REFERENCES

- [1] Clowse, et al. Effects of Infertility, Pregnancy Loss, and Patient Concerns on Family Size of Women With Rheumatoid Arthritis and Systemic Lupus Erythematosus. *Arthritis Care & Research*.2012; 64 (5):668–674
- [2] Vinet et al. Systemic Lupus Erythematosus in Women: Impact on Family Size. *Arthritis & Rheumatism (Arthritis Care & Research)*.2008; 59 (11):1656–1660

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.4441

AB1295

DISCREPANCIES BETWEEN THE RHEUMATOID ARTHRITIS PATIENT POPULATION IN RANDOMIZED CONTROLLED TRIALS OF BIOLOGICS AND THAT IN REAL-WORLD SETTINGS: A STUDY USING THE IORRA COHORT

Eri Sugano¹, Eiichi Tanaka¹, Eisuke Inoue¹, Mai Abe¹, Mika Kawano¹, Kumiko Saka¹, Naohiro Sugitani², Yoko Shimizu¹, Moeko Ochiai¹, Rei Yamaguchi¹, Naoki Sugimoto¹, Katsunori Ikari¹, Ayako Nakajima², Atsuo Taniguchi¹, Hisashi Yamanaka¹. ¹*Institute of Rheumatology Tokyo Women's Medical University, Tokyo, Japan*; ²*Mie University Hospital, Center for Rheumatic Diseases, Mie, Japan*

Background: Randomized controlled trials (RCTs), which are currently considered to provide the highest level of evidence, include patients with high disease activity and exclude those with comorbidities often seen in real-world settings. With the increasing recognition of the importance of real-world evidence, attention is being paid to discrepancies between RCT-based evidence and the patient population in routine clinical practice; however, few reports assessing these gaps in the context of rheumatoid arthritis (RA) are available.

Objectives: To evaluate the proportion of patients meeting the inclusion criteria in RCTs of biologics for the treatment of RA conducted in Japan using the real-world IORRA cohort.

Methods: The inclusion criteria used in Phase 2 or Phase 3 RCTs of the following biological DMARDs (bDMARDs) were extracted: infliximab (IFX), etanercept (ETN), adalimumab (ADA), golimumab (GLM), certolizumab (CZP), abatacept (ABT), tocilizumab (TCZ), and infliximab BS (IFX-BS). Patients participating in the IORRA study during the period when each RCT was conducted (Cohort A) and those who initiated treatment with each bDMARD at our institute in 2016 (Cohort B) were included in the analysis. The proportion of RA patients in Cohorts A and B who met the RCT inclusion criteria was assessed.

Results: A total of 19 RCTs were conducted in Japan (IFX, 2; ETN, 1; ADA, 2; GLM, 2; CZP, 3; ABT, 2; TCZ, 6; IFX-BS, 1). Key trial inclusion criteria were age, RA duration, tender joint count (TJC), swollen joint count (SJC), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), methotrexate (MTX) use, corticosteroid use, and prior bDMARD therapy. The number of patients participating in the IORRA analysis during the period when each RCT was conducted ranged from 1,777 to 6,843 (mean: 5,470) (Cohort A). The median/average [range] proportion of RA patients meeting all RCT inclusion criteria was 0.6%/2.3% [range: 0.0%-16.2%]. The proportion by criterion was 93.9%/92.4% [59.7%-99.9%] for age, 68.9%/57.1% [9.0%-99.6%] for RA duration, 11.6%/16.0% [4.5%-33.0%] for SJC, 14.6%/17.2% [3.7%-33.9%] for TJC, 27.8%/32.1% [20.1%-49.8%] for CRP, 60.2%/58.7% [43.7%-66.8%] for ESR, 14.8%/40.6% [13.1%-73.9%] for MTX use, 99.5%/99.3% [98.5%-99.8%] for prednisolone (PSL) use, and 91.9%/92.0% [85.6%-98.0%] for prior bDMARD use. In Cohort A, the proportion of RA patients meeting the RCT inclusion criteria was low, particularly with respect to SJC, TJC, and MTX use. Among 337 patients who initiated bDMARD therapy at our institute in 2016, a total of 139 biologic-naïve patients (IFX, 3; ETN, 33; ADA, 11; GLM, 21; CZP, 17; ABT, 25; TCZ, 28; IFX-BS, 1) were included in the analysis (Cohort B). In Cohort B, the median/average [range] proportion of RA patients meeting all RCT inclusion criteria was 0%/8.2% [0.0%-54.2%]. The proportion by criterion was 100%/99.1% [94.1%-100%] for age, 20.8%/26.5% [0.0%-57.1%] for SJC, 11.8%/17.0% [0.0%-50.0%] for TJC, 33.3%/34.9% [0.0%-66.7%] for CRP, 58.3%/57.3% [0.0%-75.0%] for ESR, 23.5%/35.5% [0.0%-100%] for MTX use, and 100%/100% [100%] for PSL use. As in Cohort A, the proportion of RA patients meeting the inclusion criteria was low in Cohort B, particularly with respect to SJC, TJC, and MTX use.

Conclusion: It is important to note that evidence from RCTs of bDMARDs is based on a limited RA population in real-world settings.

Disclosure of Interests: Eri Sugano: None declared, Eiichi Tanaka Speakers bureau: Abbvie, Asahi Kasei pharma co., Bristol Myers Squibb,

Chugai Pharmaceutical, Daiichi Sankyo Co., Eisai Pharmaceutical, Janssen Pharmaceutical K.K., Nippon Kayaku, Pfizer, Takeda Pharmaceutical, Taisho Toyama Pharmaceutical Co., and UCB Pharma., Eisuke Inoue: None declared, Mai Abe: None declared, Mika Kawano: None declared, Kumiko Saka: None declared, Naohiro Sugitani: None declared, Yoko Shimizu: None declared, Moeko Ochiai: None declared, Rei Yamaguchi: None declared, Naoki Sugimoto: None declared, Katsunori Ikari: None declared, Ayako Nakajima Grant/research support from: Asahi Kasei pharma co., Chugai Pharmaceutical, Daiichi Sankyo Co., Pfizer, Kissei Pharmaceutical Co., and Mitsubishi Tanabe Pharma Corporation., Atsuo Taniguchi: None declared, Hisashi Yamanaka Grant/research support from: AbbVie, Eisai, Bristol-Meyers, Novartis, Behringer, Astellas, Kaken, Nippon-Shinyaku, Pfizer, UCB, Ayumi, Ono, Daiichi-Sankyo, Taisyo-Toyama, Takeda, Tanabe-Mitsubishi, Chugai, Teijin Pharma, Torii, YLbio, Speakers bureau: Bristol-Meyers, Astellas, Pfizer, Daiichi-Sankyo, Takeda, Tanabe-Mitsubishi, Chugai, Teijin Pharma, YLbio

DOI: 10.1136/annrheumdis-2019-eular.6570

AB1296

PREGNANCY IN WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS: MATERNAL AND FETAL COMPLICATIONS

Tatiana Kirsanova¹, Olga Tsatsulina², Maria Vinogradova¹, Tatiana Fedorova¹, Nina Rozina², Elizaveta Rumyantseva². ¹*Federal State Budget Institution "Research Center for Obstetrics, Gynecology and Perinatology", Moscow, Russian Federation*; ²*Moscow State University, Fundamental Medicine, Moskva, Russian Federation*

Background: Systemic lupus erythematosus is a chronic autoimmune disease often affecting women in fertile age. The physiological changes in T-helpers (Th1/Th2) activity balance during pregnancy can cause SLE flare. Women with SLE are at high risk for maternal and fetal complications. The high SLE activity is associated with higher risk of PE and lower birth weight, compared with population controls. Nevertheless, no detailed analysis of the relationship between clinical features/laboratory parameters and unfavorable pregnancy outcome in patients with SLE has been carried out in the recent studies.

Objectives: This study aimed to analyze influence of SLE activity, laboratory parameters and medications on risk of maternal and fetal complications.

Methods: A retrospective single-center cohort study 11/2014-12/2018: 43 pregnancies in 42 patients with proved SLE and > 20 weeks of gestation, mean age was 31,5 years. Renal function at conception and after delivery, pregnancy outcomes, clinical and laboratory parameters were collected. PE was diagnosed by the 2008 WHO criteria. The sFIT/PIGF ratio was used as the main differential marker to exclude lupus nephritis exacerbation in cases of increased proteinuria.

Age of the patients, SLE activity, hemoglobin and platelet levels, glomerular filtration rate, serum creatinine, AST, ALT, fibrinogen, D-dimer, aPTT, antinuclear factor and antiphospholipid antibodies concentrations, the using/non-use of glucocorticoids, hydroxychloroquine, low molecular weight heparins and aspirin were analyzed as potential risk factors of unfavorable pregnancy outcomes: PE, premature delivery, low birth weight, low Apgar score at 1 and 5 minutes after birth.

Results: In 12 cases (27.9%) there was no activity of SLE, in 16 cases (37.2%) there was low activity, in five (11.6%) – moderate, in three (7%) – high, in seven cases (16.3%) SLE activity was not assessed. SLE activity showed significant negative correlation with week at which labor occurred ($p = 0.003$, $R = -0.477$) and birth weight ($p = 0.005$, $R = -0.461$) and we found a significant fivefold increase in preeclampsia in patients with high activity of SLE ($p = 0.011$, $OR = 4.95$, 95% CI 1.449 to 16.931). Hemoglobin levels in third trimester correlated positively with birth weight ($p = 0.04$, $R = 0.322$). The dosage of glucocorticoids showed a significant correlation with week of delivery ($p = 0.011$, $R = -0.382$). Interestingly, the increase of aPTT in the third trimester had an almost significant effect on the risk of developing PE ($p = 0.059$, $OR = 1.237$, 95% CI 0.958-1.596). Unfortunately, lupus anticoagulant (LA) at that moment was not measured. Other studied parameters were not associated with risk of PE.

Conclusion: High SLE activity significantly increases the risk of gestational complications and unfavorable pregnancy outcomes. We suggest that regular monitoring of antiphospholipid antibodies, especially LA, is needed. In this study, laboratory parameters did not significantly affect the risk of PE.