Figure 1

Disclosure of Interests: None declared
DOI: 10.1136/annrheumdis-2019-eular.6980

FRI0041 INCIDENCE AND TREND OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML) IN PATIENTS WITH RHEUMATOID ARTHRITIS IN SPAIN. (TREND-AR STUDY)

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Background: Treatment with biological agents is recognized as a potential risk factor for the development of Progressive Multifocal Leukoencephalopathy (PML), a rare and often fatal demyelinating disease of the CNS caused by John Cunningham Virus infection.

Objectives: Analyze the incidence and trend of hospital admissions for PML in patients with RA, in Spain, during the period between 1999 and 2015.

Methods: Population study based on the analysis of a national administrative database that includes a Minimum Basic Data Set (MBDS) of the income of patients with RA (ICD 9 714). Period: January 1, 1999, to December 31, 2015. The cases of PML were identified due to the presence in the primary and secondary diagnosis of the codes ICD 9 046.0 to 046.9. The population at risk was estimated through the population census of the National Institute of Statistics, with an estimated prevalence

of RA of 0.5% in both sexes (0.2% in men and 0.8% in women). Crude and adjusted rates were calculated at national level. The trend was analyzed using Generalized Linear Models (MLG) using the variable year as the analysis variable.

Results: Of the total of 338,343 hospital admissions in patients with RA during the 17 years of the study period, only 14 cases (0.004%) of PML were recorded, nine (64.3%) were women and 5 (35.7%) men. The mean age was 69.5 years (SD 16.8); 74.56 (SD14.8) in women and 60 (SD18.1) in men (p = 0.145). Five patients (35.7%) died during admission (2 women and 3 men) (p = 0.266). The average of the Charlson index was 2.21 (SD 1.7); 3 (SD 2.5) in women and 1.78 (SD 1.1) in men (p = 0.227).

The crude incidence rate of PML was 0.54/100,000 inhabitants * year, 0.85/100,000 inhabitants * year in men and 0.37/100,000 inhabitants * year in women. The Relative Risk male: female was 2.34. The gross rate of PML increased from 0.32/105 * year in the period 1999-2002, to 0.74 between 2011 and 2015, both in women (from 0.19 in the period 1999-2002 to 0.52 from 2011 to 2015) as well as men (from 0.82 in the period 1999-2002 to 1.64 during 2011-2015). It is estimated that this increase is of 19.7% per year.

Conclusion: In Spain, between 1999 and 2015, there has been an increase in the incidence rate of PML in patients with RA. We estimate an annual increase of 19.7%.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.2478

FRI0042 CERTOLIZUMAB PEGOL EFFECTIVENESS IN WOMEN OF CHILDBEARING AGE WITH RHEUMATOID ARTHRITIS: RETROSPECTIVE ANALYSIS OF AN INTERNATIONAL MULTICENTRE COHORT

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Background: Even though certolizumab pegol (CZP) has been licensed for the treatment of rheumatoid arthritis (RA) a long time ago, observational data in real-life settings are still lacking. Moreover, recent data on the lack of transplacental passage (1) make CZP particularly appealing for the treatment of RA women with a desire of pregnancy.

Objectives: To evaluate in a real-life international cohort the frequency of use, the clinical response, and the retention rate of CZP in RA women of childbearing age.

Methods: Data were retrospectively extracted from the Italian LORHEN and the Romanian Registry of Rheumatic Diseases (RRBR) registries, which include all RA patients treated with CZP between December 2010 and October 2018. The analysis was limited to women who received CZP as first-line biologic agent. The study population was stratified according to childbearing age (18-49 versus >49 years). The 6-, 12- and 24-month clinical response was evaluated as the proportion of patients achieving Disease Activity Score 28 (DAS28) remission and compared between the subgroups by a chi-squared test. The 5-year retention rate was calculated by the Kaplan-Meier method and compared between the subgroups by log-rank test.

Results: The whole cohort included 630 RA patients treated with CZP. According to the inclusion criteria, the study population consisted of 308 female RA patients (mean [± standard deviation, SD] age 54.2±12.1 years; mean disease duration 8.7±8.4 years; baseline DAS28 5.25±1.72, positive anti-citrullinated peptide antibody 161/254 [63.4%], positive rheumatoid factor 213/297 [71.7%]). Apart from mean age (39.6±6.6 vs 60.8±7.2, respectively; p<0.001), no other significant differences in baseline characteristics between the childbearing (n=97, 31.5%) and non-childbearing age (n=211, 68.5%) groups were observed. In the overall population, DAS28 remission was achieved by 29.9%, 42.1%, and 39.7% of patients at 6, 12, and 24 months, respectively. This proportion was significantly higher in childbearing compared with non-childbearing women at each timepoint (39.4% vs 25.4, p=0.02 at 6 months; 52.8% vs 37%, p=0.014 at 12 months; 52% vs 34.2%, p=0.014 at 24 months). The overall 5-year retention rate was 37.1%, with a higher (but not statistically significant) persistence in the childbearing versus non-childbearing subgroup (55.1%