good/moderate E-resp rate was higher in switchers to a nonTNF-i (70% in TNF-i, 8.3% in nonTNF-i, p=0.006). In ADA+ subpopulation (n=34), no differences were found in clinical response at v-end in DAS28 (3.7±1.2 TNF-i, 3.9±1.1 non-TNF-i, p=0.64), ΔDAS28 (0,63±1,6 in TNF-i, 1,4±1,4 in nonTNF-i, p=0,35) and good/moderate E-resp rate (30% in TNF-i, 91% in nonTNF-i, p=0,703). In pts who changed to a 2nd TNF-i, those with ADA to 1st TNF-i had a higher good response rate than ADA- pts (65% in ADA +, 30% in ADA-, p=0.07)

Demographic characteristics	ADA+ subpopulation	ADA- Subpopulation	p
Age (years)	62,3±14,6	65,7±14,9	0,203
Sex (female)	28 (82%)	23 (88%)	0,719
Smokers	7 (20,6%)	4 (26%)	0,537
BMI	26,9±8,9	23,9±4,2	0,39
Disease duration (years)	19,3±8,05	24,1±8,2	0,844
RF +	32 (94%)	20 (77%)	0,067
Anti-CCP +	32 (94%)	22 (88%)	0,641
Basal CPR	15,1±18,2	20,4±21,7	0,46
Basal ESR	41±27,9	38±20	0,28
Basal DAS	5,31±1,4	5,51±1,3	0,18

Conclusions: The development of ADA to the first TNF-i entails a better response when switching to a 2nd TNF-i, with a similar efficacy to the pts who switched to a nonTNF-i. In those pts who did not develop immunogenicity to the 1st TNF-I, there is a better response when changing therapeutic target. The ADA measurement can help to select the pts who can benefit from a 2nd TNF-i

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FRI0187 RADIOGRAPHIC PROGRESSION BY DISEASE ACTIVITY STATES IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH SB2 OR REFERENCE INFLIXIMAB

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Background: Based on the totality of evidence, SB2 has shown to be similar with reference infliximab (INF) and has been approved as a biosimilar by the European Medical Agency. It is, however, hitherto unknown, if SB2 also shares similar structural efficacy in the different disease activity states when compared with INF.

Objectives: To evaluate the disease activity by simplified disease activity index (SDAI) and clinical disease activity index (CDAI) at weeks 14, 30 and 54 in patients with rheumatoid arthritis (RA) treated with SB2 or INF from a phase III study and to assess the radiographic progression at week 54 in patients by disease activity states (remission, low disease activity [LDA], moderate disease activity [MDA], or high disease activity [HDA]).

Methods: Patients with RA were randomised to receive either SB2 or INF 3 mg/kg at weeks 0, 2, 6, and then every 8 weeks thereafter until week 46 with background methotrexate. Dose increments were allowed after week 30 by 1.5 mg/kg up to a maximum dose of 7.5 mg/kg. Disease activities by SDAI, and CDAI were compared at weeks 14, 30, and 54. The radiographic progression was measured by modified Total Sharp Score (mTSS) at weeks 0 and 54.

Results: Up to week 54, comparable proportions of patients achieved ACR-EULAR-index remission between SB2 and INF (by SDAI: 13/279 [4.7%] vs. 13/283 [4.6%] at week 14; 24/250 [9.6%] vs. 29/263 [11.0%] at week 30; 34/226 [15.0%] vs. 24/224 [10.7%] at week 54; by CDAI: 12/279 [4.3%] vs. 12/283 [4.2%] at week 14; 22/253 [8.7%] vs. 31/265 [11.7%] at week 30; 33/227 [14.5%] vs. 24/225 [10.7%] at week 54 in SB2 and INF, respectively). The proportions of radiographic non-progressors (defined as change in mTSS ≤0) by disease activity were comparable between SB2 and INF at week 14, 30 and 54 (Table 1). Patients treated with SB2 as well as INF also exhibited the lowest progression of radiographic damage in remission and the largest progression in HDA, but also very small increases in mTSS in LDA and MDA, in line with previous findings on INF.

Table 1. The proportion of radiographic non-progressors (mTSS progression ≤ 0) and mean change from baseline in mTSS at week 54 by disease activity states at weeks 14, 30, and 54

Disease activity state at each visit		CDAI				SDAI			
		SB2		INF		SB2		INF	
		Radiographic non-progressors	Mean change	Radiographic non-progressors	Mean change	Radiographic non-progressors	Mean change	Radiographic non-progressors	Mean change
Week 14	HDA	43/62 (69.4)	0.44	42/59 (71.2)	0.61	25/41 (61.0)	0.80	31/45 (68.9)	1.03
	MDA	64/86 (74.4)	0.27	57/82 (69.5)	0.64	81/105 (77.1)	0.10	63/89 (70.8)	0.45
	LDA	43/56 (76.8)	0.54	49/58 (84.5)	-0.38	44/58 (75.9)	0.63	53/64 (82.8)	-0.27
	Remission	7/9 (77.8)	0.17	6/8 (75.0)	1.44	7/9 (77.8)	0.17	7/9 (77.8)	1.00
Week 30	HDA	29/43 (67.4)	0.93	33/47 (70.2)	1.20	25/37 (67.6)	0.79	24/33 (72.7)	1.32
	MDA	57/76 (75.0)	0.14	49/71 (69.0)	0.43	59/80 (73.8)	0.24	58/84 (69.0)	0.54
	LDA	55/74 (74.3)	0.40	52/67 (77.6)	-0.10	56/74 (75.7)	0.42	54/69 (78.3)	-0.23
	Remission	16/20 (80.0)	0.05	22/24 (91.7)	-0.13	17/21 (81.0)	0.07	20/22 (90.9)	0.07
Week 54	HDA	31/43 (72.1)	0.39	25/42 (59.5)	1.59	25/36 (69.4)	0.65	23/36 (63.9)	1.71
	MDA	47/69 (68.1)	0.69	46/66 (69.7)	0.30	50/73 (68.5)	0.57	44/68 (64.7)	0.35
	LDA	51/67 (76.1)	0.20	62/78 (79.5)	0.29	54/69 (78.3)	0.18	66/82 (80.5)	0.24
	Remission	28/33 (84.8)	-0.11	23/23 (100.0)	-1.39	27/33 (81.8)	-0.08	23/23 (100.0)	-1.22

Disease activity was defined as following:
by CDAI: remission, CDAI ≤ 2.8; LDA, 2.8 < CDAI ≤ 10.0; MDA, 10 < CDAI ≤ 22.0; HDA, 22.0 < CDAI
by SDAI: remission, SDAI ≤ 3.3; LDA, 3.3 < SDAI ≤ 11.0; MDA, 11 < SDAI ≤ 26.0; HDA, 26.0 < SDAI
Patients with available mTSS at both baseline and week 54 were included.

Conclusions: The proportion of patients achieving remission or LDA was comparable up to week 54 upon treatment with both SB2 and INF. Inhibition of radiographic progression was also comparable in each disease activity state. The proportion of radiographic non-progressors was also similarly high in patients achieving remission, and overall very low radiographic progression rates were seen even in LDA and MDA in both treatment arms. These data further confirm the comparability of SB2 and INF.

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FRI0188 EFFECTIVENESS OF ADALIMUMAB COMBINATION THERAPY WITH METHOTREXATE AND NON-METHOTREXATE CSDMARDS: RESULTS FROM THE CORRONA RHEUMATOID ARTHRITIS REGISTRY

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Background: Combination therapy of methotrexate (MTX) with biologics results in superior outcomes vs. monotherapy. However, little is known on the effectiveness of adalimumab (ADA) combination therapy with non-MTX conventional synthetic disease modifying anti-rheumatic drugs (csDMARD).

Objectives: To evaluate whether ADA in combination with non-MTX csDMARD has similar effectiveness as MTX combination therapy on clinical and patient report outcomes (PROs).

Methods: Adult RA patients, naïve to other monoclonal antibodies, who initiated standard dose ADA (40mg q2w) in combination with MTX or ≥1 non-MTX csDMARD between 2003–2016 and had a 6 month follow-up visit were included. The primary outcomes were mean change in clinical disease activity index (CDAI) and mean change in PROs (mHAQ, pain, fatigue, morning stiffness) from baseline to 6 months. Secondary outcomes included achievement of remission (CDAI≤2.8)/low disease activity (LDA: CDAI≤10). Outcomes were evaluated adjusting for covariates that differed at the time of initiation using mixed model linear regression. Kaplan-Meier survival analysis was used to examine the persistency of ADA between the two groups.

Results: A total of 754 patients were included: N=519 ADA+MTX and N=235 ADA+non-MTX csDMARD. Patients on ADA+MTX were slightly younger (mean age: 54.5 vs 57.4 years), with shorter disease duration (median: 3 vs 5 years), more likely to be biologic naïve (77% vs 69%) compared to patients on ADA+nonMTX csDMARD (all p<0.05). Disease activity and PROs were comparable in both groups at the time of initiation (mean CDAI: 20.4 vs 22.8; mean pain: 45.3 vs 45.9; mean fatigue: 46.3 vs 47.8; mean patient global assessment: 42.8 vs 42.9 (on a VAS 0–100) in ADA+MTX and ADA+nonMTX csDMARD group respectively. Adjusted analysis showed that patients on ADA+MTX had significantly lower mean CDAI at 6 months and higher change in CDAI vs patients in the ADA+non-MTX csDMARD group (p<0.05). In addition, patients on ADA+MTX were more likely to achieve LDA compared to the ADA+non-MTX csDMARD group (Table). Change in PROs and persistency of ADA was comparable in both groups.

Table: Outcomes at 6 months among ADA+MTX and ADA+nonMTX csDMARD therapy

	ADA +MTX	ADA + nonMTX csDMARD[a]	Unadjusted[b]	Adjusted[b,c]
6 month outcomes	Mean (SD)	Mean (SD)	β (95% CI)	β (95% CI)
Mean CDAI at 6 months	11.9 (11.5)	15.7 (13.1)	4.07 (2.09 to 6.04)	3.15 (1.11 to 5.18)
Change in CDAI	-8.8 (13.4)	-7.4 (13.4)	1.72 (-0.85 to 4.29)	3.15 (1.11 to 5.18)
Change in mHAQ	-0.11 (0.39)	-0.1 (0.4)	0.01 (-0.07 to 0.08)	0.01 (-0.07 to 0.08)
Change in pain	-10.1 (26.5)	-9.7 (30.7)	0.68 (-4.51 to 5.88)	1.61 (-3.58 to 6.80)
Change in fatigue	-2.7 (25.9)	-5.3 (25.1)	-2.64 (-9.13 to 3.84)	-2.58 (-9.22 to 4.07)
	Response rate n (%)	Response rate n (%)	Odds Ratio[†] (95% CI)	Odds Ratio[††] (95% CI)
Achievement of Remission (CDAI≤2.8)	46 (15.5%)	13 (8.6%)	0.52 (0.26, 1.06)	0.58 (0.27, 1.26)
Achievement of LDA (CDAI≤10)	136 (45.9%)	47 (31.1%)	0.51 (0.32, 0.80)	0.59 (0.37, 0.96)

mHAQ: modified Health Assessment Questionnaire; LDA: Low Disease Activity; nonMTX csDMARD: non-methotrexate conventional synthetic disease modifying anti-rheumatic drug. [a] Includes leflunomide, sulfasalazine, and hydroxychloroquine. [b] Compared with MTX combination therapy as a reference; [c]Adjusted for age, duration of RA, work status (part-time, full-time, disabled, retired, other), insurance status (none, private, Medicare), prior biologic count, MTX continuation, baseline CDAI, baseline patient pain.

Conclusions: In this real world study, patients on ADA+MTX had significantly greater improvements in disease activity compared to patients on ADA+nonMTX