Data collected from each study was: Author and year of publication of the study, study design and population included, number of patients treated, treatment administered and percentage of patients treated for HZ in each treatment arm.

Results: Results: In clinical trials of these drugs, a greater number of opportunistic infections due to varicella zoster virus have been identified compared to placebo, which leads to the appearance of HZ.

The role of different JAKs in the immune response may suggest differences in safety profiles between these drugs, which could have clinical implications. Therefore, we analyze the results separately for each JAK:

Tofacitinib: Of the 14 selected works, 4 are phase II, 8 phase III and 2 extension studies. We observe that the incidence of HZ ranges between 1% and 11%, the latter being the case of the Wollenhaupt extension study with a data collection period of nine and a half years. It is remarkable that in some of the studies included in this review there was no case of HZ and in others this information was not even collected.

Barcitnib: Two phase II studies, 6 phase III studies and one extension study were analyzed, with an incidence of HZ between 1% and 8%, data similar to those obtained with tofacitinib.

Upadactinib: An incidence of HZ between 1% and 4% was observed according to the 6 clinical trials (two phase II studies and four phase III studies) published as clinical product development.

Filgotinib: Data similar to upadactinib, with frequencies between 1% and 4% of HZ according to the studies (three phase II studies and one phase III study).

Peficitinib: The incidence of HZ ranged between 4% and 7.5% (three phase III studies, two phase III studies, and one extension study).

Decertinib: There are only published three phase II trials, of short duration and with only 4% of cases collected from HZ.

Conclusion: Conclusions: Opportunistic HZ infection have been reported between 1% and 11% in JAKI clinical trials. The results of the included studies seem to suggest that selective JAK1 inhibitors (Upadacitinib and Filgotinib) develop HZ as a treatment complication less frequently than other JAKi, but more studies are needed to support this conclusion.

Disclosure of Interests: Carmen Olga Sánchez González: None declared, Juan Carlos Nieto Speakers bureau: Pfizer, Abbvie, MSD, Novartis, Janssen, Lilly, Nordic Pharma, BMS, Gebro, FAES Farma, Roche, Sanofi

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THU0150 INTERSTITIAL LUNG DISEASE RELATED TO RHEUMATOID ARTHRITIS. WHAT DO WE DON'T KNOW? THE LIRA STUDY (LUNG INVOLVEMENT IN RHEUMATOID ARTHRITIS).

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Background: Interstitial lung disease (ILD) is one of the more frequent and potentially severe extra-articular manifestation of rheumatoid arthritis (RA). ILD significantly decreases the survival and quality of life of patients and influences the treatment approach to the patient.

Despite its clinical relevance, the prevalence, incidence and survival of RA-ILD is unknown and supposed on the base of retrospective data or registry-based studies.

Objectives: For the first time, the Lung Involvement in Rheumatoid Arthritis (LIRA) study aims to investigate epidemiology, features and prognosis of RA-ILD patients in a prospective international multicentre study.

Methods: All RA patients referring to the involved centres will be evaluated every six months with a digital stethoscope and a software able to identify velcro crackles with a diagnostic accuracy of 83.9% (VECTOR). In fact, velcro crackles are virtually identified in all stages of fibrosing alveolitis like RA-ILD, and their search is as a simple and reliable method to screening patients to be undergone to high resolution computed tomography (HRCT).

For each patient, clinical and serological data are recorded at baseline and every six months; when velcro crackles or other conditions suspicious for ILD, such as cough or dyspnoea, are detected, a HRCT is requested to confirm ILD. Patients
with ILD periodically perform pulmonary function tests to monitor lung function evolution.

**Results:** At now, 205 RA patients have been enrolled (female/male 161/44, mean age 64.8±12.9 years, mean disease duration 14.2±8.9 years), anti-citrullinated peptides antibodies (ACPA) and rheumatoid factor (RF) were positive in 77.1% and 78.1%, respectively. The prevalence of ILD was 21% (43 patients).

In other 13 patients the HRCT is ongoing; therefore, we could suppose up to a prevalence of 27.3%. Patients with ILD were symptomatic in 53.3% of cases (23 patients), they are more frequently males and were older than patients without ILD (mean age 73.2±7.4 and 62.7±13.2; p<0.0001, female/male ratio 139/23 vs 22/21; p<0.0001) without significant differences regarding disease duration, positivity for ACPA or RF.

**Conclusion:** The prevalence and the incidence of RA-ILD is still not well defined. Preliminary data of our study confirm a prevalence of ILD higher than 20%, patients are asymptomatic in almost the half of cases and more frequently males and elderly. Our study can help to define the clinical history of these patients, the possible association with clinical and serological features and the supposed role of some drugs.

**References:**


**Disclosure of Interests:** Marco Sebastiani: None declared, Caterina Vacchi: None declared, Giulia Cassone: None declared, Fabiola Atzeni: None declared, Martina Biggioggero: None declared, Antonio Carriero: None declared, Gian Luca Erro: None declared, Anna Laura Fedele: None declared, Federica Furniti: None declared, Paola Tomietto: None declared, Vincenzo Venerito: None declared, Belén Atienza-Mateo: None declared, Giovanni Della Casa: None declared, Stefania Cerri: None declared, Adalgisa Palermo: None declared, Elena Galli: None declared, Fabrizio Pancaldi: None declared, Miguel A Gonzalez-Gay Grant/research support from: Pfizer, Abbvie, MSD.

**Background:** Objectives: To estimate the incidence rate of malignancies in csDMARD-treated RA patients and to compare it to that of general population and to biologic-treated RA patients.

**Methods:** We conducted an historical cohort study within the national claim database that prospectively records individual health resource use of 86% of the French population (65 million inhabitants). RA adult patients were identified based on ICD-10 code (M05 or M06) between 2007-2016. Patients with previous cancer history were excluded. Treatment exposures were incident first use of any treatment: csDMARD (methotrexate, leflunomide, sulfasalazine, azathioprine, hydroxychloroquine) or biologics (anti-TNF, rituximab, abatacept, tocilizumab, ustekinumab, anakinra). To identify incident treatment periods, only patients who did not receive any treatment in the 1-year period before the index date were selected. Exposure was defined with a 90-day latency after treatment initiation and a 180-day carry-over period after drug discontinuation.

To compare the risk of malignancies between csDMARD-treated patients and general population, standardized incidence ratio (SIR [95%CI]) were calculated using FRANCIM ("France Cancer Incidence et Mortalité") estimations as reference.

To compare the risk of malignancies between csDMARD and biologics treated patients, a dynamically propensity score (including age, sex, year of first occurrence of RA code, date of treatment initiation, number of previous DMARDs, Charlson’s comorbidity index, diagnosis of tobacco and/or alcohol-associated disorders, number of hospitalizations for RA, cumulative corticosteroid dose) was constructed using pooled logistic regression. Hazard Ratios (HRs) for risk of cancer were estimated using Cox proportional hazards model after dynamically propensity score matching. Exposure was considered as a time-dependent variable.

**Results:** Between 2007 and 2016, 83,706 RA patients exposed to csDMARD (n=63,837) and/or biologics (n=19,727) were identified.

As compared to the general population, csDMARD treated patients had an increased risk of lung cancer (SIR=1.29 [1.14; 1.45]), invasive melanoma (SIR=1.52 [1.24; 1.86]) and a borderline increased risk of breast cancer (SIR=1.11 [1.01;1.22]). By contrast, they had a decreased risk of pancreatic cancer (SIR=0.68 [0.51;0.9]) and liver cancer (SIR=0.43 [0.27; 0.67]). This later is due to a protopathic bias.

**Conclusion:** Using a large nationwide representative healthcare database, the overall risk of malignancies and the risk of organ-specific cancers and hematologic malignancies in biologic treated RA patients did not differ from that of patients treated with csDMARD. Compared to general population, patients treated with csDMARD had an increased risk of lung cancer and melanoma, but a decreased risk of pancreatic cancer.

**Disclosure of Interests:** Raphaaele Seror Consultant of: BMS, Medimmune, Novartis, Pfizer, GSK, Lilly, Alexandre Lafourcade: None declared, yann de-rycke: None declared, Bruno Fautrel Grant/research support from: Abbvie, Lilly, MSD, Pfizer, Consultant of: Abbvie, Biogen, BMS, Boehringer Ingelheim, Celgene, Lilly, Janssen, Medac MSD France, Nordic Pharma, Novartis, Pfizer, Roche, Sanofi Aventis, SOBI and UCB, Xavier Mariette Consultant of: BMS, Gilead, Medimmune, Novartis, Pfizer, Servier, UCB, Florence Tubach Grant/research support from: Florence TUBACH is head of the Centre de Pharmacopédiologie (Cephepi) of the Assistance Publique – Hôpitaux de Paris and of the Clinical Research Unit of Pitié-Salpêtrière hospital, both these structures have received research funding, grants and fees for consultant activities from a large number of pharmaceutical companies, that have contributed indiscriminately to the salaries of its employees. Florence Tubach didn't receive any personal remuneration from these companies.

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**THU0151**

**RISK OF MALIGNANCIES ASSOCIATED WITH CS DMARDS IN RHEUMATOID ARTHRITIS: COMPARISON WITH GENERAL POPULATION AND BIOLOGIC TREATED PATIENTS (ANALYSIS OF A NATIONAL CLAIM DATABASE)**


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**Background:** Objectives: To estimate the incidence rate of malignancies in csDMARD-treated RA patients and to compare it to that of general population and to biologic-treated RA patients.

**Methods:** We conducted an historical cohort study within the national claim database that prospectively records individual health resource use of 86% of the French population (65 million inhabitants). RA adult patients were identified based on ICD-10 code (M05 or M06) between 2007-2016. Patients with previous cancer history were excluded. Treatment exposures were incident first use of any treatment: csDMARD (methotrexate, leflunomide, sulfasalazine, azathioprine, hydroxychloroquine) or biologics (anti-TNF, rituximab, abatacept, tocilizumab, ustekinumab, anakinra). To identify incident treatment periods, only patients who did not receive any treatment in the 1-year period before the index date were selected. Exposure was defined with a 90-day latency after treatment initiation and a 180-day carry-over period after drug discontinuation.

To compare the risk of malignancies between csDMARD-treated patients and general population, standardized incidence ratio (SIR [95%CI]) were calculated using FRANCIM ("France Cancer Incidence et Mortalité") estimations as reference.

To compare the risk of malignancies between csDMARD and biologics treated patients, a dynamically propensity score (including age, sex, year of first occurrence of RA code, date of treatment initiation, number of previous DMARDs, Charlson’s comorbidity index, diagnosis of tobacco and/or alcohol-associated disorders, number of hospitalizations for RA, cumulative corticosteroid dose) was constructed using pooled logistic regression. Hazard Ratios (HRs) for risk of cancer were estimated using Cox proportional hazards model after dynamically propensity score matching. Exposure was considered as a time-dependent variable.

**Results:**

<table>
<thead>
<tr>
<th>Type of malignancies</th>
<th>HR [95%CI] csDMARD vs biologics</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All malignancies (excl. non-melanoma skin cancer)</td>
<td>0.99 [0.86;1.14]</td>
<td>p&lt;0.9</td>
</tr>
<tr>
<td>Solid cancer (excl. non-melanoma skin cancer)</td>
<td>0.95 [0.82;1.11]</td>
<td>p=0.5</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>1.35 [0.72;2.53]</td>
<td>p=0.3</td>
</tr>
<tr>
<td>Other hematologic malignancies</td>
<td>1.18 [0.56;2.46]</td>
<td>p=0.7</td>
</tr>
</tbody>
</table>

**Conclusion:** Using a large nationwide representative healthcare database, the overall risk of malignancies and the risk of organ-specific cancers and hematologic malignancies in biologic treated RA patients did not differ from that of patients treated with csDMARD. Compared to general population, patients treated with csDMARD had an increased risk of lung cancer and melanoma, but a decreased risk of pancreatic cancer.

**Disclosure of Interests:** Raphaæle Seror Consultant of: BMS, Medimmune, Novartis, Pfizer, GSK, Lilly, Alexandre Lafourcade: None declared, yann de-rycke: None declared, Bruno Fautrel Grant/research support from: Abbvie, Lilly, MSD, Pfizer, Consultant of: Abbvie, Biogen, BMS, Boehringer Ingelheim, Celgene, Lilly, Janssen, Medac MSD France, Nordic Pharma, Novartis, Pfizer, Roche, Sanofi Aventis, SOBI and UCB, Xavier Mariette Consultant of: BMS, Gilead, Medimmune, Novartis, Pfizer, Servier, UCB, Florence Tubach Grant/research support from: Florence TUBACH is head of the Centre de Pharmacopédiologie (Cephepi) of the Assistance Publique – Hôpitaux de Paris and of the Clinical Research Unit of Pitié-Salpêtrière hospital, both these structures have received research funding, grants and fees for consultant activities from a large number of pharmaceutical companies, that have contributed indiscriminately to the salaries of its employees. Florence Tubach didn’t receive any personal remuneration from these companies.

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**THU0152**

**THE ADVANTAGES OF DISTANCE BLOOD PRESSURE MONITORING IN PATIENTS WITH RHEUMATOID ARTHRITIS**

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**Background:** Cardiovascular complications are very common in patients with rheumatoid arthritis (RA). The monitoring of the course of RA and comorbid conditions is the key aspect of the prevention of early mortality.