limit value was 10%. The difference test was used for the comparison between the IGU+MTX and MTX monotherapy arms. Two-way ANOVA was used to analyze the difference of the changes of mTSS score of each arm compared with baseline value (0 week).

Results: A total of 895 patients were randomized to IGU 25mg bid (n=297), MTX 10-15mg qw(n=293), and IGU+MTX (n=305). Baseline characteristics were comparable between the arms (Table 1).

Table 1. Demographic and Other Baseline Characteristics (SAS)

	IGU	MTX	IGU+MTX
Number of Subjects	297	293	305
Age, mean (SD) years	46.87(10.67)	47.63(10.70)	48.37(10.69)
Female/male, %	77.44/22.56	79.18/20.82	78.03/21.97
Duration of RA, mean(SD) years	11.67±7.16	11.60±7.98	11.67±7.27
CRP, mean(SD) mg/L ²	22.32±35.47	20.67±26.61	19.74±31.38
Tender joint count, mean (SD)	14.59±9.16	14.83±9.30	14.93±9.88
Swollen joint count, mean (SD)	9.81±6.63	9.73±7.20	9.51±6.22
DAS28-CRP, mean (SD)	5.084±0.994	5.102±0.979	5.103±0.956
HAQ score, mean (SD)	15.82±11.25	15.24±10.93	16.06±10.92

SAS: Safety Analysis Set; CRP: C-reactive protein;

DAS28: disease activity score; HAQ: Health Assessment Questionnaire

The study met its primary endpoints. More concretely, IGU monotherapy and IGU+MTX were found to be superior to MTX at week 52 with a higher ACR20 response of 77.44%(230/297, P=0.0019) and 77.05%(235/305, P=0.0028) versus 65.87%(193/293) (fig 1). As shown in fig 1

, the structural remission (Δ mTSS $\leq$ 0.5) was statistically significant for IGU monotherapy (57.4%, P=0.0308) but not for IGU+MTX arm (55%) versus MTX monotherapy (47.8%).

FAS: Full Analysis Set; ACR20: American College of Rheumatology 20%; Δ mTSS: the change of modified total Sharp scoring

Overall incidence of the adverse events (AEs) leading to study discontinuation were reported in 13.8% (41/297) in IGU monotherapy arm, 11.26% (33/293) in MTX monotherapy arm and 11.51% (35/305) patients in IGU+MTX arm. The incidence of adverse drug reactions (ADR) leading to study discontinuation were 11.45% (34/297), 8.53% (25/293) and 9.21% (28/305), respectively. There was no one death and no significant difference in all the safety indicators among the three arms.

Conclusion: Igaratimod alone or in combination with MTX demonstrated superior efficacy with acceptable safety compared to MTX for patients with active RA who have not previously used MTX bDMARDs.

Disclosure of Interests: None declared

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POS0665 TRAJECTORIES OF GLUCOCORTICOID-THERAPY IN EARLY RHEUMATOID ARTHRITIS: FIRST RESULTS OF A SCOPING SYSTEMATIC REVIEW AND META-ANALYSIS OF OBSERVATIONAL COHORT STUDIES

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Background: Glucocorticoids (GCs) are regularly used as a bridging therapy in early rheumatoid arthritis (eRA). As long-term treatment, especially at higher dosages, may lead to undesirable adverse events, GCs should be tapered as rapidly as clinically feasible.

Objectives: To assess real-world trajectories of GC-therapy initiated in patients with eRA and in methotrexate-naïve RA patients.

Methods: We conducted a scoping search in MEDLINE (via PubMed) to find articles (years 2005 – 2020) reporting on eRA (or methotrexate-naïve RA) patients from observational cohorts who start or take GCs at baseline. Articles had to describe either dosages or proportions of patients who took GCs or were able to taper GCs at two (minimum) pre-specified time points. The articles were screened by one reviewer (AP). Random-effects meta-analyses pooled results per outcome and time point if $\geq$ 3 studies were available. R software with package

metafor was used for statistical analyses. A research protocol was published with protocols.io (10.17504/protocols.io.bpyfmptn).

Results: Our highly specific search strategy yielded 165 results. Twelve articles on nine cohorts were finally included. Eight cohorts originated in Europe, one in Africa. At baseline, about half of the patients with eRA were prescribed GCs with a mean dosage of 8mg/d prednisone equivalent (fig 1). Over time, both the proportion taking GCs and the mean dosage declined. There was substantial heterogeneity between studies.

Conclusion: Our results indicate that GCs remain regularly used drugs in eRA patients and in methotrexate-naïve patients with RA. While about 40% of patients still receive GCs after 24 months, mean dosages were tapered to “low” dosages ($\leq$ 7.5mg/d prednisone equivalent)¹ in all cohorts that reported respective data. Heterogeneity might be caused by country-specific differences. Unfortunately, the validity of sensitivity analyses would be poor due to the paucity of published data regarding GC dosages and proportions of patients taking GCs in observational RA cohorts. Major limitations of this scoping review are the very specific (and consequently less sensitive) search strategy and that the screening was conducted by one reviewer only.

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Figure 1. Meta-analyses of proportions taking glucocorticoids and mean dosages at baseline and 24 months. GCs: Glucocorticoids; CI: Confidence interval.

Disclosure of Interests: None declared

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POS0666 TREATMENT EFFECTIVENESS OF UPADACITINIB AT 3 MONTHS IN US PATIENTS WITH RHEUMATOID ARTHRITIS FROM THE UNITED RHEUMATOLOGY NORMALIZED INTEGRATED COMMUNITY EVIDENCE (NICE(TM)) REAL-WORLD DATA

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Background: Upadacitinib (UPA), an oral Janus kinase inhibitor (JAKi), has demonstrated efficacy in the phase 3 SELECT clinical program, conducted across a range of patients (pts) with rheumatoid arthritis (RA).¹⁻⁶ Real-world data for UPA, including in pts previously treated with a JAKi, have not yet been reported since global approvals beginning in 2019.

Objectives: To assess the characteristics of US-based pts receiving UPA and its effectiveness in clinical practice at 3 months.

Methods: This observational study included US-based pts from the United Rheumatology Normalized Integrated Community Evidence (UR-NICE) database who initiated UPA 15mg once daily from FDA approval (August 2019) to July 31, 2020 and had $\geq$ 6-month pre-baseline data available. Effectiveness was assessed in pts with a reported Clinical Disease Activity Index (CDAI) score at 3 months after UPA initiation and included proportions of pts achieving CDAI remission ($\leq$ 2.8), CDAI low disease activity ($\leq$ 10), other disease activity measures, and pt-reported outcomes. A subgroup analysis assessed UPA effectiveness in pts with or without prior tofacitinib (TOFA) treatment.