Patient Characteristics and Outcomes in Patients With Rheumatoid Arthritis Treated With Upadacitinib: The OM1 RA Registry

POS0436

Martin Bergman[1], Namita Tundia[2], Allison Bryant[3], Ia Topuria[3], Tom Brecht[3], Mira Ali[2], Allan Gibofsky[4]

[1]Drexel University College of Medicine, Philadelphia, Pennsylvania, United States; [2]AbbVie Inc., North Chicago, Illinois, United States; [3]OM1, Inc., Boston, Massachusetts, United States; [4]Weill Cornell Medicine, Hospital for Special Surgery, New York, New York, United States

Presented at the European Congress of Rheumatology, 2–5 June 2021

BACKGROUND

- Upadacitinib (UPA), has demonstrated efficacy in the treatment of rheumatoid arthritis (RA) in randomized controlled trials,[1–6] but there are limited data available on its real-world use and effectiveness in patients with RA
- Examining the effect of UPA in a clinical practice setting provides an opportunity to gain deeper insight into the benefits of treatment with UPA in a heterogenous patient population outside a well-controlled clinical trial setting and assist physicians in making decisions regarding appropriate treatment for their patients

OBJECTIVE

- The aim of this study was to describe the characteristics and clinical outcomes at 3 and 6 months among real-world patients with RA initiating UPA

METHODS

DATA SOURCE

- The data source for this study was the OM1 RA Registry, a subset of the OM1 Real-World Data Cloud (OM1, Inc., Boston, MA, US)
- The OM1 Real-World Data Cloud is one of the largest, linked clinical and administrative datasets in the US and is derived from medical and pharmacy claims, electronic medical record data, and death data

STUDY POPULATION

- RA patients included in the current analysis:
  - Initiated UPA during or after August 2019
  - Had a least 1 prescription for UPA (index date was the date of the first UPA prescription)
  - Were at least 18 years old at the index date
  - Had at least 6 months of available data in the OM1 RA Registry before the index date (baseline period)
  - Had at least 1 baseline disease activity measure
  - Had at least 1 follow-up disease activity measure (3 or 6 months after index date)

OUTCOMES

- Disease activity measures included
  - Routine Assessment of Patient Index Data 3 (RAPID3) score (0–10)
  - Clinical Disease Activity Index (CDAI) score (0–76)
- Disease Activity Categories
  - Remission: CDAI ≤2.8
  - Low disease activity (LDA): CDAI >2.8 to 10
  - Moderate disease activity: CDAI >10 to 22
  - High disease activity: CDAI >22 to 76
- Other clinical outcomes assessed
  - Visual analog scale for pain (0–10)
  - Fatigue score (0–10)
  - Multidimensional Health Assessment Questionnaire (MDHAQ) Physician Global Assessment (PhGA, 0–10)
  - MDHAQ Patient Global Assessment (PtGA, 0–10)
  - MDHAQ Functional Index (0–10)

ANALYSIS

- Outcomes were assessed as the change from baseline to Months 3 and 6
- Multivariate analyses were conducted using a mixed-effects linear model adjusting for age, sex, and baseline scores
- Outcomes were also assessed by
  - Therapy status (monotherapy [UPA only] or combination therapy [UPA and non-biologic disease-modifying antirheumatic drug])
  - Targeted immunomodulator (TIM) use (naïve vs experienced)

RESULTS

STUDY POPULATION

- Inclusion criteria were met by 1892 patients, of whom, 53% were on monotherapy and 47% were on combination therapy
- Approximately 19% were TIM-naïve and 81% were TIM-experienced
- Baseline characteristics were similar between the monotherapy and combination therapy groups
- A higher proportion of comorbidities were reported in the TIM-experienced group compared with the TIM-naïve group **(Table 1)**

Table 1. Baseline Characteristics

Parameter	Type of therapy at index		TIM status at index	
	Monotherapy N = 1012	Combination therapy N = 880	TIM-naïve N = 352	TIM-experienced N = 1540
Age, mean ± SD	58.0 ± 11.7	56.6 ± 11.4	56.4 ± 11.3	57.6 ± 11.7
Female, n (%)	838 (82.8)	712 (80.9)	286 (81.3)	1264 (82.1)
White, n (%)[a]	675 (87.4)	596 (84.1)	204 (79.7)	1067 (87.1)
Prior treatment with bDMARD, n (%)	787 (77.8)	597 (67.8)	0	1384 (89.9)
Prior treatment with any JAKi, n (%)	503 (49.7)	342 (38.9)	0	845 (54.9)
Osteoarthritis, n (%)	626 (61.9)	535 (60.8)	192 (54.5)	969 (62.9)
Psoriatic arthritis, n (%)	62 (6.1)	44 (5.0)	9 (2.6)	97 (6.3)
Osteoporosis, n (%)	198 (19.6)	143 (16.3)	42 (11.9)	299 (19.4)
Psoriasis, n (%)	51 (5.0)	35 (4.0)	7 (2.0)	79 (5.1)
Ankylosing spondylitis, n (%)	29 (2.9)	11 (1.3)	2 (0.6)	38 (2.5)
Stroke, n (%)	29 (2.9)	24 (2.7)	9 (2.6)	44 (2.9)

[a]N = 772, 709, 256, and 1225 for monotherapy, combination therapy, TIM-naïve, and TIM-experienced groups, respectively.
bDMARD, biologic disease-modifying antirheumatic drug; JAKi, Janus kinase inhibitor, SD, standard deviation; TIM, targeted immunomodulator.

- Baseline clinical outcome scores were similar in patients treated with monotherapy and combination therapy **(Table 2)**
- Baseline scores were also similar in TIM-naïve and TIM-experienced patients

Table 2. Baseline Clinical Outcome Scores by Therapy and TIM Status

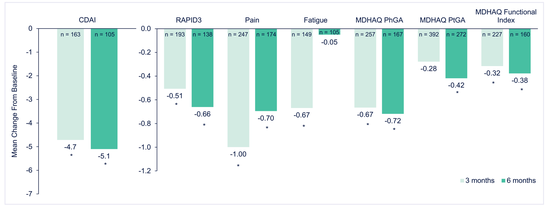
Outcome	Type of therapy at index				TIM status at index			
	Monotherapy N = 1012		Combination therapy N = 880		TIM-naïve N = 352		TIM-experienced N = 1540	
	n	mean ± SD	n	mean ± SD	n	mean ± SD	n	mean ± SD
CDAI	314	18.9 ± 12.4	327	21.4 ± 13.1	112	19.7 ± 12.9	529	20.3 ± 12.8
RAPID3	400	4.6 ± 2.5	391	4.6 ± 2.2	185	4.6.± 2.3	606	4.6 ± 2.4
Pain	480	5.8 ± 2.8	465	5.7 ± 2.6	213	5.8 ± 2.5	732	5.8 ± 2.8
Fatigue	255	5.4 ± 3.0	270	5.3 ± 2.9	125	5.1 ± 3.1	400	5.5 ± 2.9
MDHAQ PhGA	440	3.2 ± 2.7	448	3.7 ± 2.8	178	3.3 ± 2.9	710	3.5 ± 2.7
MDHAQ PtGA	646	5.3 ± 2.8	594	5.3 ± 2.7	243	5.1 ± 2.8	997	5.3 ± 2.7
MDHAQ Functional Index	463	3.1 ± 2.4	442	3.2 ± 2.3	203	3.0 ± 2.3	702	3.2 ± 2.3

CDAI, Clinical Disease Activity Index; MDHAQ, Multidimensional Health Assessment Questionnaire; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; RAPID3, Routine Assessment of Patient Index Data 3; SD, standard deviation; TIM, targeted immunomodulator.

THERAPY STATUS (MONOTHERAPY OR COMBINATION THERAPY)

- In patients receiving monotherapy at index, significant improvements from baseline were reported in CDAI, RAPID3, pain, fatigue, MDHAQ PhGA, and MDHAQ Functional Index scores at 3 months after UPA initiation **(Figure 1)**
- Generally, improvements in clinical outcome were maintained at 6 months

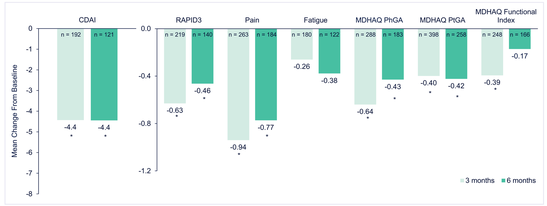
Figure 1. Clinical Outcomes at 3 and 6 Months: Monotherapy



*Statistically significant change from baseline ($P < .05$).
CDAI, Clinical Disease Activity Index; MDHAQ, Multidimensional Health Assessment Questionnaire; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; RAPID3, Routine Assessment of Patient Index Data 3.

- In patients receiving combination therapy at index, significant improvements from baseline were reported in CDAI, RAPID3, pain, MDHAQ PhGA, MDHAQ PtGA, and MDHAQ Functional Index scores at 3 months after UPA initiation **(Figure 2)**
- Generally, improvements in clinical outcomes were maintained at 6 months

Figure 2. Clinical Outcomes at 3 and 6 Months: Combination Therapy



*Statistically significant change from baseline ($P < .05$).
CDAI, Clinical Disease Activity Index; MDHAQ, Multidimensional Health Assessment Questionnaire; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; RAPID3, Routine Assessment of Patient Index Data 3.

CHANGE IN DISEASE ACTIVITY CATEGORY AFTER UPA INITIATION

- At 3 months, 39% (140/355) of patients were in LDA/remission **(Table 3)** and 33% (116/355) showed improvement in disease activity
- Of 147 patients with moderate disease at baseline, 51 (35%) were in LDA/remission at 3 months

Table 3. Shift in Disease Activity Category From Baseline to 3 Months

Baseline disease activity category	Disease activity category[a] at 3 months				Total
	Remission	Low	Moderate	High	
Remission	13 (72.2%)	3 (16.7%)	0 (0.0%)	2 (11.1%)	18 (100%)
Low	5 (7.9%)	44 (69.8%)	11 (17.5%)	3 (4.8%)	63 (100%)
Moderate	10 (6.8%)	41 (27.9%)	84 (57.1%)	12 (8.2%)	147 (100%)
High	2 (1.6%)	22 (17.3%)	36 (28.3%)	67 (52.8%)	127 (100%)

[a]Remission: CDAI ≤2.8; low disease activity: CDAI >2.8 to 10; moderate disease activity: CDAI >10 to 22; high disease activity: CDAI >22 to 76.
CDAI, Clinical Disease Activity Index.

- At 6 months, 35% (80/226) of patients were in LDA/remission **(Table 4)** and 36% (81/226) of patients showed improvement in disease activity
- Of 92 patients with moderate disease at baseline, 27 (29%) were in LDA/remission at 6 months

Table 4. Shift in Disease Activity Category From Baseline to 6 Months

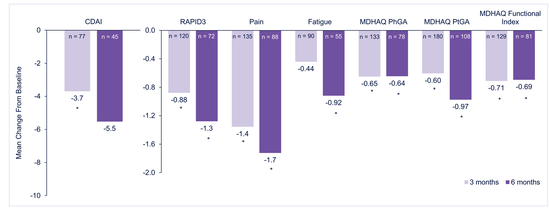
Baseline disease activity category	Disease activity category[a] at 6 months				Total
	Remission	Low	Moderate	High	
Remission	6 (66.7%)	1 (11.1%)	2 (22.2%)	0 (0.0%)	9 (100.0%)
Low	7 (17.1%)	20 (48.8%)	12 (29.3%)	2 (4.9%)	41 (100.0%)
Moderate	9 (9.8%)	18 (19.6%)	54 (58.7%)	11 (12.0%)	92 (100.0%)
High	2 (2.4%)	17 (20.2%)	28 (33.3%)	37 (44.0%)	84 (100.0%)

[a]Remission: CDAI ≤2.8; low disease activity: CDAI >2.8 to 10; moderate disease activity: CDAI >10 to 22; high disease activity: CDAI >22 to 76.
CDAI, Clinical Disease Activity Index.

TIM STATUS

- In TIM-naïve patients, significant improvements from baseline were reported in CDAI, RAPID3, pain, MDHAQ PhGA, MDHAQ PtGA, and MDHAQ Functional Index scores at 3 months after UPA initiation **(Figure 3)**
- Improvements in clinical outcomes were futher improved or maintained at 6 months

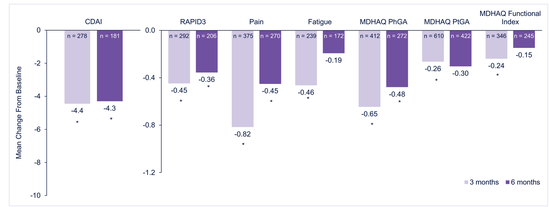
Figure 3. Clinical Outcomes at 3 and 6 Months: TIM-Naïve



*Statistically significant change from baseline ($P < .05$).
CDAI, Clinical Disease Activity Index; MDHAQ, Multidimensional Health Assessment Questionnaire; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; RAPID3, Routine Assessment of Patient Index Data 3; TIM, targeted immunomodulator.

- In TIM-experienced patients, significant improvements from baseline were reported in CDAI, RAPID3, pain, fatigue, and MDHAQ PhGA, MDHAQ PtGA, and MDHAQ Functional Index scores at 3 months after UPA initiation **(Figure 4)**
- Generally, improvements in clinical outcome were maintained at 6 months

Figure 4. Clinical Outcomes at 3 and 6 Months: TIM-experienced



*Statistically significant change from baseline ($P < .05$).
CDAI, Clinical Disease Activity Index; MDHAQ, Multidimensional Health Assessment Questionnaire; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; RAPID3, Routine Assessment of Patient Index Data 3; TIM, targeted immunomodulator.

LIMITATIONS

- Exposures and outcomes of interest were captured only if a patient had an interaction with the healthcare system
- Availability of disease activity measure may have been impacted by the COVID-19 pandemic
- Covariates that were not recorded in the data may result in unmeasured confounding
- Due to the open nature of the claims data used in this study, continuous enrollment was approximated by patterns of encounters for individual patients during the study period
- Filled prescriptions are only proxies for actual consumption, it was assumed that patients took their medication as directed
- Patients were analyzed according to their treatment status at index, regardless of whether they later discontinued UPA or switched treatment status (eg, monotherapy/combination therapy)
- Results may not be generalizable beyond the study sample

CONCLUSIONS

- Approximately half of the patients assessed in this study were treated with UPA as monotherapy, even those who were previously treated with a Janus kinase inhibitor
- Significant improvements in disease activity were consistently observed at 3 months and maintained at 6 months after UPA initiation regardless of monotherapy, combination therapy, or prior TIM use

REFERENCES

1. Fleischmann R. *Arthritis Rheumatol.* 2019;71:1788–800.
2. Smolen JS. *Lancet.* 2019;393:2303–11.
3. Burmester GR. *Lancet.* 2018;382:2505–12.
4. Genovese MC. *Lancet.* 2018;391:2513–24.
5. van Vollenhoven R. *Arthritis Rheumatol.* 2020;72:1607–20.
6. Rubbert-Roth A. *N Engl J Med.* 2020;383:1511–21.

DISCLOSURES AND ACKNOWLEDGMENTS

Financial support for the study was provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the poster. All authors contributed to the development of the publication and maintained control over the final content. The design, study conduct, and financial support for the study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the poster. No honoraria or payments were made for authorship.

Martin Bergman is a consultant/speaker for AbbVie, Amgen, BMS, Genentech, Gilead, Janssen, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sandoz and a shareholder of JNJ (parent of Janssen). **Namita Tundia** and **Mira Ali** are employees and stockholders of AbbVie. **Ia Topuria, Tom Brecht,** and **Allison Bryant** are employees of OM1. **Allan Gibofsky** is a consultant/speaker for AbbVie, Acquist, Amgen, Lilly, Merck, Pfizer, Sandoz, Samumed and a shareholder of AbbVie, Amgen, Horizon, J&J, Pfizer, and Regeneron.

Medical writing services were provided by Joann Hettasch of Fishawack Facilitate Ltd., part of Fishawack Health, Conshohocken, PA, and funded by AbbVie.

Scan QR code to download an electronic version of this presentation and other AbbVie EULAR scientific presentations.

QR code expiration: May 31, 2022.