Drug Retention of TNFi Biosimilars and Bio-Originals in Daily Rheumatology Care in Germany: Insights from the RABBIT register

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Conclusion

After adjusting for differences in patient characteristics, TNFi biosimilars (BS) and bio-originals (BO) do not show a significant difference in drug retention. These results are in line with the findings of other observational studies and strengthen the current perspective on the equivalence of BS with their BO. Possible limitations are the considerably lower numbers of treatment episodes in the BO groups compared to BS.

Background

TNFi biosimilars are increasingly prescribed as treatments of rheumatoid arthritis (RA) in Germany. Reliable information on their efficacy and safety in everyday practice used to be sparse, but is now becoming increasingly available [1,2].

Objectives

To compare drug retention between TNFi biosimilars (BS) and bio-originals (BO) for the active substances adalimumab (ADA), etanercept (ETN) and infliximab (IFX).

Methods

- Data source: German biologics register RABBIT
- Enrolment: RA patients initiating a biologic (b) or targeted synthetic (ts) disease-modifying anti-rheumatic drug (DMARD) or a conventional synthetic (cs) DMARD after at least one DMARD failure
- Evaluation of treatment episodes of ADA, ETN and IFX from the calendar year following EU marketing authorization of the first respective BS until June 2023
- Data analysis
  - ➢ Drug retention was analysed using Kaplan-Meier curves
  - ➢ Hazard ratios (HR) for treatment discontinuation were calculated by unadjusted and adjusted Cox-based regression (Andersen-Gill)
  - – Adjustment factors: age, sex, disease duration, DAS28-ESR, number of previous b/tsDMARDs, concomitant glucocorticoid use, sum of comorbidities, BMI, smoking, educational level and employment status
  - – Treatment discontinuation was only considered when resulting from adverse events (including death), treatment failure or non-compliance
  - – Termination of treatment episodes for other reasons were censored at the end of the episode
  - – The respective BO treatment served as reference group for presenting HR

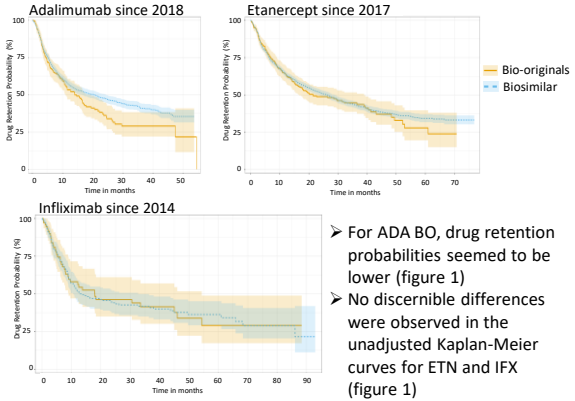
Results

- ➢ 5143 patients contributed to 5749 treatment episodes
- ➢ Patients with BS treatment were similar to those with the respective BO, but had a shorter disease duration and less prior treatment failures (table 1)

Table 1: Patient characteristics at start of bio-original (BO) or biosimilar (BS) treatment of adalimumab (ADA), etanercept (ETN) and infliximab (IFX); values are given as counts (%) or mean ± SD

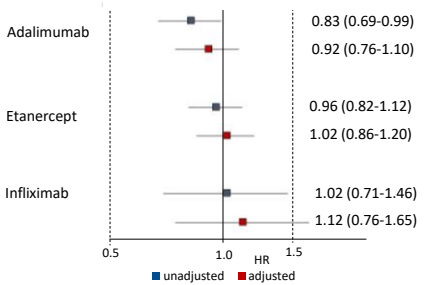
	ADA BO	ADA BS	ETN BO	ETN BS	IFX BO	IFX BS
First inclusion year	2018		2017		2014	
No. of treatment episodes	254	1857	352	2994	72	220
Female	200 (78.7)	1350 (72.7)	268 (76.1)	2182 (72.9)	49 (68.1)	149 (67.7)
Age (years)	57.1 ± 12.5	58.5 ± 12.4	58.8 ± 13.7	60.2 ± 12.6	55.5 ± 12.2	56.7 ± 13.0
Disease duration (years)	11.1 ± 8.2	10.5 ± 9.1	11.7 ± 9.3	9.9 ± 8.6	12.1 ± 9.7	11.2 ± 9.7
Disease activity DAS28-ESR	3.8 ± 1.4	3.9 ± 1.4	4.1 ± 1.5	4.2 ± 1.4	4.1 ± 1.3	4.0 ± 1.5
Oral glucocorticoid use	144 (56.7)	1082 (58.3)	215 (61.3)	1971 (65.9)	56 (77.8)	136 (61.8)
No. of previous b/tsDMARDs	2.0 ± 1.7	1.2 ± 1.5	1.6 ± 1.7	0.9 ± 1.3	2.9 ± 2.3	2.2 ± 2.3
No. of comorbidities	2.1 ± 2.0	2.0 ± 1.9	2.4 ± 2.1	2.2 ± 2.0	1.8 ± 2.2	1.6 ± 1.8

Figure 1: Kaplan-Meier curves of bio-originals (orange) and biosimilars (blue) for adalimumab, etanercept and infliximab



- ➢ For ADA BO, drug retention probabilities seemed to be lower (figure 1)
- ➢ No discernible differences were observed in the unadjusted Kaplan-Meier curves for ETN and IFX (figure 1)

Figure 2: Estimated Hazard ratios (HR) for discontinuation of biosimilars compared to the respective bio-original (=reference)



- ➢ Estimated HR for discontinuation from unadjusted Cox regression yielded similar results to Kaplan-Meier curves (figure 2, blue squares)
- ➢ Using adjusted models, no significant differences were found in any of the groups (figure 2, red squares)

References

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