regarding whether there is any research on Humira® that has shown any risk factors related to the heart.

I have perused some clinical research databases, spoken to several clinicians, and queried the drug information department of the drug manufacturer. The results of my efforts lead me to the conclusion that there is no current research attempting to equate whether there is a relationship between Humira® and the occurrence of congestive heart failure.

When I spoke to the manufacturer (Abbott Labs), they told me that in their clinical studies, 2,000 subjects were enrolled and only six patients experienced congestive heart failure. However, of these six patients, three received Humira® and three subjects received placebo treatment. They concluded that there was no relationship between Humira® treatment and the development of congestive heart failure. However, the length of treatment was anywhere from six months to over a year. Abbott Labs did not publish the results of all their clinical studies.

On the other hand, I located an interesting article that might shed some light on the issue. In one database, I found a recently published article in the American Journal of Medicine in 2004. The authors reviewed data from 13,171 patients with rheumatoid arthritis and 2,568 patients with osteoarthritis and found that treatment with anti–TNF rheumatoid arthritis drugs (infliximab and etanercept) seemed to reduce the risk of heart failure. That is, the prevalence of heart failure in anti–TNF users was 3.1%, significantly ($P < .05$) lower than the 3.8% rate observed in rheumatoid arthritis patients not treated with such drugs. Still, the authors observed that the benefit was noted only in rheumatoid arthritis patients with pre-existing cardiovascular disease. Thus, their conclusion was that the findings suggest that rheumatoid arthritis increases the risk of heart failure, which may be ameliorated by anti–TNF therapies.

In the prescribing information for Humira®, it is stated that in clinical trials, the serious adverse event of congestive heart failure occurred at an incidence of less than 5% in patients treated with Humira®. This suggests that congestive heart failure can occur in susceptible individuals.

Although the information gathered may seem a bit confusing, your cardiologist should tell you whether to continue taking Humira® for your arthritic condition.

I hope that this information may benefit you and your final decision with Humira®. I would be happy to hear from you as to the outcome of your decision.

Sincerely,

Marvin M. Goldenberg, PhD, RPh, MS