Real-World Analysis of Initial Clinical Response and Future Outcomes Among Patients With Rheumatoid Arthritis Initiating and Remaining on a First-Line Tumor Necrosis Factor Inhibitor in the United States

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OBJECTIVE

 To evaluate the subsequent treatment response among patients with RA who initiated and remained on a first-line TNF inhibitor (TNFi) after achieving or not achieving an initial treatment response

BACKGROUND

- Current guidelines identify low disease activity (LDA) and remission as treatment targets for RA and recommend evaluation of treatment response and tolerance at 3 and 6 months after initiating a new therapy^{1,2}
- TNFis are a common first-line advanced therapy option for patients with inadequate response to, or intolerance of, conventional synthetic DMARDs
 - Still, many patients who initiate TNFis continue with treatment for many months, despite not achieving guideline-recommended treatment targets³
- It is currently unknown whether patients who do not achieve an initial response with a first-line TNFi, yet still remain on the same TNFi, are likely to achieve a response at later timepoints

METHODS

DATA SOURCE

OM1® RA Registry

- The OM1[®] RA Registry (OM1, Inc; Boston, MA) follows patients in the US managed by rheumatologists longitudinally with data derived from medical and pharmacy claims linked to electronic medical record (EMR) data
 - The registry includes over 200,000 patients with RA since 2013
 - Claims include information on procedures, diagnoses, administered and dispensed medications, and patient insurance
 - EMR data includes laboratory results and prescribing information, patient-reported outcomes, and measures of treatment response and disease activity can be derived

STUDY DESIGN

Inclusion Criteria

- Patients ≥ 18 years of age, diagnosed with RA, and followed for a 12-month baseline period
- Initiated TNFi as first-line advanced therapy between January 2016 and March 2023
- · Received the same TNFi for at least 12 months

METHODS (CONTINUED)

· Rheumatologist visit with valid CDAI assessment available at:

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- TNFi initiation (index date)
- 3- or 6-months post-index
- 12-months post-index
- Moderate or high disease activity (CDAI > 10) at TNFi initiation

Figure 1. Study Design

January 2015	12-month baseline	Initiation of TNFi (Index Date)	Latest Date: March 2024 12 months
•		3 months	6 months

TNFi, TNF inhibitor

STUDY OUTCOMES

Two Measures of Initial Treatment Response

• These outcomes were evaluated in 2 separate analyses at 3-months and 6-months post-index

Primary Outcome:

 Proportion of patients achieving CDAI LDA or remission (CDAI ≤ 10)

Secondary Outcome:

- Proportion of patients achieving minimum clinically important difference (MCID) in CDAI
 - ≥ 6-point improvement from baseline for patients initiating TNFi in moderate disease activity (MDA)
 - ≥ 12-point improvement from baseline for patients initiating TNFi in high disease activity (HDA)

Two Measures of Subsequent Treatment Response

- Treatment response status at 12-months post-index
- Maintenance of initial treatment response at all visits between 3- and 12-months or 6- and 12-months post-index

Figure 2. Study Outcomes

	12-month baseline	Index date (Initiation of TNFi)	12 months
•		3 months	All visits between 3 and 12 months
			6 months All visits between 6 and 12 months

HDA, high disease activity; LDA, low disease activity; MDA, moderate disease activity; TNFi, TNF inhibitor.

RESULTS





HDA, high disease activity; LDA, low disease activity; MDA, moderate disease activity; TNFi, TNF inhibitor.



Figure 4. Subsequent Response at 12 Months Based on 6-Month Response Status

HDA, high disease activity; LDA, low disease activity; MDA, moderate disease activity; TNFi, TNF inhibitor.

RESULTS (CONTINUED)

Figure 5. Subsequent Response at 12 Months Based on 3-Month Response Status



HDA, high disease activity; MCID, minimal clinically important difference; MDA, moderate disease activity; TNFi, TNF inhibitor. MCID; defined as ≥6-point improvement from baseline CDAI in MDA and ≥ 12-point improvement from baseline CDAI in HDA.





HDA, high disease activity; MCID, minimal clinically important difference; MDA, moderate disease activity; TNFi, TNF inhibitor. MCID; defined as ≥6-point improvement from baseline CDAI in MDA and ≥ 12-point improvement from baseline CDAI in HDA.

CONCLUSIONS

- Among patients with RA initiating a first-line TNFi, the majority of those who did not achieve an initial treatment response did not achieve a subsequent response through 12 months
- Approximately 1 in 4 patients who initially achieved LDA/remission were no longer in LDA/remission at 12-months post-index
- These results may inform clinical decision-making on treatment continuation after initial nonresponse in RA patients initiating first-line TNFi therapy

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