Conclusion: A pooled analysis of TNF inhibitor biosimilars and reference products showed that about 20-30% of responders lost their response, while about 20-30% gained it. Thus, the overall stability of disease fluctuation in our 1-year phase III studies is a consequence of a similar success and failure rate. The validity of these data can be seen by the similarities in these outcomes between different types of TNF-inhibitors and similarity between biosimilars and respective reference products.

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Table 1. Proportion of responders at 1 year based on 6-month clinical outcomes

Group	ACR20 responders* at 1 year (n/n, %)		DAS28 responders at 1 year (n/n, %)		SDAI responders at 1 year (n/n, %)		CDAI responders at 1 year (n/n, %)	
	Responder at 6 month	Non-responder at 6 month	Responder at 6 month	Non-responder at 6 month	Responder at 6 month	Non-responder at 6 month	Responder at 6 month	Non-responder at 6 month
All Tx Combined	450/1048 (81.1%)	140/413 (33.9%)	302/434 (69.6%)	193/1027 (18.8%)	509/854 (77.8%)	215/804 (26.7%)	489/635 (77.0%)	206/826 (24.9%)
BS Combined	365/564 (82.4%)	85/231 (36.8%)	177/241 (73.4%)	118/554 (21.3%)	287/359 (79.9%)	112/433 (25.9%)	275/350 (78.6%)	114/445 (25.6%)
RP Combined	385/484 (79.5%)	55/182 (30.2%)	125/193 (64.8%)	75/473 (15.9%)	222/295 (75.3%)	103/371 (27.8%)	214/285 (75.1%)	92/381 (24.1%)
SB4+ETN	359/433 (82.9%)	46/126 (36.5%)	121/175 (68.1%)	73/384 (19.0%)	218/270 (81.1%)	77/289 (26.6%)	207/255 (81.2%)	73/304 (24.0%)
SB2+INF	252/334 (75.4%)	49/184 (26.6%)	83/133 (62.4%)	51/385 (13.2%)	157/217 (72.4%)	59/300 (19.7%)	156/218 (71.6%)	54/300 (18.0%)
SB5+ADA	239/281 (85.1%)	45/103 (43.7%)	98/126 (77.8%)	69/258 (26.7%)	133/167 (79.6%)	79/215 (36.7%)	126/162 (77.8%)	79/222 (35.6%)
SB4	183/220 (83.2%)	27/67 (40.3%)	67/93 (72.0%)	41/194 (21.1%)	118/145 (81.4%)	36/142 (25.4%)	111/137 (81.0%)	39/150 (26.0%)
ETN	176/213 (82.6%)	19/59 (32.2%)	54/82 (65.9%)	32/190 (16.8%)	101/125 (80.8%)	41/147 (27.9%)	96/118 (81.4%)	34/154 (22.1%)
SB2	123/161 (76.4%)	24/92 (26.1%)	44/65 (67.7%)	28/188 (14.9%)	80/108 (74.1%)	25/144 (17.4%)	79/108 (73.1%)	25/145 (17.2%)
INF	129/173 (74.6%)	25/92 (27.2%)	39/68 (57.4%)	23/197 (11.7%)	77/109 (70.6%)	34/156 (21.8%)	77/110 (70.0%)	29/155 (18.7%)
SB5	159/183 (86.9%)	34/72 (47.2%)	66/83 (79.5%)	49/172 (28.5%)	89/106 (84.0%)	51/147 (34.7%)	85/105 (81.0%)	50/155 (32.3%)
ADA	80/98 (81.6%)	11/31 (35.5%)	32/43 (74.4%)	20/86 (23.3%)	44/61 (72.1%)	28/68 (41.2%)	41/67 (71.9%)	29/72 (40.3%)

ACR, American college of rheumatology; ADA, reference product adalimumab; BS, biosimilars; CDAI, Clinical Disease Activity Index score; DAS28, disease activity score based on 28-point count; ETN, reference product etanercept; INF, reference product infliximab; RP, reference products; SDAI, Simplified Disease Activity Index score; Tx, treatment.

*Responders included patients who achieved an ACR20 response or low disease activity (including remission) by DAS28, SDAI, or CDAI.

Disclosure of Interests: Josef S. Smolen Grant/research support from: AbbVie, Eli Lilly, Janssen, MSD, Pfizer Inc, Roche, Consultant for: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Speakers bureau: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Michael E. Weinblatt Shareholder of: Stock option: CanFite, Lycera, Scipher, Inmedix, Grant/research support from: Crescendo Bioscience, Bristol Myers Squibb, Sanofi, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, CanFite, Corrona, Crescendo, GlaxoSmithKline, Gilead, Horizon, Lilly, Lycera, Merck, Novartis, Pfizer, Roche, Samsung, Scipher, Set Point, Paul Emery Grant/research support from: Pfizer, MSD, AbbVie, Bristol-Myers Squibb, Roche, Consultant for: Pfizer, MSD, AbbVie, Bristol-Myers Squibb, UCB, Roche, Novartis, Gilead, Samsung, Sandoz and Lilly, Jung-Yoon Choe: None declared, Jonathan Kay Grant/research support from: Gilead Sciences, Pfizer, UCB Pharma, Consultant for: AbbVie, Boehringer Ingelheim GmbH, Celltrion Healthcare, Merck Sharp & Dohme Corp., Novartis Pharmaceuticals, Pfizer, Samsung Bioepis, Sandoz, UCB Pharma, Jieun Lee Employee of: Samsung Bioepis, Gihyun Myung Employee of: Samsung Bioepis, Hyoryeong Seo Employee of: Samsung Bioepis, Jeehoon Ghil Employee of: Samsung Bioepis

DOI: 10.1136/annrheumdis-2019-eular.6611

SAT0163 LOW CARDIOVASCULAR EVENT RATE DURING TOCILIZUMAB TREATMENT IN THE NON-INTERVENTIONAL STUDY ICHIBAN

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Background: Rheumatoid arthritis (RA) patients (pts) have a 1.5 to 2-fold increased risk for cardiovascular (CV) events and CV mortality [1]. Traditional risk factors as well as underlying disease, including therapy with glucocorticoids (GC) contribute to the increased CV risk. Typical risk factors include age, male sex, hypertension, adiposity, and diabetes mellitus [2].

Objectives: The exploratory post-hoc analysis of the non-interventional study (NIS) ICHIBAN (NCT 01194401, final dataset) investigated the CV risk of RA pts during intravenous tocilizumab (TCZ) treatment over 2 years.

Methods: Data of 3164 pts (total) who received at least one dose of TCZ were available. Analysis focuses on the CV events myocardial infarction (MI), coronary heart disease (CHD), and stroke. The incidence of respective treatment-emergent adverse events (TEAEs) (according to MedDRA preferred term) and/or AEs of special interest (AESIs, recorded by the investigator) was evaluated. The following risk factors (at baseline [BL]) were analysed: sex, age, smoking status, RA duration, DAS28, CDAI, seropositivity, CRP, comorbidities, previous therapies, concomitant therapies, and combinations thereof.

Results: At BL, pts were more frequently female (74.8%), on average 55.5 years old, had a mean BMI of 26.9 kg/m², and mean RA duration of 9.7 years. 72% of pts suffered from comorbidities (37% hypertension, 17% osteoporosis, 10% diabetes mellitus). The majority (66.4%) was pre-treated with TNF inhibitors, while 30.0% received csDMARDs only. Co-medication was csDMARDs in 50.7% of pts and GC in 80.6%.

Overall, 46.6% of pts experienced at least 1 TEAE. The rate of pts who experienced a CV event was 0.8% for MI, 0.4% for CHD, and 0.6% for stroke (Table 1).

Table 1 Treatment-emergent adverse events (TEAEs) during TCZ treatment

	Total (n = 3164)
AEs	
• No. of patients with AE, % (n)	46.6 (1474)
• Rate of AEs per 100 patient years	108.4
SAEs	
• No. of patients with SAE, % (n)	14.9 (472)
• Rate of SAEs per 100 patient years	23.9
Fatal	
• No. of patients with fatal event, % (n)	0.6 (19)
• Rate of fatal events per 100 patient years	0.9
Myocardial infarction	
• No. of patients with MI, % (n)	0.8 (26)
• Rate of MIs per 100 patient years	0.8
Coronary heart disease	
• No. of patients with CHD, % (n)	0.4 (14)
• Rate of CHDs per 100 patient years	0.5
Stroke	
• No. of patients with stroke, % (n)	0.6 (18)
• Rate of strokes per 100 patient years	0.6

For patients with typical risk factors a higher rate of CV events was observed: male pts, pts of higher age, pts who were anti-CCP negative, and pts who suffered from diabetes mellitus, coronary heart disease (only for CHD), asthma, and renal insufficiency (see Table 2 for details; exploratory p-values are given).

Interestingly, no differences were observed between subgroups of smoking status, RA duration, DAS28, CDAI, CRP, previous therapies, concomitant therapies, and combinations thereof (data not shown).

Table 2 Observed occurrence of cardiovascular events (TEAEs) in different subgroups (based on pts with respective TEAE)

Risk factor (at BL)	Myocardial infarction	Coronary heart disease	Stroke
Sex, % (n)			
• Male (n = 797)	1.4 (11)	0.8 (6)	0.9 (7)
• Female (n = 2367)	0.6 (15)	0.3 (8)	0.6 (11)
• p value	0.0435	0.1270	0.1794
Age groups, % (n)			
• < 50 years (n = 924)	0.4 (4)	0.2 (2)	0.3 (3)
• 50 - 65 years (n = 1496)	0.9 (13)	0.4 (6)	0.7 (10)
• > 65 years (n = 744)	1.2 (9)	0.8 (6)	0.7 (9)
• p value	0.2068	0.2042	0.5328
Seropositivity, % (n)			
• Anti-CCP positive (n = 983)	0.9 (9)	0.3 (3)	0.7 (7)
• Anti-CCP negative (n = 203)	2.0 (4)	0.8 (1)	2.0 (4)
• p value	0.2547	0.5286	0.0094
Diabetes mellitus, % (n)			
• With (n = 314)	2.5 (8)	1.9 (5)	1.3 (4)
• Without (n = 2844)	0.6 (18)	0.3 (8)	0.5 (14)
• p value	0.0004	<0.0001	0.0960
Coronary heart disease, % (n)			
• With (n = 140)	0.7 (1)	3.6 (5)	0.9 (0)
• Without (n = 3018)	0.8 (25)	0.3 (9)	0.6 (18)
• p value	1.0000	<0.0001	1.0000
Asthma, % (n)			
• With (n = 111)	1.8 (2)	0.9 (1)	0.9 (1)
• Without (n = 3047)	0.8 (24)	0.4 (13)	0.6 (17)
• p value	0.2318	0.3947	0.4758
Renal insufficiency, % (n)			
• With (n = 90)	2.2 (2)	2.2 (2)	3.3 (3)
• Without (n = 3055)	0.8 (24)	0.4 (12)	0.5 (15)
• p value	0.1684	0.0555	0.0134

* Percentages refer to the number of pts with remission data available

TEAE: Treatment-emergent adverse event

P values from Chi-Square test. In case Chi-Square test was not valid, Fisher's exact test was used

Conclusion: In the NIS ICHIBAN, with its long-lasting patient population, the rate of CV events during TCZ treatment was comparable to former

investigations [1, 3, 4]. In pts with the typical risk characteristics at BL, i. e. male sex, higher age, diabetes mellitus, and CHD, higher rates of CV events were observed. In addition, increased rates were also found in anti-CCP negative pts and in pts with asthma or renal insufficiency

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Disclosure of Interests: Christof Specker Grant/research support from: Boehringer, Chugai, GSK, Roche, Consultant for: AbbVie, Boehringer Ingelheim, Chugai, Lilly, Novartis, Sobi, UCB, Speakers bureau: AbbVie, Celgene, Chugai, Janssen-Cilag, Lilly, MSD, Novartis, Pfizer, Roche, UCB, Annette Alberding Grant/research support from: This study was supported by Roche Pharma AG (Grenzach-Wyhlen, Germany) and Chugai Pharma Europe Ltd. (Frankfurt am Main, Germany). Financial support went directly to Dr Alberding's employer: Internal Rheumatology Department, St. Josef Hospital, Wuppertal, Germany., Martin Aringer Grant/research support from: Roche, Consultant for: AstraZeneca and Eli Lilly, Gerd Rüdiger Burmester Consultant for: Roche, Sanofi-Genzyme, Speakers bureau: Roche, Sanofi-Genzyme, Michael W. Hofmann Employee of: Chugai Pharma Europe Ltd., Peter Kästner Grant/research support from: Roche, Herbert Kellner Grant/research support from: Roche, Consultant for: Roche, Christina Luig Employee of: Roche Pharma, AG., Frank Moosig Grant/research support from: Roche, Maren Sieburg Grant/research support from: Roche, Hans-Peter Tony Grant/research support from: Roche, Consultant for: Roche Pharma, Abbvie, BMS, Chugai, Janssen, Novartis, Sanofi, Lilly, Speakers bureau: Roche Pharma, Abbvie, BMS, Chugai, Janssen, Novartis, Sanofi, Lilly., Gerhard Fliedner Grant/research support from: Roche

DOI: 10.1136/annrheumdis-2019-eular.3994

SAT0164

COMPARISON OF THE RETENTION RATE OF EACH BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUG GROUP ACCORDING TO THE STATUS AND CONCENTRATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY AND RHEUMATOID FACTOR: DOUBLE CENTERCLINICAL STUDY

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Background: Although biological disease-modifying antirheumatic drugs (bDMARDs) have markedly improved the clinical course for patients with rheumatoid arthritis (RA), there are no reliable predictors of treatment response in individual patients. The drug retention rate in observational studies can be considered as a composite measure and index of drug effectiveness¹.

Objectives: The aim of this study was to investigate potential predictors for bDMARDs by clarifying and comparing the retention ratio of bDMARDs according to the status and concentration of anti-cyclic citrullinated peptide antibody (anti-CCP), rheumatoid factor (RF), and anti-nuclear antibody (ANA).

Methods: We included consecutive RA patients from Mitsui Memorial Hospital and Kawakita General Hospital (both in Tokyo) who received bDMARD treatment between April 2018 and August 2018. We obtained data on the administered bDMARDs and the reason for discontinuation for each patient, and collected patient information, including the status of RF and ANA, at the initiation of each bDMARD, as well as the baseline status and concentration of anti-CCP. We categorized infliximab, etanercept, adalimumab, golimumab, and certolizumab pegol as TNF inhibitors (TNFi), and compared the TNFi group with the tocilizumab (TCZ) group and abatacept (ABT) group in terms of patient characteristics and retention rate. Statistical analysis of the group comparison was performed using one way ANOVA and Kruskal-Wallis tests, and categorical data were assessed by Fisher's exact test. The retention ratio was compared using the Kaplan-Meier generalized Wilcoxon test.

Results: This study included 214 patients (male 34, female 180, mean age 66.8) and 305 bDMARD cases were analyzed. The TNFi group

included 160 cases, and the TCZ group and ABT group comprised 66 and 79 cases, respectively. Overall, the ABT group had the highest retention rate compared with the TNFi and TCZ groups, and the persistency rate of the ABT group at 60 months was 66.1%. Reasons for discontinuation of bDMARDs were insufficient efficacy (63.0%) and adverse events (29.4%). There was no significant difference regarding to the retention rate between anti-CCP negative and -positive patients or between RF-negative and -positive patients in each bDMARD group. After stratifying all patients according to anti-CCP status and concentration, among the three bDMARD groups, the ABT group (n=70) had the highest retention rate ($p<0.05$) in the anti-CCP-positive category, whereas the TCZ group (n=12) had the highest retention rate ($p=0.27$) in the anti-CCP-negative category. Regarding the concentration of anti-CCP, in the ≥ 100 U/ml category, the ABT group (n=42) had the highest retention rate ($p<0.05$), but such differences were not found in the $4.4 - <100$ U/ml category. The persistency rates of the ABT group in the ≥ 100 U/ml category at 60 months was 73.4%. Moreover, the ABT group (n=59) had the highest retention rate ($p<0.05$) in the RF-positive category, whereas the TCZ group (n=20) had the highest retention rate in the RF-negative category ($p=0.15$). The persistency rate of the ABT group in the RF-positive category at 60 months was 68.3%. There were no significant differences in the retention rate among the three bDMARD groups in the ANA-negative or -positive categories.

Conclusion: The status and concentration of anti-CCP, and the status of RF were found to be useful predictors for bDMARD efficacy in patients with RA.

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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.1946

SAT0165

PERSPECTIVES OF WOMEN WITH CHRONIC RHEUMATIC DISEASES ON THEIR JOURNEY TO MOTHERHOOD: COMPARISON OF SURVEYS FROM ASIA-PACIFIC AND EUROPE

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Background: The onset and diagnosis of chronic rheumatic disease (CRD) in women often overlap with their peak reproductive years. A previous survey¹ reported fears and misconceptions amongst women with CRD in Germany, France, UK, Italy and Spain (EU5) on their journey to motherhood.

Objectives: To explore the perspectives of women with CRD in Asia-Pacific (APAC) regarding disease management and pregnancy, and the support they receive compared with patients in Europe.

Methods: Women of childbearing age (18–45 years) with self-reported moderate to severe CRD (rheumatoid arthritis [RA], psoriatic arthritis [PsA], axial spondyloarthritis [axSpA]/ankylosing spondylitis [AS]) from Australia (AUS), Japan (JPN) and Hong Kong/Taiwan (HK/TW) completed a 20-min online survey (Sep–Nov 2018), similar to the previous EU5 survey.¹ Participants had been pregnant in the past 2–5 years.

Results: 210 APAC participants had CRD (RA: n=122, PsA: n=48, axSpA/AS: n=40); 306 EU5 participants had CRD. Most APAC patients had moderate CRD (77%; severe: 23%). In their most recent pregnancy, 40% of the women were actively trying to get pregnant, 40% were neutral and 20% were either not thinking about a pregnancy or were actively trying to avoid it. Prior to pregnancy, more women consulted rheumatologists (62%) vs primary care physicians (26%) or OB/GYNs (20%; multiple responses were possible). Pregnancy planning was first discussed with a healthcare professional (HCP) at diagnosis (33%), at treatment initiation