was good in 64% (n = 25), reaching remission in 17 (31%) of the patients, and moderate response in 21% (n = 8) of them (Figure 1). Only 2 (4%) patients were treated with GCC at the end of the follow-up, p<0.0001 compared to baseline. The daily dose of PDM at the end of follow-up was 6 mg in a case and 12 mg in the other, p<0.0001 compared to baseline. At the end of the follow-up 24% of the patients (n = 13) changed or discontinued the drug: 9 changed due to secondary failure, 2 suspended due to adverse events, 1 due to death due to prior neoplastic process and 1 due to complete disease remission. Survival at 1, 2, 3, 4, 5, 6 and 7 years was 92%, 92%, 82% 78%, 75%, 75% and 65% respectively; with a mean survival rate of 90 months (Figure 1).

Conclusion: The results of our analysis show that patients with RA undergoing RTX treatment have adequate control show of disease activity and drug survival rates, like published data. RTX treatment allowed stopped GCC treatment in 31 cases (90%).

References:

Disclosure of Interests: Gonzalo Jurado Quijano: None declared, Lila Fernández de la Fuente: None declared, Blanca Hernández-Cruz: Speakers bureau: Sociedad Española de Reumatología, Abbvie, Roche, Bristol, MSD, Lilly, Pfizer, Agen, Sanofi, Consultant of: Abbvie, Lilly, Sanofi, STADA, UCB, Grant/research support from: Fundación para la Investigación Sevilla, Junta de Andalucía, Fundación Andaluza de Reumatología, Paloma Muñoz Reinoso: None declared, Vicente Merino Bohóquez: None declared, José Javier Pérez Venegas: None declared.

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AB0214 SURVIVAL, EFFICACY AND SAFETY OF GOLIMUBAB IN PATIENTS WITH RHEUMATOID ARTHRITIS AND SPONDYLOARTHITIS: DATA FROM AN ARGENTINEAN COHORT


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Background: Golimumab is a human monoclonal antibody directed against TNFα in its soluble and transmembrane forms. It can be used subcutaneously or intravenously and has shown efficacy for use in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Golimumab treatment in real life patients in Argentina has shown good efficacy and safety. Drug survival was over 4 years and almost 80% were still using golimumab after one year. Prior treatment with other b-DMARDs or small molecules was associated with lower treatment survival.

Objective: The aim of this study was to evaluate the efficacy, safety, and cumulative survival of golimumab in patients with RA, PsA and AS from different rheumatology centers in Argentina.

Methods: We performed a longitudinal study of consecutive adult patients with RA (ACR/EULAR 2010 criteria), PsA (CASPAR criteria) and AS (ASAS 2009 criteria), who have started treatment with subcutaneous or intravenous golimumab according to medical indication in each center. Data was obtained by review of medical records. Sociodemographic and clinical data, musculoskeletal manifestations, comorbidities, previous treatments were recorded. In reference to golimumab treatment, start date, route of administration and concomitant treatments were identified. Disease activity was assessed using DAS28 for RA patients, DAPSA and MDA for PsA and BASDAI for AS. The presence of adverse events (AE) was recorded. If golimumab was stopped, date and cause was documented. Patients were followed up until golimumab discontinuation, loss of follow-up, or study completion (November 30, 2020). Statistical analysis: Chi2 test or Fisher exact test and T test or Mann Whitney and ANOVA or Kruskal Wallis, as appropriate. The incidence of EA was assessed in events every 100 patient/year. Kaplan-Meier curves and log Rank analysis. Cox proportional regression.

Results: One hundred eighty two patients were included, 116 with a diagnosis of RA, 5 with PsA and 35 with AS (70%) were women. Patients had a median (m) age of 55 years (IQR 43.8-64) and m disease duration of 7 years (IQR 4-12.7) at treatment initiation. At least one prior biological DMARD or a small molecule was received by 63 patients (34.6%). The most frequent indication cause was conventional DMARD failure. In 84.8% of the patients Golimumab was administered subcutaneously, and in 80.6% in association with conventional DMARDs, the most frequently used was methotrexate. Total follow-up was 318.1 patients/year.

Golimumab treatment showed clinical improvement in all three groups of patients. In RA patients DAS28 significantly decreased during the first 12 months of follow-up, m 5.9 (IQR 4.9-6.6) at baseline, 3.8 (IQR 2.6-4.8) at 6 months and 2.8 (IQR 2.1-3.6) at 12 months, p <0.0001. In PsA, m DAPSA-ESR value was 32.2 (IQR 24.2-47.7), 10.1 (IQR 5.8-18.3) and 11.2 (IQR 3.4-24) at baseline. 6 adventuates of 7 patients received Golimumab in a biological (p <0.0001). In AS, m BASDAI was 6.2 (IQR 4-7.3) 2.8 (IQR 1.7-4.1) and 2.2 (IQR 1.1-3.2), at baseline, 6 and 12 months respectively (p <0.0001).

The incidence of adverse events was 6.6 per 100 patients/year, being infections the most frequent ones. During follow-up, 50 patients (27.5%) discontinued golimumab, the most frequent cause was treatment failure (68%), followed by lack of health insurance (16%) and adverse events (10%). Golimumab persistence was 79% and 57% at 12 and 24 months, respectively. Treatment survival was 50.2 months (95% CI 44.4-55.9). Patients who had received prior treatment with biological DMARDs or small molecules showed lower survival (Figure 1). In the multivariate analysis, adjusting for age, sex and disease duration, those patients showed twice the risk of suspending treatment (HR 2.01, 95% CI 1.4-3.7).

Conclusion: Golimumab treatment in real life patients in Argentina has shown good efficacy and safety. Drug survival was over 4 years and almost 80% were still using golimumab after one year. Prior treatment with other b-DMARDs or small molecules was associated with lower treatment survival.

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AB0215

COMPARISON BETWEEN RITUXIMAB ORIGINATOR THERAPY AND ITS BIOSIMILAR IN THE INCIDENCE OF LATE-ONSET NEUTROPNENIA IN ADULT PATIENTS WITH RHEUMATOID ARTHRITIS AND OTHER AUTOIMMUNE DISEASES

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Background: Late-onset neutropenia (LON) occurs when the absolute neutrophil count drops below 1.5 x 10⁹/L four weeks after Rituximab infusion.¹ It is a condition recognised more in haematological malignancy patients treated with Rituximab with a reported prevalence of 8% or higher. ² LON was reported in condition recognised more in haematological malignancy patients treated with 6.5% of rheumatological patients¹, while a French registry found a prevalence of 1.3% in rheumatoid arthritis patients.³

Almost all patients receiving Rituximab originator therapy at our Rheumatology department were switched to its biosimilar starting from November 2017. Our haematology team observed LON cases in their patients after this period.

Objectives: We wanted to establish whether there is increased LON occurrence with the biosimilar than the originator therapy, requiring specific monitoring.

Methods: This is a cross-sectional retrospective review of 12 months period before and after switching to the biosimilar of all patients who received Rituximab for the first time. We reviewed the patients’ blood monitoring for up to 12 months after receiving Rituximab. We used a proforma to collect the age, sex, diagnosis, date of the first infusion, use of other DMARDs, LON occurrence within 12 months after the infusion and neutropenia within the 12 months before it in addition to the frequency of the blood monitoring after the infusion.

Results: For the originator, between 1/1/2016 and 31/12/2016, 142 patients received Rituximab, 47 (33.09%) of them were given the treatment for the first time. Their median age was 62 years, 28 (59.5%) were females. The most common diagnosis was rheumatoid arthritis 38 (80.8%), and 35 (74.4%) patients were on other disease-modifying agents (DMARDs). Two patients (4.2%) developed LON. One patient (2.77%) developed grade 2 LON one month after Rituximab. Another patient with known autoimmune neutropenia was excluded. In all the Three patients with LON in both groups, neutrophil count recovered in less than a month, and they had normal IgG before the infusion.

The frequency of blood monitoring after Rituximab infusion was done 1-3 monthly in 32 (68%) patients and 23 (63.8%) patients in the originator and biosimilar groups, respectively.

Four (8.5%) patients and three (8.3%) patients in the originator and biosimilar groups respectively had a frequency of blood monitoring done less than six-monthly.

Conclusion: In our patients’ cohort, LON incidence following switching to the Rituximab biosimilar was not higher than the originator therapy.

References:

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Figure 1. Changes of the disease activity during follow-up

Table 1. Changes of the main inflammatory activity measures, Me [25th; 75th percentile]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>0</th>
<th>12 months</th>
<th>6 years</th>
</tr>
</thead>
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<tr>
<td>SDAI</td>
<td>28.27 [18.79; 40.73]</td>
<td>5.67 [2; 11.98]</td>
<td>15.06 [9.32; 21]</td>
</tr>
<tr>
<td>ESR (mm/hr)</td>
<td>32 [19; 50]</td>
<td>16 [8; 30] *</td>
<td>16 [10; 25] *</td>
</tr>
<tr>
<td>CRP (mg/l)</td>
<td>26.55 [6.4; 45.30]</td>
<td>3.85 [1.5; 11.3] *</td>
<td>2.2 [0.9; 4.8] *</td>
</tr>
</tbody>
</table>

* p<0.05 in all cases.

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