Methods: A systematic literature review, in accordance with PRISMA guidelines, was conducted looking at trials investigating the use of IA MTX and/or TNF- α against IA CS, in managing inflammatory monoarthritis in patients with RA. A trained librarian conducted search of Ovid MEDLINE, Ovid EMBASE, Scopus, and Web of Science databases. Included studies were assessed for risk of bias as per the Cochrane tool.

Results: A total of 1013 citations were retrieved from the medical database searches. 12 studies were included in the final review. 6 studies investigated IA MTX while 5 studied IA etanercept. One study investigated different biologic agents: infliximab, etanercept, or adalimumab. Multitude of dosing regimens and administration protocols were used in various studies. 5 of the 6 MTX studies only included knees. IA MTX was compared against saline, CS and as combined MTX/CS vs CS alone. There was no evidence to support the use of IA MTX as a superior or equivalent agent to the comparator groups. Unlike MTX, etanercept was investigated in multiple joint types e.g. elbows, knees and wrists. IA etanercept was found to have utility as a successful IA alternative to CS. The only study investigating infliximab and adalimumab found them to be superior to IA CS across multiple joint types. All therapies were generally well tolerated. Etanercept studies had low risk of bias while the MTX studies mostly suffered from higher risk of bias.

Conclusion: Etanercept may be used as an IA agent in select patients with inflammatory arthritis when systemic treatment is not an option and IA corticosteroids cannot be used. Limited data also supports the utility of IA adalimumab and infliximab as better IA agents compared to CS. IA MTX, however, did not have such supporting data.

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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1016

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ANALYSIS OF FACTORS ASSOCIATED WITH THE EFFECTIVENESS OF ABATACEPT IN THE ORIGAMI STUDY

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Background: The ORIGAMI study is a multicenter, observational study to evaluate the effectiveness, safety, and patient-reported outcomes of abatacept (ABA) in Japanese patients with csDMARD-resistant, Simplified Disease Activity Index (SDAI)-moderate, biologic-naïve rheumatoid arthritis (RA). ABA has shown better effectiveness/efficacy in RA patients with anti-cyclic citrullinated peptide antibody (ACPA) positive (1) and high ACPA titer (2) compared to ACPA negative and low ACPA titer, respectively. However, more accurate predictors of effectiveness in clinical practice are needed than ACPA status.

Objectives: This post-hoc analysis is aimed to determine the association between ACPA and ABA effectiveness (disease activity and physical function) or retention rate and to investigate other factors associated with the effectiveness of ABA in patients enrolled in the ORIGAMI study.

Methods: Of the 279 patients in the effectiveness analysis set of the ORIGAMI study, 270 patients with baseline ACPA measurement were analyzed. The patients were divided into the ACPA-positive group (ACPA +ve, ≥ 4.5 U/mL at baseline) and the ACPA-negative group (ACPA -ve, <4.5 U/mL). Patients' characteristics, changes in disease activity and physical function (Japanese Health Assessment Questionnaire; J-HAQ) through 52 weeks, and retention rates of ABA at week 52 were evaluated. Baseline characteristics and use of concomitant drugs were analyzed as independent variables by multiple regression analysis using a standard linear model adjusted by SDAI at week 0 to identify factors associated with SDAI change at week 52. In addition, the

interaction effects among ACPA status, RF status, and the factor that was significantly associated with SDAI change in multiple regression analysis on changes in SDAI were explored.

Results: The numbers of ACPA +ve and -ve patients were 226 and 44, respectively. ACPA values (mean $\pm$ SD, U/mL) were 280.3 ± 376.8 and 0.9 ± 0.7 , and rheumatoid factor (RF) values were 174.8 ± 302.6 and 20.9 ± 61.7 in the ACPA +ve and -ve groups, respectively. Mean (95% confidence interval) changes in SDAI at week 52 were -11.3 (-12.4 to -10.3) and -8.0 (-10.5 to -5.5), and those in J-HAQ were -0.27 (-0.34 to -0.20) and -0.16 (-0.34 to 0.01) in the ACPA +ve and -ve groups, respectively. In the Kaplan-Meier analysis, the retention rates of ABA at week 52 in the ACPA +ve and -ve groups were 72.1% and 58.7%, (discontinuation for any reason), and 91.6% and 75.7% (discontinuation because of lack of effectiveness), respectively. In a multiple regression analysis, the duration of disease (<1 year) was associated with the change in SDAI at week 52. With respect to SDAI changes, the estimated difference of ACPA +ve and disease duration (<1 year), ACPA +ve and disease duration (≥ 1 year), and ACPA -ve and disease duration (<1 year), versus ACPA -ve and disease duration (≥ 1 year), were -4.26 ($p = 0.022$), -0.82 ($p = 0.618$), and -0.93 ($p = 0.716$), respectively (Fig. 1). The estimated difference of ACPA +ve and RF +ve, ACPA +ve and RF -ve, and ACPA -ve and RF +ve, versus ACPA -ve and RF -ve, were -2.48 ($p = 0.060$), -2.77 ($p = 0.107$), and -5.48 ($p = 0.087$), respectively.

Conclusion: A higher retention rate as well as better effectiveness of ABA on disease activity and physical function in ACPA +ve group versus ACPA -ve group were shown in the simple subgroup analysis. ABA effectiveness on the SDAI change was significantly better in patients with disease duration <1 year and ACPA +ve compared to those with ACPA -ve and disease duration ≥ 1 year.

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Fig.1 Interaction of ACPA and disease duration with change in SDAI

Interaction analysis adjusted for RF, age, sex, comorbidity, SDAI, J-HAQ, steroid use, MTX use and csDMARDs use (except for MTX) were performed. ACPA, anti-cyclic citrullinated peptide antibody; SDAI, simplified disease activity index; RF, rheumatoid factor; J-HAQ, Japanese Health Assessment Questionnaire; MTX, methotrexate; csDMARDs, conventional synthetic disease modifying anti-rheumatic drugs.

Disclosure of Interests: Kenta Misaki Speakers bureau: Eisai Co., Ltd., AbbVie GK, Eli Lilly Japan K.K., Ono Pharmaceutical Co., Ltd., Grant/research support from: Ono Pharmaceutical Co., Ltd., Eiichi Tanaka Speakers bureau: AbbVie GK, Asahi Kasei Pharma Corporation, Astellas Pharma Inc, Ayumi Pharmaceutical Corporation, Chugai Pharmaceutical Co., Ltd., Eisai Co., Ltd., Eli Lilly Japan K.K., GlaxoSmith-Kline K.K., Kyowa Pharma Chemical Co., Ltd., Janssen Pharmaceutical K.K., Mochida Pharmaceutical Co., Ltd., Pfizer, Takeda Pharmaceutical Co., Ltd. and Teijin Pharma Ltd., Eisuke Inoue Speakers bureau: Pfizer Japan, Bristol-Myers Squibb K.K., Katsuki Tsuritani Employee of: Bristol-Myers Squibb K.K., Shigeru Matsumoto Employee of: Ono Pharmaceutical Co., Ltd., Hisashi Yamanaka Consultant of: Bristol-Myers Squibb K.K., masayoshi harigai Speakers bureau: AbbVie GK, Ayumi Pharmaceutical Corporation, Bristol-Myers Squibb K.K., Chugai Pharmaceutical Co., Ltd., Eisai Co., Ltd., Eli Lilly Japan K.K., Pfizer Japan Inc., and Takeda Pharmaceutical Co., Ltd., Consultant of: AbbVie GK, Bristol-Myers Squibb K.K., Chugai Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., and Gilead Sciences Inc., Grant/research support from: AbbVie GK, and Asahi Kasei Corp., Astellas Pharma Inc., Ayumi Pharmaceutical Corporation, Bristol-Myers Squibb K.K., Chugai Pharmaceutical Co., Ltd. Daiichi-Sankyo, Inc., Eisai Co., Ltd., Mitsubishi Tanabe Pharma Corporation., Nippon Kayaku Co., Ltd., Taisho Pharmaceutical Co., Ltd., and Takeda Pharmaceutical Co., Ltd.

DOI: 10.1136/annrheumdis-2021-eular.1028