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Persistence of Infliximab Biosimilar versus Originator in Patients with Crohn's Disease: A Retrospective Cohort Study in China

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Objective

Infliximab (IFX) is widely used in the treatment of Crohn's disease (CD), but the persistence difference between the originator infliximab (O-IFX) and biosimilar infliximab (B-IFX) remains insufficiently studied. This study aimed to compare the persistence of O-IFX and B-IFX in Chinese CD patients.

Methodology

Study design

- **Participant:** Patients diagnosed with CD at Sir Run Run Shaw Hospital between October 2021 and February 2024
- **Intervention:** B-IFX
- **Comparison:** O-IFX
- **Outcome:** Treatment persistence. Discontinuation was defined as the cessation of IFX therapy for any reason during the 1-year follow-up period, specifically referring to either: (1) an interval > 120 days between two consecutive IFX administrations; (2) a duration of >120 days between the last IFX administration and the follow-up endpoint
- **Study:** A single-center cohort study

Patients were divided into two groups based on the type of IFX they received: the B-IFX group and the O-IFX group. Additionally, patients were further stratified into subgroups based on their history of biologic use: the biologic-naïve B-IFX subgroup (biologic-naïve-B-IFX) and the biologic-naïve O-IFX subgroup (biologic-naïve-O-IFX).

Statistical analysis

- Treatment persistence was evaluated via Kaplan-Meier survival analysis, with survival time defined as the duration from IFX initiation to either the occurrence of treatment discontinuation or the end of follow-up (whichever occurred first).
- Between-group differences were assessed using the Log-rank test.
- Cox proportional hazards regression models were constructed to estimate hazard ratios (HRs) and 95% CIs after adjusting potential confounders.

Results

- A total of 473 patients who were first-time IFX users were included, comprising 128 in the B-IFX group and 345 in the O-IFX group. Two group were generally comparable in terms of demographic and disease characteristics. Differences in treatment history were observed between the two groups: the O-IFX group had a higher rate of prior immunosuppressant use (17.10% vs. 7.03%, P = 0.006), while the B-IFX group had a significantly higher proportion of prior biologic use compared to the O-IFX group (29.69% vs. 15.07%, P < 0.001).

➢ **Treatment persistence**

- During the 1-year follow-up period, 471 patients (B-IFX group: 127 patients; O-IFX group: 344 patients) completed follow-up. No significant differences in discontinuation rates were observed between the groups (P = 0.452, **Figure 1**). After adjusting for baseline CDAI severity, disease location, and prior exposure to biologics/immunomodulators, Cox proportional hazards regression revealed no statistically significant difference in discontinuation risk (adjusted HR = 1.15, 95% CI: 0.49–2.72, P = 0.741).
- In the biologic-naïve subgroup analysis, 381 patients (biologic-naïve-B-IFX group: 89 patients; biologic-naïve-O-IFX group: 292 patients) completed follow-up. Similarly, no significant intergroup difference in discontinuation rates was detected (P = 0.267, **Figure 2**). Multivariable adjustment for potential confounders use demonstrated comparable discontinuation risks between subgroups (adjusted HR = 0.84, 95% CI: 0.31–2.25, P = 0.730).

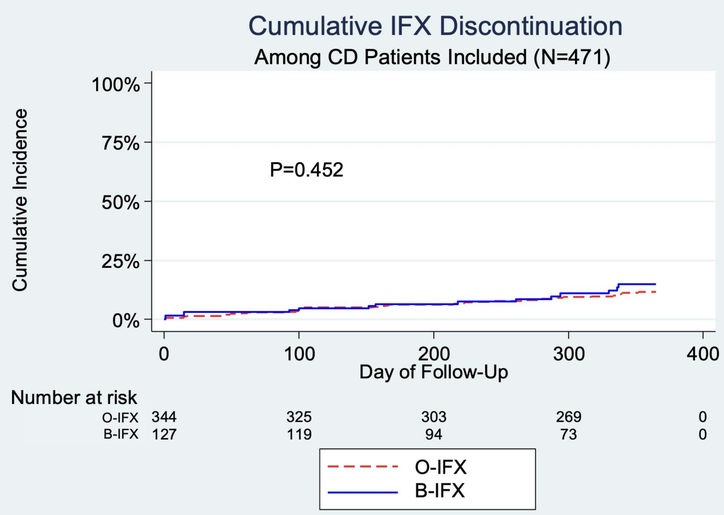

Figure 1. Cumulative discontinuation rate curve

Results (Cont'd)

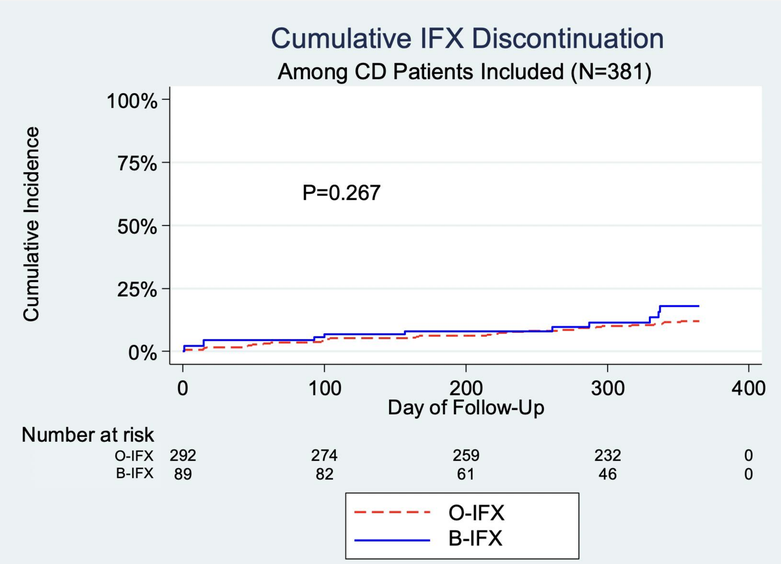

Figure 2. Cumulative discontinuation rate curve in biologic-naïve patients

Conclusion

In Chinese CD patients, original and biosimilar IFX had comparable persistence in 1-year follow-up. This provides valuable information for clinical decisions, yet further research on long-term persistence is warranted.

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