Methods: Patient demographics, disease characteristics and medication history were collected. Patients starting treatment either with biological Disease-Modifying Anti-Rheumatic Drugs (bDMARDs) or targeted synthetic (ts)DMARDs (baricitinib, tofacitinib, upadacitinib and filgotinib) were included in the analysis. Data were extracted from the GISEA (Gruppo Italiano di Studio sull’Early Arthritis) registry.

Results: From January 2018 to December 2022 overall 4424 patients with RA were included in the GISEA registry (3622 F: 802 M, mean age 57.9±12.8 years, mean disease duration 12.9±9.8 years). Overall, the number of patients starting bDMARDs and tsDMARDs in 2018, 2019, 2020, 2021 and 2022 was 725, 784, 1204, 794 and 913, respectively; 306 (42%), 319 (40,7%), 278 (23%), 291 (36.6%) and 335 (36.7%) started a JAK inhibitor. Figure 1 summarizes the prescription pattern of bDMARDs and tsDMARDs during the 5 years of observation (A) and the percentage of patients starting each JAK inhibitor (B). The prescription of JAK inhibitors was stable from 2018 to 2022 with the only exception of 2020 (coinciding with the beginning of the pandemic) when we recorded a significant decrease in JAK inhibitors prescribed (p<0.00001 vs 2019) and a significant increase in the number of patients treated with abatacept (from 12.1% to 17.1%, p=0.0024) and anti-IL-6R (from 16.3% to 23.7%, p=0.000067). Conversely, in 2021 the number of patients who started JAK inhibitors significantly increased (p<0.00001 vs 2020) and those starting anti-IL-6R significantly decreased (from 23.7% to 13.4%). From 2018 to 2022 the percentage of bDMARD-naive patients increased, without reaching a statistical significance, from 30.7%, 36%, 43.5%, 44.4%, 40.3% of patients starting a JAK inhibitor after MTX-failure (Figure 1C).

Conclusion: The use of JAK inhibitors for treating RA of patients in Italy is stable from 2018 onward with a shift towards an earlier line of treatment and a significant change in the prescription pattern within the class over time.

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POS0863 BARISUR STUDY: DESCRIPTIVE STUDY OF BARicitinib SAFETY IN SPANISH PATIENTS WITH RHEUMATOID ARTHRITIS

Keywords: Safety, Rheumatoid arthritis, Descriptive studies

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Background: Baricitinib (BCT) and tofacitinib (TFC) are the most widely used JAK inhibitors worldwide and both were approved in Spain in 2017. Data from Oral Surveillance showed in 2021 an increased risk of malignancies and major adverse cardiovascular events (MACEs) in patients treated with TFC versus anti-TNF drugs. However, there is no clear position among rheumatologists regarding the risk of MACE, thromboembolic events (TEE) or other safety concerns of JAK inhibitors. Although JAK inhibitors have a common mechanism of action, each drug has specificities such as selective affinity to different targets, pharmacodynamics, metabolism and dosing, conferring differences between drugs. Therefore, it is to be expected that the safety profile may be different.

Objectives: The aim of this study is to collect real world data from Spanish patients to analyze efficacy trends, daily use patterns and a descriptive analysis of the safety profile of rheumatoid arthritis treatments in southern Spain.

Methods: A multicenter, observational, retrospective study was conducted, collecting data from patients with rheumatoid arthritis previously treated with methotrexate (MTX) and other prior biologic therapies.

Results: Data from 270 patients were analyzed, 73% were female, the mean age was 58 years (SD: 12.7) and the mean age at diagnosis was 47 years (SD:14.33). Of the population, 95.1% had some risk factor for MACE or TEE; specifically 75% had previous cardiac events, 2.6% and 9.4% had previous TEE and malignancies, respectively. The distribution of baseline treatment is shown in the Table 1. Median use of prior disease-modifying treatments (DMT) was 1 for the total population, but 2 for BCT patients. BCT patients had 10.5 (SD: 9.0) mean years of disease progression and initiated treatment at 57 (SD: 12.25) years mean age. After the first 12 months of follow-up, there was a trend towards reduce the use of NSAIDs (28.9% to 24.2%), prednisone 85% to 58.4%) and MTX (46.2% to 36.6%). Simultaneously, Disease Activity Score 28 (DAS28), VSG and PCR also decreased during the period from 4.92 (SD:0.84), 24.41 (SD: 15.78) mm/h and 11.89 (SD:9.69) mg/l to 3.06 (SD: 1.13), 20.79 (SD: 13.31) mm/h, and 8.21 (SD: 9.14) mg/l respectively. BCT safety profile was well tolerated, with 33 adverse events at 6 months of follow-up and 3 serious adverse events (TEE, pneumonia and stroke) during the period. Of BCT population, 576% stopped treatment due to toxicity or lack of efficacy.

Conclusion: Taking into account the heterogeneity and the age of our population, these preliminary results showed low risk of MACE and cancers with BCT for the Spanish cohort. Future analysis is guarantee in order to understand the safety profile in the long term.

REFERENCES:


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POS0864 EFFECTIVENESS OF ANTIFIBROTICS IN RHEUMATOID ARTHRITIS-INTERSTITIAL LUNG DISEASE. NATIONAL MULTICENTER STUDY OF 50 PATIENTS IN CLINICAL PRACTICE

Keywords: Lungs, Rheumatoid arthritis, Descriptive studies
Background: Interstitial lung disease (ILD) is a severe complication of rheumatoid arthritis (RA). Abacatcept and rituximab are the preferred disease-modifying antirheumatic drugs (DMARDs) for RA-ILD [1-4]. However, progression of ILD despite its use is not uncommon. A subgroup analysis of the INBUILD trial has shown a slower decline in forced vital capacity (FVC) in patients with progressive fibrosing autoimmune disease-related ILDs with the antifibrotic nintedanib (NINTE) [5].

Objectives: A) To assess the efficacy of antifibrotic drugs, NINTE and pirfenidone (PIRFE), in Spanish RA-ILD patients with a progressive phenotype in clinical practice. B) To compare the profile of clinical practice RA-ILD patients with the RA-ILD patients included in the INBUILD trial [5].

Methods: National multicenter study of RA-ILD patients to whom NINTE or PIRFE were added due to progressive fibrosing ILD. Demographic and clinical variables were collected from all patients. These features were compared with those of RA-ILD patients included in the INBUILD trial (n=45, 42 treated with NINTE and 47 with placebo). Forced vital capacity (FVC) evolution was the primary endpoint. Results are expressed as percentage, mean±SD or median [IQR].

Results: A total of 50 patients (19 women/31 men) from clinical practice were collected (NINTE=45, PIRFE=5), mean age 70±8 years. Median ILD duration up to antibiotic initiation was of 45 [19-72] months. Mean FVC one year before antifibrotic start was 81±20 % (p < 0.05), whilst mean baseline FVC was 72±23 % (p < 0.05). Comparison of baseline characteristics of RA-ILD patients treated with NINTE in clinical practice (n=45) and RA-ILD patients of the INBUILD trial is shown in Table 1. The evolution of FVC and DLCO in our patients from the previous year of antifibrotic initiation is shown in Figure 1. After a median follow-up of 16 [5-24] months, no decline in mean FVC and DLCO values was observed. Stabilization or improvement of dyspnea was found in 83% of patients. NINTE was withdrawn in 8 patients due to: gastrointestinal adverse events (GAE) (n=6), Death (n=1) or hemorrhagic risk (n=1). PIRFE was withdrawn in 2 patients due to GAE.

Conclusion: Antifibrotics, specially NINTE, seem to slow ILD progression in patients with RA-ILD. In clinical practice, patients are treated later in the evolution of the disease, but results are satisfactory. Combination of antifibrotics and DMARDs in RA-ILD is possible and safe.

REFERENCES:

Table 1. Baseline characteristics of RA-ILD patients treated with NINTE in clinical practice and RA-ILD patients of the INBUILD trial.

<table>
<thead>
<tr>
<th>Clinical practice</th>
<th>INBUILD trial (n=89, 42 NINTE vs 47 PCB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>mean±SD</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>18 (40)</td>
</tr>
<tr>
<td>Smoker ever, n (%)</td>
<td>34 (76)</td>
</tr>
<tr>
<td>Time since ILD diagnosis, years mean±SD</td>
<td>72±24</td>
</tr>
<tr>
<td>RF, n (%)</td>
<td>40 (89)</td>
</tr>
<tr>
<td>ACPA, n (%)</td>
<td>34 (76)</td>
</tr>
<tr>
<td>FVC (% pred) means±SD</td>
<td>72±24</td>
</tr>
<tr>
<td>DLCO (% pred) means±SD</td>
<td>51±15</td>
</tr>
<tr>
<td>Dyspnea mMRC median [IQR]</td>
<td>2 [2-3]</td>
</tr>
<tr>
<td>UPL-like fibrotic pattern on HRCT, n (%)</td>
<td>31 (69)</td>
</tr>
<tr>
<td>Concomitant IS therapy, n (%)</td>
<td>45 (100)</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>34 (76)</td>
</tr>
<tr>
<td>cDMARDS</td>
<td>14 (31)</td>
</tr>
<tr>
<td>bDMARD</td>
<td>19 (42)</td>
</tr>
<tr>
<td>JAKI</td>
<td>4 (9)</td>
</tr>
</tbody>
</table>

Figure 1. Evolution of FVC and DLCO in patients with RA-ILD treated with antifibrotics in clinical practice from the previous year of initiation.

Keywords: Rheumatoid arthritis, Disease-modifying drugs (DMARDs) H. Ramón de Dios (HU Araba), Líbe Ibarrola (HU de Navarra), Carmen González Montagut (HCU de Valladolid), Sergi Ordoñez (H. Arnuán de Villanueva), Ana Mª Brandy (HU Cuabueses), Fernandino Lozano (HCD Gómez Ulla), María López Lasanta (HU Vall d'Hebron), Cristina Campos (CHGU de Valladura), María Garjo (HU de Sagunto), Ivette Casabot (HU Germans Trias i Pujol), Mónica Caldentón (H. José Molina Orosa), Carlota Iñiguez (HU Lucus Augusti), Francisco Ortiz-Sanjuán (HUP La Fe), Emílio Giner (H. Royo Villanova), Ignacio Braña (HU Central de Asturias).

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POS0865 THE CORRELATION BETWEEN FOUR ADHERENCE MEASUREMENTS METHODS IN PATIENTS WITH RHEUMATOID ARTHRITIS USING METHOTREXATE

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Background: Methotrexate (MTX) is the cornerstone in the pharmacological treatment of rheumatoid arthritis (RA) patients. However, medication adherence to MTX is not ideal, which might lead to suboptimal treatment outcomes. Consequently instruments to assess medication non-adherence are warranted to detect and intervene on non-adherence. To date there is no consensus on the best method to determine adherence to MTX.

Objectives: The aim of this study was to assess the correlation between compliance measured with MEMS (gold standard) versus pill count, MTX-polyglutamate (PG) concentration and Compliance Questionnaire Rheumatology (CQR) in patients with established RA. Second, correlations between these methods and the Disease Activity Scores of 28 joints (DAS28) were examined.

Methods: Adult patients with established RA treated with MTX were included. Multivariable linear and logistic regression were used, with taking compliance assessed with MEMS as dependent variable versus pill count, MTX-PG concentrations, CQR, as independent variables, and DAS28 score versus each of the 4 adherence measurements methods. Comedication, age and use of corticosteroids and NSAIDs were included as covariates in the analysis.

Results: 190 consecutive RA patients were included. Median follow-up time was 4.9 months (IQR 3.6 – 6.2). Pill count correlated with taking compliance assessed with MEMS (linear regression, β = 0.690, p < 0.001), whereas MTX-PG concentrations and CQR were not. Logistic regression only confirmed the correlation between dichotomized taking compliance MEMS and pill count [β = 5.64, p < 0.001].

Appendix