

Biologic treatment for rheumatoid arthritis and the risk of cancer

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The relationship between rheumatoid arthritis (RA), an autoimmune disease marked by chronic inflammation of the joints and tissue surrounding vital organs, and the incidence of cancer is complicated. Epidemiologic studies have generally demonstrated that blood, lung, and skin cancers are increased among RA patients, while breast and colon cancers are decreased.

Whether these cancer rates are caused by the nature of RA or by immunosuppressive drugs used to treat RA is an issue of ongoing debate and investigation. Findings of various clinical trials and observational studies conflict over the risk of malignancy related to the use of tumor necrosis factor alpha (TNF α) blockers, a biologic therapy shown effective at controlling the symptoms of RA in patients who fail to respond to traditional disease-modifying antirheumatic drugs (DMARDs).

To assess the risk of cancer among biologic-treated RA patients, comprehensively and conclusively, two research specialists, Frederick Wolfe, MD, University of Kansas School of Medicine, and Kaleb Michaud, PhD, University of Nebraska Medical Center, turned to two sweeping databases, the National Data Bank for Rheumatic Diseases and the US National Cancer Institute SEER (Surveillance, Epidemiology, and End-Results). Gathering and comparing data from both, they studied the incidence of cancer in 13,001 RA patients, over a total span of close to 49,000 years. Nearly half of these patients, 49 percent, had a history of exposure to anti-TNF α drugs. As Dr. Wolfe and Dr. Kaleb found, and

report in the September 2007 issue of *Arthritis & Rheumatism*, biologic treatment of RA increases a patient's risk of skin cancers, including melanoma, but not any other specific cancers—not lung, liver, brain, or bone cancers, not Hodgkin's or leukemia, not solid tumors or lymphoma—and not of developing cancer in general.

Among the study population, Dr. Wolfe and Dr. Kaleb identified 623 cases of skin cancer and 537 cases of other cancers. Then, they set out to determine the impact of biologic drug use on cancer occurrence. As an estimate of the relative risk of developing different types of cancer, the team calculated the odds ratio for every cancer afflicting the subjects, performing conditional logistic regression to reduce the effect of variations in treatment duration. They also controlled for the variables of sex, smoking history, education level, disease severity, and baseline use of prednisone. In addition to assessing the risk of various cancers associated with biologic treatment in general, Dr. Wolfe and Dr. Kaleb extended the analyses to individual TNF α blockers, etanercept and infliximab.

Collectively and individually, anti-TNF α therapy was linked to an increased risk of skin cancers. The odds ratio for developing melanoma was 2.3. Biologic use had no impact on any other type of cancer. The overall risk for all malignancies was 1.0—a result substantially different from the overall risk of 3.3 noted in a meta-analysis of clinical trials of biologic treatment of RA.

“Although our data do not show associations between malignancy and biologic therapy, except for skin cancers, the mean and median exposure to biologics was only 3.0 years,” notes Dr. Michaud. “It is possible that with increasing time of followup or of exposure, the association between malignancy and biologic therapy would become stronger. However, true associations are regularly seen within this time frame.”

Despite its potential limitations, this study offers reassurance to RA patients who are currently being treated with etanercept or infliximab, as well as to those considering biologic therapy as a possible option.

Article: “Biologic Treatment of Rheumatoid Arthritis and the Risk of Malignancy: Analyses From a Large US Observational Study,” Frederick Wolfe and Kaleb Michaud, *Arthritis & Rheumatism*, September 2007; (DOI: 10.1002/art.22864).

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