

Serious Infection Rates Similar Among Biologics

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BIRMINGHAM, ENGLAND — No important differences in rates of serious infections have been reported among patients treated with etanercept, infliximab, or adalimumab, according to a report from the British Society for Rheumatology Biologics Register (BSRBR).

Since January 2002 all patients in the United Kingdom with rheumatic diseases who are treated with biologic agents have been enrolled in the register. They are being followed with the goal of determining the incidence and nature of any short- or long-term adverse effects. Will Dixon, Ph.D., said at the joint meeting of the British Society for Rheumatology and the German Society for Rheumatology.

To date, data have been analyzed for 2,602 patients who have received etanercept, 2,871 treated with infliximab, and 915 given adalimumab with follow-up for at least 6 months, he said.

Patients in the three groups had similar demographics: The mean age in all groups was 54 years, and median disease duration was 12 years. Three-quarters were women.

Thus far, there have been 132 serious infections among patients on etanercept, 205 in those on infliximab, and 40 in those on adalimumab.

Incidence rates for the three groups were 52.6, 52.1, and 62.4 per 1,000 patient years, respectively. The differences in incidence rates were not statistically significant, said Dr. Dixon of the BSRBR Arthritis Research Campaign epidemiology unit at the University of Manchester (England).

Serious infections were defined as those requiring intravenous antibiotics, leading to a hospital admission, or being in any way life threatening, he said. The most common sites of serious infections also were broadly similar (see the chart).

All three drugs are inhibitors of tumor necrosis factor (TNF)- α , which is a cytokine with a central role in the inflammatory process of rheumatoid arthritis, Dr. Dixon explained. However, it also has a role in infection control, acting synergistically with interferon- γ . In its anti-infection capacity, TNF- α is particularly crucial for the control of intracellular infections such as tuberculosis, where its inhibition can lead to dissemination of the infection.

With regard to these types of infection, there have been 11 cases of tuberculosis, 9 in patients on infliximab and 2 in patients on etanercept; incidence rates for tuberculosis were 2.3 and 0.8 per 1,000 patient-years for the two drugs, respectively. Despite the fact that the rate was more than 2.5-fold higher with infliximab, the difference was not statistically significant because of the small numbers, he said.

There were two cases of Salmonella septic arthritis and one of Salmonella gastroenteritis, all in patients receiving etanercept, Dr. Dixon said. One case of Legionella pneumonia was reported following treatment with infliximab.

When an audience member asked if concurrent steroid therapy might be a contributing factor to the development of infection, Dr. Dixon replied that the strongest predictor of infection was diabetes, followed by a high Health Assessment Questionnaire score, and then steroid use. About 50% of patients were on steroids at baseline. ■

Incidence of Serious Infections per 1,000 Patient-Years

	Etanercept	Infliximab	Adalimumab
Lower respiratory tract	16.7	21.6	18.7
Skin and soft tissue	10.4	9.4	12.5
Bone and joint	6.0	5.3	4.7
Urinary tract	4.8	3.3	9.4
Intracellular infections	2.8	2.5	0

Source: Dr. Dixon

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‡ Statistical significance was not observed consistently for every secondary end point at each point of measurement across all studies.

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