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Biologics Vs. Biosimilars Utilization Among Rheumatoid Arthritis (RA) Patients

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BACKGROUND

- Biologics including adalimumab, etanercept, infliximab, and rituximab represent major first-line and second-line therapies for rheumatoid arthritis (RA) patients.[1]
- Biosimilars are medications that are highly similar in safety and efficacy to their original reference biologic products.
- Currently, 15 biosimilar products are approved or launched in US for rheumatoid arthritis and other immune-mediated inflammatory diseases.[2]
- Despite the bioequivalence and the potential for lower cost of care, market penetration of biosimilars has been limited in US.[3]
- While the perception of biosimilars among payers and providers continues to grow, real-world evidence on utilization of biosimilars compared to biologics among patients with rheumatoid arthritis (RA) is limited.

OBJECTIVES

- Describe the incidence of biosimilar vs. biologic prescription among patients with newly-diagnosed RA
- Evaluate time to first biologic or biosimilar prescription among newly-diagnosed RA patients.
- Examine the baseline characteristics associated with utilization of biosimilars vs biologics among newly-diagnosed RA patients.

METHODS

Study design: Retrospective cohort study

Data Source: Administrative claims, Optum Research Database (ORD)

Study Participants:

- Commercial and Medicare Advantage Part D (MAPD) enrollees ≥18 years of age with ≥1 claim for new RA diagnosis between 1/1/2016 and 12/31/2021 (Index date = First RA diagnosis).
- Subjects with missing demographics (age, sex, race/ethnicity, region), and <6 months of medical and pharmacy continuous enrollment (CE) before or after index date were excluded.
- Patients were followed for at least six months after the index date to evaluate follow-up clinical outcomes.

Measures:

- **Baseline characteristics** included demographics (age, gender, insurance plan, race/ethnicity, and region), and Charlson comorbidity index score (CCI).
- **Treatment characteristics** included ≥1 medical or pharmacy claims for biosimilar or biologic medication(s) initiation – infliximab, rituximab, etanercept, or adalimumab; concomitant use of RA medications (NSAIDs and DMARDs); and history of biologics prior to biosimilar initiation.

Statistical methods:

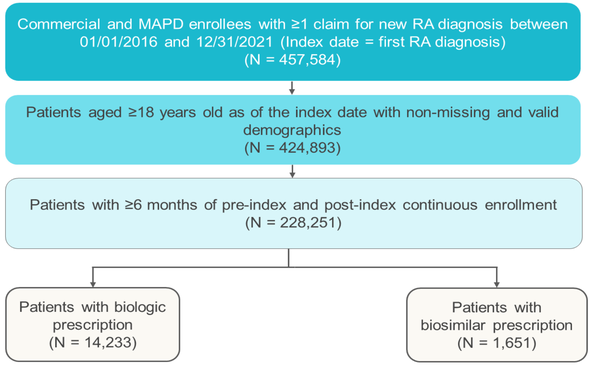
- Demographics were assessed on/near the index date. Clinical characteristics were measured in the 6-month baseline, and treatment patterns were assessed until the first of biologics or approved biosimilars prescription, disenrollment, or study conclusion.
- Incidence rates were calculated as patients initiating biologics or biosimilars during follow-up per 10,000 person-years (PY) at risk.
- Time to biologic or biosimilar initiation was assessed using KM analysis.
- Cox proportional hazard (CPH) model was constructed to evaluate factors associated with utilization of biosimilars among newly-diagnosed RA patients, adjusting for baseline covariates.
- All tests were two-sided, α=0.05, using SAS 9.4, SAS Institute Inc.

DMARD – Disease modifying anti-rheumatics drugs; NSAID - Non-steroidal anti-inflammatory drugs; KM – Kaplan-Meier

RESULTS

Final Patient Sample

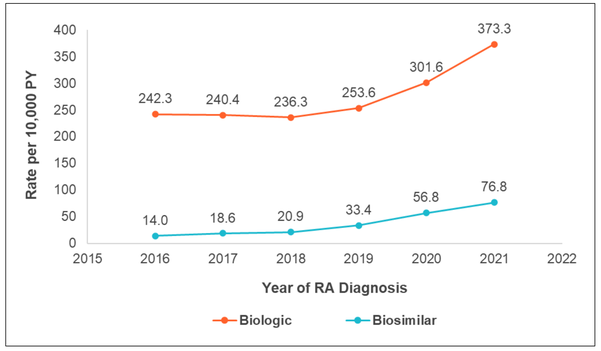
Figure 1: Study Subject Identification and Attrition



- A total of 228,251 eligible subjects (Fig. 1) were identified.
- The mean ±SD age was 60.53 ± 15.05 and females comprised 70.30% of the eligible population.
- White patients, Hispanic patients, and Black/AA patients comprised 65.60%, 13.83%, and 13.07% of the eligible sample, respectively. The sample was approximately evenly split (~50% each) between Commercial and MAPD.
- 40.18% had at least 1 Charlson comorbidity, the most common being Diabetes with (9.57%) or without (21.56%) complications and Chronic pulmonary disease (17.0%).

Utilization Trends over Time

Figure 2: Biologic vs Biosimilar Incidence rates among RA patients



- Only 6.96% of patients initiated biologic or biosimilar therapy during follow-up.
- Among patients initiating biosimilars, 48.03% had a history of biologic prescription.
- The incidence rate of biosimilar initiation increased 5.5-fold between 2016 and 2021 (p<0.001), while the rate of biologic initiation increased 1.5-fold during the same time period (p<0.001).

Time to First Prescription from RA Diagnosis

Figure 3: Time to First Biologic Prescription, By Index Year

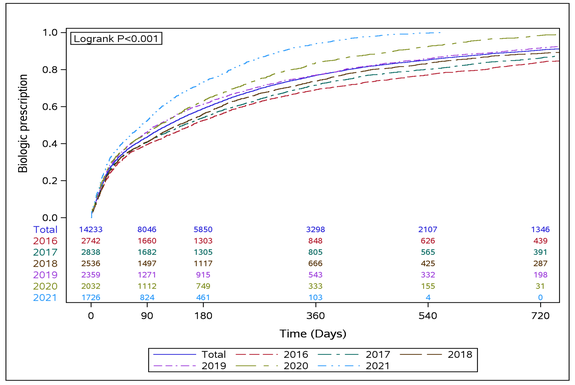
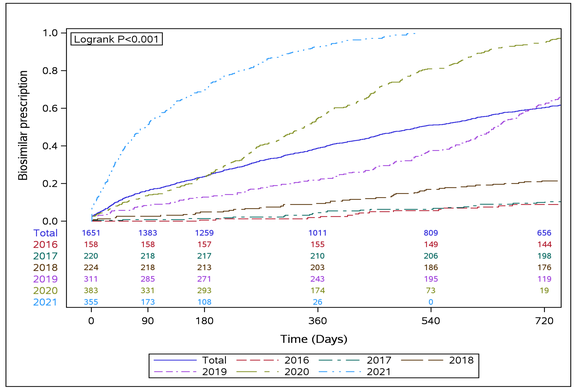
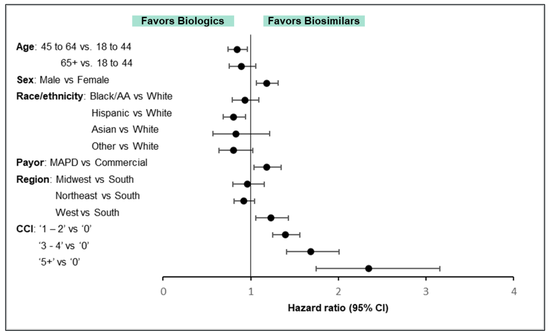


Figure 4: Time to First Biosimilar Prescription, By Index Year



- In KM analysis, the overall distributions of incident biologic prescription as well as biosimilar prescription were significantly different by index year (p<0.001) (Figure 3 & 4).
- Prior to multivariable adjustment, older age (Age 65+ vs. <45: Hazard Ratio (HR) 1.34, p<0.001), male vs. female sex (HR 1.18, p=0.003), MAPD vs. commercial insurance (HR 1.41, p<0.001), higher Charlson comorbidity score (5+ vs. 0: HR 2.92, p<0.001), Hispanic race/ethnicity vs. White (HR 0.84, p=0.02), and West vs. South geographic region (HR 1.26, p=0.003) were associated with biosimilar vs. biologic prescription.
- Most associations remained after multivariable adjustment, with the exception of age (Age 65+ vs. <45: adjusted HR 0.89, p=0.21) (Fig. 5).

Figure 5: Multivariable Cox Proportional Hazards Model for Incidence of Biosimilar vs. Biologic Prescription



Among 15,884 patients prescribed either biologic or biosimilar during the follow-up period.
*Mutually adjusted for age, sex, race/ethnicity, insurance type, region, year of RA diagnosis, and CCI score (categorical)

LIMITATIONS

- As with all claims-based retrospective studies, there is potential for misclassification of both outcome and exposure since claims were collected for the purpose of payment.
- Our study lacks information on disease severity and first- or second- lines of therapy, which may impact observed biologic or biosimilar prescription patterns.
- Provider characteristics such as specialty were not captured in this study which might influence biologic vs biosimilar prescription.

CONCLUSIONS

- Biologic and/or biosimilar utilization is limited (<10%) in newly diagnosed RA patients.
- Although biologic use is more common, between 2016 and 2021, the biosimilar initiation increased nearly four times as much as that for biologics.
- Male vs. female sex, MAPD vs. Commercial insurance type, more recent year of RA Diagnosis, higher Charlson comorbidity score, White vs. Hispanic ethnicity, and West vs. South geographic region were independently associated with increased likelihood of biosimilar vs. biologic prescription.
- Further research is needed to understand overall biosimilar vs biologic uptake trends and switching patterns.

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Disclosure: This study was conducted exclusively for research purposes and all authors declare no conflict of interest.

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