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Acknowledgements: To all patients, nurses, and doctors who contributed to the data collection

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2022-eular.392

## POS0109 IMPACT OF EARLY AGE AT MENOPAUSE ON DISEASE OUTCOMES IN POSTMENOPAUSAL WOMEN WITH RHEUMATOID ARTHRITIS: RESULTS FROM A LARGE OBSERVATIONAL COHORT OF KOREAN PATIENTS WITH RHEUMATOID ARTHRITIS

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**Background:** The increased prevalence of rheumatoid arthritis (RA) in women has led to studies exploring how female reproductive factors affect disease outcomes in women RA. While a few studies have investigated how early menopause (EM) affects RA outcomes, they had relatively small sample size and have shown inconsistent results [1, 2]. Moreover, none has evaluated the association between age at menopause and longitudinal changes in validated disease activity indices or patient-reported outcomes (PROs) of RA.

**Objectives:** We aimed to assess the differences in clinical outcomes between RA patients with EM (age at menopause <45 years) and usual menopause (UM) (age at menopause  $\geq$ 45 years), and identify potential impact of EM on longitudinal changes in RA activity and PROs during follow-up period.

**Methods:** A total of 2,878 postmenopausal women with RA were included from the Korean Observational Study Network for Arthritis, a nationwide prospective RA cohort of Korea. Each patient was examined at baseline and for 5 consecutive years using the simplified disease activity index (SDAI), health assessment questionnaire-disability index (HAQ-DI), and other PROs. Among patients with a baseline SDAI >11, generalized estimating equation (GEE) analyses were performed to evaluate the impact of EM on longitudinal changes in RA activity and PROs during follow-up.

Results: The EM group (N=437) was younger than the UM group (N=2,441) [58.0±9.5 vs. 60.8±8.0 years, p<0.001], but RA duration was similar between the two groups. The EM group had higher education level and was more likely to be seronegative at enrollment. Moreover, the EM group demonstrated higher disease activity [SDAI 15.4±11.7 vs. 13.9±10.0, p=0.011] and patient-reported visual analogue scale (VAS) scores for global assessment, fatigue, and sleep disturbance (all p<0.05), and worse EQ-5D-VAS [59.9 ±22.2 vs. 63.0±19.5, p= 0.006] at baseline. The rate of previous fracture and neoplastic disease, especially uterine/cervical neoplasm, was higher while that of hypertension was lower among the EM group. The GEE model revealed that EM significantly influenced the rate of SDAI change ( $\beta$ =1.265, p=0.004), after adjusting for age, RA duration, biologic use, and SDAI at baseline. The EM group was also significantly associated with increase in HAQ-DI ( $\beta$ =0.088, p=0.003), and decrease in EQ-5D utility value ( $\beta$ =-0.031, p=0.016) during 5-year follow-up period.

**Conclusion:** RA patients with EM demonstrate higher disease activity and poorer health-related quality of life. EM significantly affects longitudinal changes in disease activity and PROs in RA.

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Table 1. Longitudinal analysis of predictors of the SDAI, HAQ-DI, and EQ-5D utility value over time using a GEE model among patients with a baseline SDAI >11

| Outcome | Independent variables        | Regression coefficient ( $\beta$ ) (95% CI) | Р      |
|---------|------------------------------|---|--------|
| SDAI    | Age                          | 0.013 (-0.024-0.049)                        | 0.503  |
|         | RA duration                  | 0.084 (0.046-0.122)                         | <0.001 |
|         | Baseline SDAI                | 0.580 (0.531-0.630)                         | <0.001 |
|         | Biologic use                 | 0.196 (-0.924-1.315)                        | 0.732  |
|         | Early menopause              | 1.265 (0.412-2.117)                         | 0.004  |
|         | Follow-up time               | -1.806 (-1.9641.647)                        | <0.001 |
| HAQ-DI  | Age                          | 0.007 (0.004-0.009)                         | <0.001 |
|         | RA duration                  | 0.011 (0.009-0.014)                         | <0.001 |
|         | Baseline HAQ-DI              | 0.674 (0.638-0.711)                         | <0.001 |
|         | Biologic use                 | 0.044 (-0.033-0.122)                        | 0.264  |
|         | Early menopause              | 0.092 (0.030-0.154)                         | 0.003  |
|         | Follow-up time               | -0.004 (-0.016-0.007)                       | 0.457  |
| EQ-5D   | Age                          | -0.002 (-0.0030.000)                        | 0.007  |
|         | RA duration                  | -0.003 (-0.0040.002)                        | <0.001 |
|         | Baseline EQ-5D utility value | 0.532 (0.492-0.572)                         | <0.001 |
|         | Biologic use                 | -0.012 (-0.045-0.021)                       | 0.489  |
|         | Early menopause              | -0.033 (-0.0590.006)                        | 0.016  |
|         | Follow-up time               | 0.010 (0.005-0.015)                         | <0.001 |

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2022-eular.1112

## POS0110 INCIDENCE OF MAJOR ADVERSE CARDIOVASCULAR EVENTS STRATIFIED BY GEOGRAPHIC REGION AND BASELINE CARDIOVASCULAR RISK: A POST HOC ANALYSIS OF ORAL SURVEILLANCE

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**Background:** ORAL Surveillance was a post-authorisation safety study of tofacitinib vs tumour necrosis factor inhibitors (TNFi) in patients (pts) with rheumatoid arthritis (RA) aged  $\geq$ 50 yrs with  $\geq$ 1 additional cardiovascular (CV) risk factor and an inadequate response to methotrexate (MTX).

**Objectives:** To examine associations between major adverse CV events (MACE) and the geographic region and baseline (BL) CV risk profile of pts in ORAL Surveillance.

Methods: Pts on stable MTX were randomised 1:1:1 to receive tofacitinib 5 or 10 mg twice daily (BID) or a TNFi (adalimumab 40 mg every 2 weeks in North America [NA] or etanercept 50 mg once weekly in the rest of the world [RoW]). Incidence rates (IRs; pts with first events/100 pt-yrs) were evaluated for adjudicated MACE, as well as myocardial infarction (MI) and stroke. MACE was defined as CV death (excluding CV death due to pulmonary embolism), non-fatal MI and non-fatal stroke. IRs were stratified by geographic region (NA vs RoW) and BL CV risk profile: pts were first categorised by history of coronary artery disease (HxCAD); pts without a HxCAD were then categorised by 10-yr risk of MACE (high [≥20%], intermediate [≥7.5-<20%], borderline [≥5-<7.5%] and low [<5%] risk), per the ASCVD-pooled cohort equations calculator<sup>1</sup> with a 1.5 multiplier applied.<sup>2</sup> Results: Overall, 4362 pts were included in the study (tofacitinib 5 mg BID, n=1455; tofacitinib 10 mg BID, n=1456; TNFi, n=1451). Across treatments, a higher proportion of pts in NA vs RoW had a HxCAD (Table 1). In pts without a HxCAD, across treatments, higher percentages of pts had a high 10-yr risk of MACE in NA vs RoW (Table 1). Across treatments, overall MACE IRs were higher