Biosimilar Etanercept Use in Rheumatoid Arthritis: The RHUMADATA® Registry Experience

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Background

- Biosimilars hold the potential to improve access to needed therapies at a reduced cost.
- In Canada, biosimilar etanercept (ETA) was recently approved for rheumatoid arthritis (RA), ankylosing spondylitis (AS), and psoriatic arthritis (PsA).
- We assessed therapy persistence in ETA initiators, comparing biosimilar to bio-originator among patients with RA

Methods

- We identified patients initiating biosimilar or bio-originator ETA from a practice-based registry, for the period January 2015 to November 2018.
- This included biologic-naïve users, patient transitioning from bio-originator to bio-similar and vice-versa, and switchers from other biologic agents)
- Therapy persistence for biosimilar versus bio-originator ETA initiators was compared using Kaplan-Meier methods and adjusted hazard ratios (HR).
- Our hazard models adjusted for age, sex, disease duration, methotrexate (MTX) dose at baseline, and comorbidities (Charlson comorbidity index, CCI).

Disclosure

CS Moura, None; **S Bernatsky,** None; **L Coupal**, None; **L Bessette**, (Amgen, BMS, Janssen, Roche, UCB Pharma, AbbVie Inc, Pfizer, Merck, Celgene, Sanofi, Eli Lilly, and Novartis); **G Boire,** (AbbVie, Amgen, BMS, Celgene, Eli-Lilly, Merck, Novartis, Pfizer); **D Choquette,** (AbbVie, Amgen, BMS, Celgene, Eli-Lilly, Merck, Novartis, Pfizer, Sanofi-Genzyme).

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Results

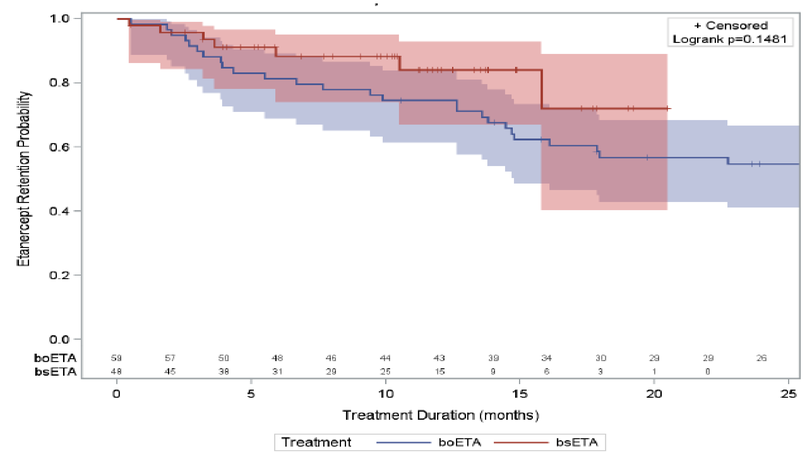
- We studied 48 patients initiating biosimilar ETA (including 37 ETA-naïve) and 59 initiating bio-originator.
- At initiation, sex distribution, age, comorbidities and disease duration were similar between groups (Table 1).
- At ETA initiation, use of conventional DMARDs was also similar; however, patients initiating bio-originators had a higher MTX dose (22.0 ± 3.5mg) versus biosimilar users (19.0 ± 5.2mg).
- Persistence on therapy was similar in both groups (Figure 1): after 12 months, 75% of originator versus 84% of biosimilar ETA initiators remained on their initial treatment.
- Adjusted HR suggested a trend for more therapy persistence in biosimilar vs. originator (HR 2.05, 95% CI 0.83, 5.04).

Table 1 – Baseline characteristics in initiators of ETA

Characteristics at ETA initiation	Bio-originator (n=59)	Biosimilar (n=48)
Female sex, N (%)	44 (74.6%)	34 (70.8%)
Mean age ±standard deviation, SD	53.9 ± 14.2	57.5 ± 14.4
Mean disease duration in years, ±SD	8.0 ± 8.7	10.3 ± 10.9
Mean age-adjusted CCI ±SD	2.6 ± 1.5	3.0 ± 1.6
DAS28-ESR at baseline ±SD	4.2 ± 1.1	3.8 ± 2.1
Drugs at treatment initiation, N (%)		
Methotrexate (MTX)	40 (67.8%)	28 (58.3%)
Hydroxychloroquine	38 (64.4%)	30 (62.5%)
Sulfasalazine	6 (10.2%)	8 (16.7%)
Leflunomide	1 (1.7%)	2 (4.2%)
Glucocorticoid	25 (42.4%)	12 (25.0%)
Baseline MTX dose (mg)	22.0 ± 3.5	19.0 ± 5.2
Previous treatment, N (%)		
Conventional DMARDs	37 (62.7)	24 (50)
Abatacept	7 (11.9)	1 (2.1)
Etanercept	0 (0.0)	11 (22.9)
Tofacitinib	3 (5.1)	5 (10.4)
Others[1]	12 (20.3)	6 (12.5)

[1]Including adalimumab, anakinra, certolizumab, infliximab,, rituximab, sarilumab, and tocilizumab.
CCI: Charlson comorbidity index; DAS28-ESR: Disease Activity Score - erythrocyte sedimentation rate.

Figure 1 - Kaplan Meier survival curves for therapy persistence per treatment group of a) boETA, and b bsETA.



Conclusions

- Baseline characteristics of patients initiating biosimilar or bio-originator ETA were similar
- We noted a strong trend for greater persistence with biosimilar versus originator
- Possibly may reflect residual confounding (e.g.: disease activity).
- Further work is ongoing to study outcomes (including safety) in a larger, multi-centre group of patients.

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