Efficacy of Belimumab for Primary Sjögren Syndrome: Systematic Review of the Literature


Background: Belimumab is a human monoclonal antibody that inhibits B-cell activating factor shown to be efficacious in systemic lupus erythematosus. In other B cell mediated autoimmune disease such as primary Sjögren’s syndrome (pSS) the efficacy is unclear.

Objectives: To evaluate the efficacy of belimumab in patients with pSS.

Methods: A systematic literature review was performed (EMBASE, MEDLINE and Cochrane) as part of the Spanish Rheumatology Society’s Recommendations for the Use of Biological Therapies in Primary Sjögren’s Syndrome. Inclusion criteria was defined as: Population: patients with pSS according to American-European Consensus Criteria 2002 Intervention: belimumab; Control: synthetic or biologic DMARDs, corticosteroids, ursodesoxicolic acid or placebo; Outcome: efficacy in RF (52 vs 69UI; p<0.01), IgM (131.9 vs 165 mg/dl; p=0.04) and BLyS (1304 vs 1779; p<0.05). The daily glucocorticoid dose was defined as: Population: patients with pSS according to American-European Consensus Criteria 2002 Intervention: belimumab; Control: synthetic or biologic DMARDs, corticosteroids, ursodesoxicolic acid or placebo; Outcome: efficacy in RF (52 vs 69UI; p<0.01), IgM (131.9 vs 165 mg/dl; p=0.04) and BLyS (1304 vs 1779; p<0.05). The study of Mariette et al 2015 evaluated the efficacy and safety of belimumab in 30 patients with systemic activity or early disease until week 28 (W28). There was a significant decrease in mean ESSDAI (8.8 to 6.3 p=0.02), ESSPRI (6.4 to 5.6 p=0.02) and VAS for dryness (7.8 to 6.2 p=0.02). Physician’s VAS for disease systemic activity also decreased in 43% as well as parotid inflammation in 76.9% of patients. Also, B cell biomarkers decreased: IgG (21.2 to 18.2 g/L; p=0.02), IgA (3.7 to 3.3 g/L; p=0.04), IgM (1.6 to 1.3 g/L; p<0.001), RF (146.2 to 106.7 UI p<0.001) and number of B cells (187.2 to 65.1/mm; p<0.001).

Disclosure of Interest: None declared


Abstract AB0518 – Figure 1

The study of De Vita et al 2015 compared results at week 52 (W52) and W28 in 19 patients, of whom 15 had previously responded to treatment. Of these 15 patients 13 maintained response and 3 out of the 4 patients that did not respond achieved primary outcome. The improvement at W52 continued for ESSDAI, glan- dular inflammation, lymphadenopathy and joints. B cell biomarkers remained sta- ble. Overall items contributing to ESSDAI decreased but only physician’s VAS for disease systemic activity was statistically significant (3.2 W28 vs 2.5 W52; p<0.04).