The baseline visits involved initiation of b/tsDMARD therapy with 100% *vs.* 88.9% bDMARD (anti-TNF: 78.8% *vs.* 58.3%; anti-IL6: 6.7% *vs.* 12.8%; CTLA4 Ig: 11.5% *vs.* 16.7%; anti-CD20: 2.9% *vs.* 1.1%) and 0% *vs.* 11.1% tsDMARD. Therapeutic decisions concerning MTX were (STRATEGE 1 vs STRATEGE 2): identical regimen maintained (pharmaceutical form + dosage): 69.2% *vs.* 76.1%; discontinuation: 4.3% *vs.* 2.2%; adjustment: 26.7% *vs.* 21.7% [with dose reduction: 18.2% *vs.* 93.5% and/or change in pharmaceutical form (p.o. to SC): 54.5% *vs.* 0%].

Main reasons for adjusting treatment were (STRATEGE 1 vs STRATEGE 2): active RA: 86.1% *vs.* 77.8%; RA not in remission: 3.5% *vs.* 21.1%; exacerbation based on clinical/laboratory parameters: 42.6% *vs.* 10%.

Conclusion: Over the five-year period, these results suggest a change in practices for RA patients with an inadequate response to MTX and initiating their first targeted therapy: now with earlier recourse to first targeted therapy, for less active RA, and more pronounced investigation of remission.

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POS0699

SIMILAR EFFICACY AND DRUG SURVIVAL RATES OF BARICITINIB MONOTHERAPY AND BARICITINIB/METHOTREXATE COMBINATION THERAPY IN REAL-LIFE TREATMENT OF RHEUMATOID ARTHRITIS - RESULTS FROM A PROSPECTIVE COHORT OF BARICITINIB-TREATED PATIENTS

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Background: In clinical trials, baricitinib (BARI), in combination with methotrexate (MTX), demonstrated efficacy in patients with rheumatoid arthritis (RA) who have not responded adequately to conventional (cs)or biologic (b) DMARDs [1]. Since MTX is often not tolerated very well [2], BARI monotherapy may be preferable over BARI/MTX combination in some patients with RA. Therefore, real-life data on BARI mono- vs. combination therapy are needed to support such decisions.

Objectives: The aim of our study was to evaluate the efficacy of BARI as mono- or combination therapy in a prospective, open label cohort of RA patients failing previous cs/bDMARD therapy.

Methods: Patients with active RA (DAS28-ESR >3.2), fulfilling the ACR/EULAR 2010 classification criteria and failing previous cs/bDMARD therapy were included. All patients received BARI either as monotherapy or in combination with MTX based on the judgement of the treating physician. Demographics, medical history, disease activity parameters such as 66/68 TJC/SJC, composite scores such as DAS28-ESR, HAQ-DI, as well as medication were prospectively recorded every 3 months according to a pre-defined protocol. Informed consent and ethics approval (19_18 B) were obtained. To evaluate clinical efficacy, DA28 ESR responses was recorded at respective visit dates (until week 96). We estimated least-square mean DAS-28 scores over time using linear mixed effects models including time-group interactions. Kaplan-Meier method was used to estimate baricitinib survival and probability of remission over time.

Results: 139 patients (98 women/41 men; aged 58.4 (12.8) years; mean disease duration of 9.7 years) were included between 4/2017-10/2021. Of these, 46 patients received a combination of BARI with MTX (BARI/MTX) and 93 patients BARI monotherapy. Baseline demographic and disease-specific characteristic were comparable between BARI/MTX and BARI patients (Table 1). Median follow up was 53.1 weeks (IQR 23.0-109.3). Decrease in DAS28-ESR showed a similar dynamics in BARI/MTX (baseline DAS28-ESR: 4.2+/-1.3; 48 weeks: 2.9 (95%CI 2.6 to 3.2)) and BARI (4.3+/-1.3; 48 weeks: 3.0 (95%CI 2.8 to 3.3)) with numerical but no significant differences (Figure 1a). 62% (95%CI 40 to 76%) patients in the BARI/MTX group and 51% (95%CI: 37 to 61%) patients in the BARI attained DAS28ESR remission after 48 weeks. Drug survival was comparable among BARI/MTX and BARI patients. (69 vs.67% at 1 year and 62 vs 56% at 2 years) (Figure 1b).

Conclusion: These data show that BARI monotherapy is efficacious in real life treatment in RA patients with insufficient response to MTX. Clinical efficacy and drug survival is comparable between BARI monotherapy and BARI/MTX combo in a real-life setting.

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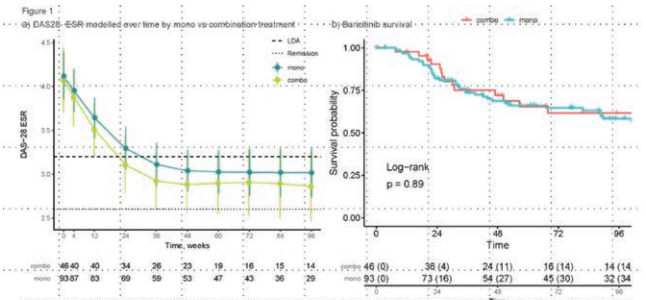

Figure 1a) shows DAS28 ESR values (SD) over time for each group including the number of patients. For example, at week 48, 47 patients in the combination group and 26 patients in the monotherapy group were still on baricitinib. At week 48 mean DAS28 ESR values for monotherapy were: 3.17 (2.95 to 3.40) compared to 2.73 (2.42 to 3.04) for combination therapy with no statistic difference. This was maintained until week 96. Figure 1b displays survival probability curve for baricitinib treatment in this cohort with respect to mono vs combination therapy

Table 1			All	combo	mono
N			139	46	93
Age		Mean (SD)	58.4 (12.8)	56.2 (14.1)	59.5 (12.0)
Sex	Female	N(%)	98 (70.5)	28 (60.9)	70 (75.3)
	Male	N(%)	41 (29.5)	18 (39.1)	23 (24.7)
CCP-AB Status	negativ	N(%)	45 (32.4)	17 (37.0)	28 (30.1)
	positiv	N(%)	94 (67.6)	29 (63.0)	65 (69.9)
Disease duration (y)		Mean (SD)	9.7 (8.5)	9.7 (7.5)	9.6 (9.1)
		Median (IQR)	6.9 (3.5-13.8)	7.5 (4.4-13.8)	6.2 (3.0-13.8)
Follow up (y)		Mean (SD)	68.9 (53.6)	61.5 (48.9)	72.5 (55.6)
		Median (IQR)	53.1 (23.0-109.3)	47.6 (21.0-112.4)	62.3 (23.1-105.0)
DAS-28 ESR		Mean (SD)	4.3 (1.3)	4.2 (1.3)	4.3 (1.3)
HAQ		Mean (SD)	1.1 (0.7)	1.1 (0.6)	1.2 (0.7)

Table1: Demographics, DAS28 ESR, Antibody Status, Follow up time, HAQ are shown for all patients as well as for the monotherapy and combination therapy arm: statistically no significant difference between the groups.

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POS0700

IMPACT OF DELAYING INITIATION OF METHOTREXATE BY 1 MONTH ON THE OUTCOME OF RHEUMATOID ARTHRITIS AT 1 YEAR

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Background: It is recommended that vaccinations should be performed prior to start methotrexate (MTX) knowing that delaying initiation of background therapy may have an impact on the progression of RA.

Objectives: To access the impact of delaying initiation of MTX by 1 month on the outcome of RA at 1 year.

Methods: The VACIMRA study is a prospective, randomized, parallel-group, multicenter trial comparing the vaccine protection obtained in patients with rheumatoid arthritis according to the 1-month delay between anti-pneumococcal vaccine PCV13

Table 1. Baseline characteristics

Variable	Modality	Total population	GROUP IMMEDIATE	GROUPE DELAY	p
Gender, n(%)		N=261	n=131	n=130	0.97
	Man	74 (28.35)	37 (28.24)	37 (28.46)	
	Woman	187 (71.65)	94 (71.76)	93 (71.54)	
Age (years)	Mean (± SD)	55.74 (± 14.68)	55.31 (± 15.27)	56.16 (± 14.11)	0.76
MTX true naive (n(% col))	No	13 (4.98)	8 (6.11)	5 (3.85)	0.40
	yes	248 (95.02)	123 (93.89)	125 (96.15)	
Age at diagnosis (years)	Mean (± SD)	N=205 55.86 (± 15.16)	n=98 55.31 (± 16.07)	n=107 56.37 (± 14.34)	0.80
Positive rheumatoid factor	n(% col)	166 (64.59)	84 (65.12)	82 (64.06)	0.86
Positive ACPA	n(% col)	174 (68.24)	89 (68.99)	85 (67.46)	0.79
CRP (mg/L)	Mean (± SD)	N=260 17.62 (± 24.87)	n=131 15.36 (± 17.95)	n=129 19.91 (± 30.23)	0.65
DAS28-ESR	Mean (± SD)	N=249 5.01 (± 1.11)	n=125 5.03 (± 1.13)	n=12 4.98 (± 1.10)	0.54
Sharp modified VdH total radiographic score	Mean (± SD)	N=93 1.53 (± 3.62)	n=47 1.57 (± 3.68)	n=46 1.48 (± 3.60)	0.88

DAS 28-ESR evolution during 1 year of follow-up

and methotrexate initiation in one arm, versus immediate introduction of MTX following vaccination in the other arm. We analyzed disease activity based on DAS28-ESR at baseline (M0), 1, 2, 3, 6 and 12 months between the 2 groups. For structural progression, we performed a radiographic analysis of 79 RA patients included in the Montpellier center at baseline, 6 and 12 months. This analysis was performed by the same physician two times, blinded to the patient's group. Structural damage progression at 6 months and 1 year was assessed according to van-der-Heijde-modified Sharp score (vSHS) on radiographs performed at inclusion, at 6 and 12 months of follow-up. Comparisons of the means of activity scores and radiographic scores were made with the non-parametric Wilcoxon-Mann-Whitney test.

Results: Of the 276 patients randomized, 261 could be analyzed (131 in the IMMEDIATE group and 130 in the DELAY group). At inclusion, there were no significant differences in demographic, disease activity (DAS28-ESR), biological and radiographic characteristics between the 2 groups (Table 1).

There was a significant difference in the means of DAS28-ESR at 1 month between the DELAY and IMMEDIAT groups (3.96 ± 1.46 vs 3.41 ± 1.33; p<0.001, respectively). There was no significant difference in the means of DAS28-ESR between the 2 groups at 3 months (3.19± 1.46 in the 2 groups p<0.91), at 6 months (3.11 ± 1.42 vs 3.24 ± 1.43; p=0.46, respectively) and at 12 months (2.96 ± 1.34 vs 2.98 ± 1.26p=0.89) (Graphic). Similarly, there was no significant difference in mean radiographic scores at 6 months (2.00 ± 4.41 vs. 1.80 ± 4.03 p=0.81) or at 12 months (2.23 ± 4.86 vs. 2.00 ± 4.07 p=0.93).

There was no significant variation between radiographic scores at 6 months compared to baseline in either group (mean difference 0.21 ± 0.52 vs. 0.36 ± 1.01, p=0.90) nor at 12 months compared to baseline (mean difference 0.40 ± 1.06 vs. 0.62 ± 1.58, p=0.85).

Conclusion: In patients with rheumatoid arthritis, initiation of methotrexate 1 month after PCV13 vaccination has no significant impact on RA activity and structural outcome at 1 year. Performing vaccinations 1 month before starting MTX can be proposed without significant impact on RA outcome at 1 year.

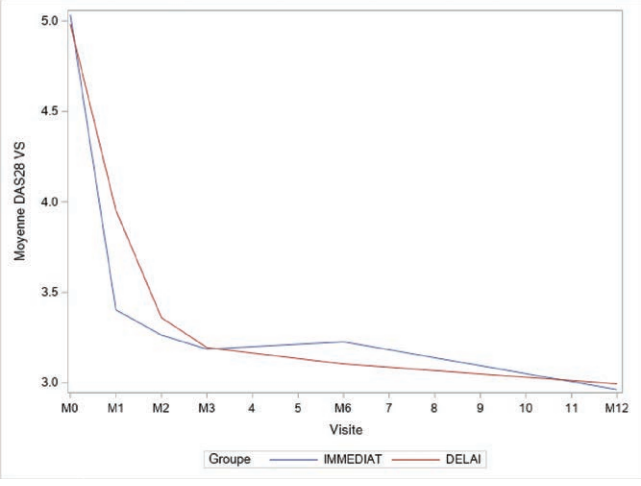

Figure 1.

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POS0701

LONG-TERM EFFICACY OF BARICITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO HAVE HAD INADEQUATE RESPONSE TO CSDMARDS: RESULTS FROM RA-BEYOND UP TO 7 YEARS OF TREATMENT

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Background: Baricitinib (BARI), an oral selective Janus kinase 1/2 inhibitor, has demonstrated efficacy in patients (pts) with rheumatoid arthritis (RA) for up to 3 years (yrs) in a long-term extension (LTE) study RA-BEYOND.[1]

Objectives: Disclose efficacy of BARI in csDMARD-IR pts in the completed LTE study (up to 7 yrs).

Methods: In RA-BUILD, csDMARD-IR pts were randomized 1:1:1 to BARI 4 mg, 2 mg, or placebo (PBO). Completers to week (wk) 24 could enter the LTE and received BARI 4 or 2 mg. In RA-BEAM, MTX-IR pts were randomized 1:1:1 to BARI 4 mg, adalimumab (ADA) 40 mg, or PBO. Completers to wk 52 received BARI 4 mg in the LTE. Pts with no response could be rescued after wk 16 in both studies. Data were analysed by treatment assigned at baseline in originating studies as observed up to time of stepdown (if applicable), study discontinuation or completion, whichever occurred earlier. Efficacy response rates (RR) were assessed as proportions of pts with observed data up to yr 7 (wk 364) for low-disease activity (LDA) (SDAI ≤ 11, DAS28-hsCRP ≤ 3.2, CDAI ≤ 10), remission (REM) (SDAI ≤ 3.3, DAS28-hsCRP < 2.6, CDAI ≤ 2.8, Boolean), and physical function (HAQ-DI ≤ 0.5). No formal statistical comparisons were conducted.

Results: Approximately 56%/25% of pts in BARI 4 mg, 80%/31% in BARI 2 mg, and 60%/25% in PBO from RA-BUILD remained active at yr 3/7; 59%/17% of pts in ADA, 54%/16% in BARI 4 mg, and 67%/14% in PBO from RA-BEAM remained active at year 3/7. SDAI and CDAI had comparable RR for LDA and REM (Table 1). DAS-28CRP LDA RR were similar to SDAI and CDAI, while REM RR were about twice those of SDAI and CDAI (Table 1). HAQ-DI ≤ 0.5 RR was achieved by 25-30% of BARI-treated pts from both trials and maintained to the end of LTE.

Conclusion: In observed data, BARI demonstrated maintained efficacy in treatment and maintenance of physical function of a csDMARDs-IR RA pt population up to 7 yrs.

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