Is There a Link between Bowel Disease and Accutane?

Actor James Marshall sued the makers of Accutane for disease that resulted in the removal of his colon. The jury concluded that Marshall had a pre-existing bowel disease and cleared Roche Pharmaceuticals of wrongdoing.

Acne Medication Unconnected to Inflammatory Bowel Disease February 20, 2013 Medscape Medical News *JAMA Dermatol*. 2013;149:216-222.

A new study of isotretinoin (originally marketed as *Accutane*), found no increased risk for inflammatory bowel disease (IBD), according to a study published in the February 20 issue of *JAMA Dermatology*. The study of more than 45,000 women found no such link between Accutane (isotretinoin) use and inflammatory bowel disease (IBD).

The researchers also failed to find an association between isotretinoin and IBD in a meta-analysis that included the present study, 3 large published epidemiological studies, and 1 large unpublished study.

The data provided by this study and others did not suggest that the risk for IBD increases with isotretinoin use. "We should not withhold isotretinoin from patients who need it because of concerns for the development of IBD," they write.

IN DEFENSE OF ISOTRETINOIN. PART II: ISOTRETINOIN AND INFLAMMATORY BOWEL DISEASE

Emily Altman, MD, Dermatology, General, 07:56AM Feb 12, 2014

Isotretinoin is an indispensible medication in dermatology. It is used for acne that is scarring, severe or resistant to other therapies. It is the only medications which can actually put acne into remission. Often it is the only systemic medication that helps. Over the recent years, it has become more and more difficult to prescribe it due to claims of dangerous side effects. Parents and the kids themselves are terrified of potential side effects and do not even wish to hear about treating acne with isotretinoin.

Accutane (isotretinoin) was introduced by Roche in the early 1980's. The first attacks came soon thereafter with claims that Accutane causes depression. Given the positive effects of Accutane we saw in our patients, many dermatologists were genuinely worried. But then study after study showed that Accutane does not cause depression. I

discussed these studies in the previous blog in this series "In defense of isotretinoin, Part I: Isotretinoin and depression."

The latest controversy regarding isotretinoin is the claim that it causes inflammatory bowel disease. Based on these claims, six large lawsuits were won against the manufacturer of Accutane, Roche, totalling 56 million dollars, the largest of which was 25 million dollars. But based on what evidence?

Thankfully for patients with severe acne and for the physicians treating them, a number of studies were published showing no relationship between isotretinoin use and inflammatory bowel disease. We will look at a few here.

In a 12-year population-based study pulished in *JID* in 2012, Alhusayen et al. analyzed the incidence of inflammatory bowel disease in 46,922 participants treated with isotretinoin, 184, 824 patients treated with topical acne medications and 1,526,946 untreated individuals and found no association between isotretinoin and IBD¹.

In the February 2013 issue of *JAMA Dermatology*, a study of isotretinoin and the risk for inflammatory bowel disease in young women, which looked at 2159 IBD cases and 43,180 controls, again showed no increased association between isotretinoin use and the risk of IBD².

So, our downtrodden hero, isotretinoin lives to see another day. I know that my patients with severe acne who have been treated with isotretinoin are grateful that despite many efforts, this indispensible drug remains in our armamentarium.

References:

- 1. Alhusayen RO et al. Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Population-Based Cohort Study. *JID* 2013;133:907-912.
- 2. Etminan M et al. Isotretinoin and Risk for Inflammatory Bowel disease. A Nested Case-Control Study and Meta-analysis of Published and Unpublished Data. *JAMA Dermatol*2013;149(2):216-220
- 3. Popescu CM, Bigby M. The Weight of Evidence on the Association of Isotretinoin Use and the Development of Inflammatory Bowel Disease. JAMA Dermatol 2013;149(2): 221-222
- 4. Alleged isotretinoin-associated inflammatory bowel disease: Disproportionate reporting by attorneys to the Food and Drug Administration Adverse Event Reporting System. *J Am Acad Dermatol* 2013;69:393-8
- 5. Mostow, E. Include Discussions and Review of Systems Regarding Inflammaotry Bowel Disease in Patients Starting Isotretinoin Therapy. *JAMA Dermatol* 2011;147(6): 729-730