Background: Neurosarcoidosis (NS) is a serious and relative uncommon complication of sarcoidosis [1]. Data on incidence is scarce and varies worldwide.

Objectives: To estimate NS epidemiology in Northern Spain.

Methods: Patients diagnosed with sarcoidosis at a University hospital in Northern Spain, between January 1999 and December 2019 were assessed. Sarcoidosis diagnosis was established according to ATS/ERS/WASOG criteria as follows: compatible clinical and radiological presentation, histopathologic confirmation, and exclusion of other granulomatous diseases. NS was diagnosed according to the NS Consortium Consensus Group [2]. Demographic and clinical data were collected. The incidence of sarcoidosis between 1999-2019 was estimated by gender, age, and year of diagnosis.

Results: NS was observed in 30 of 234 (12.8%) (19 women/11 men) (mean age: 55.0±15.8 years) patients with sarcoidosis. The underlying neurological manifestations were chronic headache (n=13, 43.4%), peripheral neuropathy (n=6, 20.0%), cranial neuropathy (n=5, 16.7%), spinal cord abnormalities (n=3, 10.0%) and aseptic meningitis (n=3, 10.0%). A comparison between different geographical areas is summarized in Table 1. There are wide variations in frequency (US:4.8% to France:33.9%), gender predominance and age at diagnosis (31 to 55 years) depending on the geographical area. Nevertheless, most of the patients were diagnosed in the 5th decade of life. Annual incidence of NS in our population area in the 1999-2019 period was 0.11 per 100,000 people, 95% CI (0.01-0.26); 0.08 (0.07-0.24) in men, 0.13 (0.09-0.24) in women. There were variations in annual incidences, ranging from a minimum value of 0.08 in 2013-2014 to a maximum of 0.19/100,000 people in 1999-2000. A downward trend in annual incidence over time was observed. Nevertheless, the correlation was weak (r²=0.1135) (Figure 1).


Table 1. Main clinical features and treatment of neurosarcoidosis in different geographical areas

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Country</th>
<th>Cases</th>
<th>Male n (%)</th>
<th>Age at onset mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastón-Bayarri et. al., 2011</td>
<td>Spain</td>
<td>445</td>
<td>60</td>
<td>33.4</td>
</tr>
<tr>
<td>Leonhard et. al, 2016</td>
<td>The Netherlands</td>
<td>52</td>
<td>22</td>
<td>48.0</td>
</tr>
<tr>
<td>Joubert et. al, 2017</td>
<td>France</td>
<td>690</td>
<td>117</td>
<td>50.0</td>
</tr>
<tr>
<td>Dorman et. al, 2019</td>
<td>USA</td>
<td>1706</td>
<td>691</td>
<td>43.5</td>
</tr>
<tr>
<td>Arun et. al, 2020</td>
<td>UK</td>
<td>80</td>
<td>35</td>
<td>44.0</td>
</tr>
<tr>
<td>Goel et. al., 2020</td>
<td>India</td>
<td>12</td>
<td>4</td>
<td>33.4</td>
</tr>
<tr>
<td>Sambon et al, 2022</td>
<td>Belgium</td>
<td>18</td>
<td>12</td>
<td>14.0</td>
</tr>
<tr>
<td>Ryg et al., 2022</td>
<td>Denmark</td>
<td>20</td>
<td>11</td>
<td>55.0</td>
</tr>
<tr>
<td>Present study, 2023</td>
<td>Spain</td>
<td>234</td>
<td>105</td>
<td>36.7</td>
</tr>
</tbody>
</table>

Abbreviations: ND: non data, NS: neurosarcoidosis, S: Sarcoidosis

Figure 1. Trends in age at neurosarcoidosis diagnosis in Cantabria, Spain, in 1999-2019 by gender

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**Figure 1.** Frequency of osteonecrosis of femoral head among rheumatic musculoskeletal diseases

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**POS0959**

**PERSISTENCE ON TREATMENT AND SAFETY OF TNF-ALPHA INHIBITORS BIOSIMILARS COMPARED TO ORIGINATORS: AN OBSERVATIONAL STUDY ON THE FRENCH NATIONAL HEALTH DATA SYSTEM**

**Keywords:** Real-world evidence, Safety, biOMARD

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**Background:** Anti TNF-alpha drugs have revolutionized the management of immune-mediated inflammatory diseases (IMIDs). Since 2015, several biosimilar products have been marketed and reimbursed after the expiry of the originator patents of infliximab (IFX), etanercept (ETA) and adalimumab (ADA), reducing the cost of these treatments. Equivalence, i.e. efficacy and safety, between biosimilar and originator products is generally demonstrated in a randomised phase 3 trial in one indication, and then extrapolated to other indications.

**Objectives:** To compare the persistence and assess the safety profile of biosimilar products compared to originator product of IFX, ETA, and ADA in treatment initiators in all the licensed indications.

**Methods:** We used data from the French National Health Data System to identify IFX, ETA and ADA initiators from the date of marketing in France of the first biosimilar of each molecule (01/2015, 05/2016 and 10/2018 respectively) and until 30 June 2021. Patients were then followed during one year. Treatment persistence was defined as the duration without treatment discontinuation (60 days gap plus theoretical coverage of the molecule without treatment delivery) or modification (for another biologic treatment), censoring the follow-up at 1 year of follow-up, death or intra-molecule comparison originator and biosimilar event rates. Various sensitivity analyses were carried out: 2-year follow-up, gap modification for discontinuation definition, intra-molecule switch defined as at least 3 consecutive deliveries of another product, restricting the analysis to at least 6-month persistent patients, and classifying the biosimilar to originator switch as an outcome and not a censoring event.

**Results:** A total of 86,776 patients were included in the study (22,670, 24,442 and 39,664 IFX, ETA and ADA initiators respectively). Within molecules, subject characteristics at inclusion were very similar between originator and biosimilar products. After weighting, the hazard ratios (HR) and relative risks of treatment discontinuation or modification in biosimilar versus originator products were close to 1 or below 1, with confidence intervals covering 1, except for ADA ABP501 which showed a minor increased risk of non-persistence compared to ADA originator in inflammatory bowel diseases (HR 1.24 [1.09-1.41] and 1.22 [1.03-1.44] in CD and UC). Crude adverse event rates were very similar between biosimilars and originator products. All sensitivity analyses were consistent with the main results.

**Conclusion:** Our study shows reassuring results regarding the persistence and safety of biosimilars compared to the originator anti-TNF alpha product in all licensed indications. Further studies need to be carried out to confirm these results, and to investigate the switch context.

**REFERENCES:**

Disclosure of Interests: None Declared.

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**POS0960**

**INCREASED INCIDENCE OF SJÖGREN’S SYNDROME IN THE FEMALE PATIENTS WITH HASHIMOTO THYROIDITIS: A LARGE PROPENSITY SCORE-MATCHED COHORT STUDY**

**Keywords:** Epidemiology, Sjögren syndrome, Comorbidities

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**Background:** In clinical practice, we notice that Sjögren’s syndrome (SS) usually coexists with Hashimoto thyroiditis (HT). There were a lot of case reports regarding the coexistence of SS and HT.

**Objectives:** To determine whether Hashimoto thyroiditis (HT) is a risk factor of Sjögren’s syndrome (SS) longitudinally in a very large cohort.

**Methods:** We conducted a cohort study using TriNetX (Cambridge, MA, USA), a global federated health research network that provides real-time electronic medical record datasets. The diagnosis of HT or SS was based on ICD10 codes. We analyzed the incidence of newly diagnosed SS in the female patients with HT within ten years. Propensity score matching including 38 factors was performed to adjust for demographic variables, comorbidities, and medication use. Kaplan-Meier analysis was used to estimate the probability of the outcome of interest. The hazard ratio (HR) and associated confidence intervals (CI) were calculated along with the proportionality test using R’s Survival Package v3.2-3.

**Results:** We identified 101,590 female patients aged 20-64 years with HT among 54,801,179 patients in the database with ≥ 2 visits between 2012/01/01–2021/12/31. Of these patients, 100,027 were included after exclusion those diagnosed with SS before index date. The control cohort was selected from those females without thyroid disorders or related therapy. After 1:1 propensity score matching, 100,027 patients in either HT or control cohort were analyzed for comparison. After one-year follow-up, the incidence (0.51%) of new cases of SS in the HT cohort was higher than that (0.098%) in the control cohort (HR 4.324, 95% CI 3.483-5.368). During the study period, higher incidence of SS in the HT cohort (1.16%) than in the control cohort (0.36%) was found (HR 3.557 , 95% CI 3.151-4.016). Increased incidences of SS in HT cohort were also confirmed in the subgroups of different ages, races and smoking status, and subgroups with or without diabetes mellitus, overweight/obesity, sleep disorder, depression, hypertension and asthma (Figure 1).

**Conclusion:** This study underlines that HT is a risk factor for developing SS, which implies that SS and HT are 2 autoimmune diseases closely related, and may share some underlying pathophysiological mechanisms.

**REFERENCES:**
