

**Use of Tumor Necrosis Factor- $\alpha$  (TNF- $\alpha$ ) Antagonists in Patients with  
Concurrent Rheumatoid Arthritis (RA) or Spondyloarthritis (SpA) and  
Hepatitis B**

**Background:** To assess the safety of biological agents in patients with rheumatic diseases associated with hepatitis B in one medical center.

**Methods:** Patients who had taken etanercept or adalimumab from January 2002 to September 2010 in Chung Shan Medical University Hospital were reviewed in the study. We retrospectively investigated a series of serum aminotransferase (ALT) levels, hepatitis serologic status including HBV surface antigen (HBsAg), HBV surface antibody (HBsAb), HBV core IgG Ab (HBcAb), and HBV-DNA. Endpoints were clinical reactivation and subclinical reactivation as defined by ALT and viral load, respectively.

**Results:** A total of 161 patients were documented to have taken etanercept or adalimumab. Among the 161 patients, 17 (10.56%) patients had chronic hepatitis B (HBsAg+) without anti-viral agent prophylaxis prior to biologics. Nine patients were excluded from the analysis due to missing data. Of these remaining 8 patients, only 1 (12.5%) patient had transient mild clinical reactivation after taking etanercept for 4

months. Spontaneous remission of this patient's HBV reactivation was noted without anti-viral therapy.

**Conclusion:** All rheumatic patients who plan to take biologics treatment should undergo tests for HBV, and they should have a close follow-up with ALT during therapy. Preemptive anti-viral therapy is commenced in patients who develop evidence of disease reactivation. For chronic hepatitis patients, it might not be necessary to use a prophylactic anti-viral agent prior to biologics.

## **Abstract**

### **Objective**

While there is consensus that treatment with disease-modifying antirheumatic drugs (DMARDs) should be started early in patients with inflammatory arthritis, confirmation that radiographic progression is inhibited with early treatment start is scarce. This study was undertaken to compare radiographic progression in patients treated with a DMARD very early in the course of their disease (within 3 months of diagnosis) and those who began DMARD treatment later.

### **Methods**

Patients included in the French observational ESPOIR (Étude et Suivi des Polyarthrites Indifférenciées Récentes [Study and Followup of Early Undifferentiated Polyarthritis]) cohort were followed up, and radiographic progression after 12 months was assessed. Propensity scores, reflecting the indication to start a DMARD, were obtained by modeling the start of DMARD therapy by disease-specific and demographic variables obtained at baseline, using logistic regression analysis. The influence of very early versus delayed DMARD start on radiographic progression was evaluated by generalized linear regression, with and without adjustment for propensity scores.

### **Results**

Six hundred sixty-one patients were analyzed. In an unadjusted analysis, patients starting DMARD therapy within 3 months of diagnosis did not show a significant difference in radiographic progression

score as compared to those starting DMARD therapy later (1.2 units versus 1.6 units;  $P = 0.37$ ). Adjustment for the propensity score revealed a statistically significant difference in mean progression (0.8 units versus 1.7 units;  $P = 0.033$ ). Analysis by propensity score quintile showed a trend suggesting that early treatment was especially beneficial for patients in the fourth and fifth quintiles (worse prognosis).

## **Conclusion**

Our findings indicate that among