An Analysis of Real-World Data on the Safety of Etanercept in Elderly Patients with Rheumatoid Arthritis

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Background/Purpose: Both rheumatoid arthritis (RA) and older age are associated with a higher risk of comorbidities, and the appropriate treatment approach for older patients is unclear. We evaluated real-world data (RWD) to determine whether there is an association between etanercept (ETN) and select adverse events (AEs) in patients with RA, stratified by age. We hypothesized that there is no difference in risk of AEs between younger (aged ≤65 yr) and older (aged >65 yr) patients.

Methods: Data from 2013 to 2018 were analyzed from the IBM Watson Health MarketScan Database which contains information on 104.5 million distinct patients, including 531,996 with RA. Patients were required to be enrolled ≥1 yr prior to RA diagnosis; the first exposure to ETN was after RA diagnosis and before the AE of interest: congestive heart failure (CHF), serious infection (SI), non-melanoma skin cancer (NMSC), or interstitial lung disease (ILD). Proportion of patients experiencing each AE was determined for patients ≤65 yr and >65 yr receiving and

not receiving ETN. Differences were evaluated using Fisher's Exact test. Logistic regression models assessed the interaction between ETN and age group. Propensity matching was performed, and logistic regression was applied using the propensity-score-matched cohort. Patients receiving and not receiving ETN were matched by age, age >65 yr, gender, and geographical region.

Results: Average age of patients with RA was 56.1±14.9 yr; 73.5% were female. Risk of experiencing CHF did not differ significantly for patients receiving vs not receiving ETN: odds ratio (OR) = 0.883, 95% CI: 0.770–1.009; *p*=0.072. However, the risks of SI, NMSC, and ILD were significantly higher in the patients receiving ETN (SI: OR=1.14, 95% CI: 1.07–1.21, *p*<0.001; NMSC: OR=1.20, 95% CI: 1.05–1.37, *p*=0.008; and ILD: OR=1.89, 95% CI: 1.56–2.29, *p*<0.001). In patients >65 yr, the occurrence of CHF was lower for patients receiving vs not receiving ETN (8.7% vs 10.7%, *p*=0.025) (Figure); the occurrence of SI and NMSC did not differ significantly; SI: 21.8% vs 20.4% for ETN vs no ETN, respectively, *p*=0.186; NMSC: 6.3% vs 5.2%, *p*=0.952. The occurrence of ILD was higher for patients receiving ETN: 3.4% vs 1.4%, *p*<0.001. The difference in AE occurrence between patients ≤65 yr and >65 yr did not differ significantly for patients receiving vs not receiving ETN for any of the AEs (Figure).

Conclusion: In this analysis of RWD of patients with RA, the risk of CHF, SI, NMSC, and ILD between younger and older patients was not modified by ETN usage. This analysis suggests an overall acceptable safety profile of ETN; however, clinicians should use caution when treating older patients.

Figure. Occurrence of AEs according to age group and ETN treatment status