Results: This analysis included 252 pts treated with UPA 15mg, of whom 98 (38.9%) received UPA monotherapy and 154 (61.1%) received UPA combined with conventional synthetic (cs) disease-modifying antirheumatic drugs (DMARDs). 64.3% of pts were from the Southern region of the USA. 86.1%, 72.2%, and 47.6% of pts had been previously treated with csDMARDs, biologic DMARDs, and JAKis, respectively. Baseline characteristics were largely similar between UPA monotherapy and combination therapy groups and those with or without prior TOFA treatment (Table 1). Pts with prior TOFA treatment had a longer duration of RA since diagnosis and higher steroid use versus those without. UPA 15mg improved disease activity scores (including CDAL) and pt-reported outcomes (including physical function and pain) after 3 months of treatment (Figure 1). Similar effectiveness was observed with UPA 15mg in pts with or without prior TOFA treatment.

Conclusion: In the UR-NICE real-world database of US-based pts, improvements in clinical and pt-reported outcomes were observed at 3 months in UPA-treated pts with RA, including those with or without prior TOFA treatment, despite the treatment-refractory population included in this dataset.

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Table 1. Baseline characteristics

n (%), unless otherwise stated	Full analysis set (n=252)		Pts with prior TOFA treatment (n=113)		Pts without prior TOFA treatment (n=139)	
Mean (SD) exposure, days	219.7 (112.1)		215.7 (116.7)		222.9 (108.5)	
Female	199 (79.0)		85 (75.2)		114 (82.0)	
Age ≥65 years	75 (29.8)		34 (30.1)		41 (29.5)	
Oral steroid use	140 (55.6)		70 (61.9)		70 (50.4)	
Prior csDMARDs	217 (86.1)		102 (90.3)		115 (82.7)	
Prior TOFA	113 (44.8)		113 (100.0)		0	
Prior biologic DMARDs	182 (72.2)		86 (76.1)		96 (69.1)	
Tumor necrosis factor inhibitor	147 (58.3)		66 (58.4)		81 (58.3)	
Interleukin-6 receptor inhibitor	87 (34.5)		47 (41.6)		40 (28.8)	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
188	4.0 (3.0)	89	5.1 (2.9)	99	3.1 (2.8)	88
					Methotrexate dose, mg/week	
17.0 (5.1)	28	17.8 (5.0)	60	16.6 (5.2)	SJC28	239
						4.8 (5.7)
108	4.5 (5.0)	131	5.0 (6.2)	TJC28	237	6.5 (6.7)
6.5 (6.8)	130	6.5 (6.6)	CDAL	225	20.4 (13.4)	107
						20.2 (13.5)
120	20.6 (13.3)	Routine assessment of patient index data 3	165	4.2 (2.3)	72	4.2 (2.4)
						93
4.3 (2.2)	Disease Activity Score in 28 joints based on C-reactive protein	167	3.9 (1.5)	83	3.9 (1.5)	84
						3.9 (1.5)
Health Assessment Questionnaire-Disability Index	170	2.5 (2.1)	74	2.4 (2.2)	96	2.5 (2.1)
						Pain
(0–10)						
229	56.5 (28.5)	104	56.9 (29.3)	125	56.1 (28.0)	
					SD, standard deviation; S/TJC, swollen/tender joint count	

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Figure UPA 15 mg effectiveness at Month 3

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POS0667

TOFACITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS IN REAL-WORLD SETTINGS: A NATIONAL MULTICENTER STUDY OF 167 PATIENTS FROM ARGENTINA

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Background: Tofacitinib (TOF), an oral JAK inhibitor, is approved for the treatment of rheumatoid arthritis (RA) either as monotherapy or in combination with background methotrexate (MTX). Despite the current evidence of efficacy from randomized controlled trials and open-label long-term extension studies, evidence of effectiveness and safety in real-world settings is limited, not only in Argentina but also in Latin America.

Objectives: To describe effectiveness, safety and persistence of TOF therapy in RA patients from public and private medical centers from Argentina. In addition, establish prognostic factors for clinical remission at 3 months and TOF monotherapy at 12 months.

Methods: A retrospective, observational and multicentre study was performed from an analysis of medical records of 10 medical centers. RA patients (ACR/EULAR, 2010) and age ≥ 18 years who had received or are under treatment with TOF until June 2020 were included. The data collection was done on a standard database that included baseline data and at 3, 6 and 12 months. Clinical remission was defined as DAS28-ESR < 2.6 . Adverse events, treatment duration, TOF treatment persistence at last visit and discontinuation cause were assessed. Comparison to baseline values was performed using Wilcoxon sign for numerical variables and McNemar's test for categorical variables. Treatment persistence was analyzed using Kaplan Meier's technique. Multivariate analysis was performed using R software and its library packages (Lme4, Tidyverse and ggpubr). A p value < 0.05 was considered significant.

Results: A total of 167 patients were included (78.4% were female). At baseline, the median age was 53 years (IQR 43-63 years), median disease duration was 4 years (IQR 2-13 years). RF was positive in 85.6% of patients, ACPA in 80.8% and structural radiological damage was present in 71.8%. Previous use of MTX was 97%, leflunomide 74.8% and biologic therapy 42.5% (28.74% 1 biologic, 11.98% 2 biologics and 1.8% ≥ 3 biologics). TOF dose: 48% 11 mg/day and 52% 5 mg BID. A statistically significant difference was observed not only in disease activity ($p < 0.0001$) but also in the requirement of MTX and PDN ($p < 0.0001$) in the 12 months evaluated. Remission significantly increased from baseline to month 3 and to a much lesser extent to month 6 ($p < 0.001$). The mean duration of treatment with TOF was 20.10 ± 15.25 months. Treatment persistence was 93.84% at 3 months and 91.24% at 6 months. In those patient who achieved REM at month 3, a statistically significant differences in duration of RA ($p = 0.0002$), structural radiological damage ($p = 0.011$), basal disease activity ($p = 0.018$) and prior treatment with biological therapy ($p = 0.017$) was found when compared with patients who remained active. Furthermore, in univariate logistic regression analysis, 5 years or more of disease duration was associated with a 3 times higher risk of not achieving clinical remission at 3 months (odds ratio = 0.35, 95% CI = 0.15-0.83). In the multivariate logistic regression analysis, previous biological therapy was the only predictor associated with a decrease in the probability of clinical remission ($p < 0.008$). Adverse events were registered in 26 patients (herpes zoster, $n = 9$).

Conclusion: The effectiveness of TOF was observed not only in the clinical response achieved but also in the dose titration or withdrawal of MTX and PDN. The safety profile did not show any difference from long-term extension studies. At 12 months, 86.81% of the patients persisted with TOF therapy. We found prognostic factors associated with clinical remission at 3 months but those associated with monotherapy at 12 months could not be defined due to small number of patients analyzed that could have generated lack of statistical power, although more studies are required to confirm these assumptions.

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POS0668 REAL WORLD EFFECTIVENESS OF BARICITINIB IN THE SWISS RHEUMATOID ARTHRITIS REGISTER (SCQM-RA)

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Background: When not responding to conventional synthetic DMARDs (csDMARDs), rheumatoid arthritis (RA) patients may receive biological DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) including baricitinib (BARI). While BARI has demonstrated efficacy in randomized controlled trials, limited studies have established comparative effectiveness in real world settings, in particular when used in b/tsDMARD-naïve patients.

Objectives: To analyze the effectiveness of BARI versus alternative bDMARDs, as assessed by drug maintenance over time and by response rates at 12 months.

Methods: This is a nested study of RA patients, within the prospective Swiss Clinical Quality Management (SCQM) observational cohort.

All treatment courses (TC) with BARI or alternative bDMARDs initiated between 2017-09-01 and 2020-06-01, with at least one follow-up visit, were included. TC with BARI were compared to TC with alternative bDMARDs (non-BARI), including all b/tsDMARDs except rituximab. The non-BARI group was then subdivided into TNF inhibitors (TNFi) and other mode of action bDMARDs (OMA), excluding tsDMARDs. A secondary analysis focusing specifically on b/tsDMARD naïve patients was conducted.

Baseline characteristics were compared using ANOVA or χ^2 tests. A Cox-model survival analysis assessed drug maintenance. 12-month response rates were estimated using an attrition-corrected, confounder-adjusted approach (1). CDAI score ≤ 10 defined low disease activity state (LDA), and CDAI score ≤ 2.8 defined remission.

Table 1. Baseline characteristics of studied population

Variable	Overall comparison: BARI vs non-BARI			Subgroup analysis 1: by bDMARD type (tsDMARD excluded)			Subgroup analysis 2: In b/tsDMARD-naïve patients			
	BARI (TC = 273; 273 patients)	Non-BARI (altogether) (TC = 945; 755 patients)	p values	TNFi (TC = 473; 408 patients)	OMA (TC = 318; 298 patients)	p values (vs BARI)	BARI (n = 46)	TNFi (n = 225)	OMA (n = 65)	p values
	Mean (SD) Otherwise: n %			Mean (SD) Otherwise: n %			Mean (SD) Otherwise: n %			
Concomitant csDMARD	41 %	46 %	0.17	54 %	41 %	<0.01	50 %	61 %	48 %	0.1
Line of Therapy	17 %	35 %	<0.01	48 %	20 %	<0.01	100 %	100 %	100 %	
-1 st (= bio-naïve)										
-2 nd	20 %	23 %		23 %	23 %					
-3 rd	19 %	16 %		11 %	24 %					
-4 th or later	44 %	26 %		18 %	33 %					
Female	78 %	74 %	<0.21	74 %	73 %	0.28	70 %	71 %	74 %	0.88
Age	59 (14)	56 (14)	0.01	52 (15)	58 (13)	<0.01	57 (15)	51 (14)	57 (16)	<0.01
Disease duration (years)	13 (10)	10 (9)	<0.01	8 (9)	11 (9)	<0.01	5.5 (6.45)	5 (7)	6.5 (9)	0.243
CDAI baseline	15 (9)	15 (10)	0.9	14 (9)	16 (11)	0.05	13 (7)	14 (9)	14 (10)	0.72
Previous tsDMARD (non-BARI)	33 %	8 %	<0.01	4 %	11 %	<0.01	0 %	0 %	0 %	
TC duration > 12-months	37 %	29 %	0.01	27 %	30 %	0.02	37 %	29 %	34 %	0.52

BARI = baricitinib, TNFi = TNF inhibitors, OMA = other mode of action, Non-BARI = TNFi + OMA + other tsDMARDs, SD = standard deviation.