TNF Cs, therapeutic ADA Cs $\geq 8$ µg/mL and IFX Cs $\geq 3.5$ µg/l.

For statistical analysis, continuous variables were expressed as mean (95% CI) or median (IQR), depending on the distribution; categorical variables were expressed as number and frequency. A univariate analysis was performed to identify variables that may affect drug concentrations, using independent samples t tests (continuous variables) or the $\chi^2$ test (categorical variables). Logistic regression was performed to quantify the influence of explanatory variables on Cs.

Results 640 Cs determinations were included (372 ADA, 247 IFX) corresponding to 185 patients (47 ulcerative colitis, 138 Crohn's disease): mean age was 41 (12) years, 50% were women and median BMI was 24 (5) kg/m$^2$. IFX Cs were significantly associated with CRP (OR 4.68 (95% CI 2.49 to 8.81); p<0.001). ADA Cs were significantly associated with CRP (OR 4.58 (95% CI 2.45 to 8.56); p<0.001), albumin (OR 2.175 (95% CI 1.06 to 4.46); p=0.034), dose intensity (OR 3.11 (95% CI 1.58 to 6.12); p=0.001) and BMI (OR 0.88 (95% CI 0.82 to 0.95); p=0.001).

Conclusion and relevance Achieving therapeutic drug concentrations increase the probability of obtaining disease control (low CRP inflammatory marker) both for ADA and IFX. High levels of albumin and intensified ADA dose increased the probability of achieving ADA therapeutic levels, while high BMI decreased the probability of achieving ADA therapeutic levels. Stabilized ADA fixed dosing may be reconsidered for tailored dosing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest
Persistence of biosimilar treatment for immune mediated inflammatory diseases in clinical practice


Background and importance Maintaining persistence is a key element in pharmacotherapy follow-up. Adverse effects of biosimilars may be one of the main causes for discontinuing treatment.

Aim and objectives To analyse persistence as an effectiveness and safety indicator for different biosimilars in immune mediated inflammatory diseases (IMID) in clinical practice.

Material and methods A retrospective study was conducted in a regional hospital with a reference area of 110 000 inhabitants and 230 biological treatments (BT). All patients with an IMID who had received a biosimilar of infliximab, etanercept or adalimumab from the first biosimilar’s entry in the pharmacotherapeutics guide until February 2020 were included. Variables studied were demographic data (gender, age), medical speciality, previous treatments and time receiving the biosimilar. Reasons for discontinuation and activity of the disease were registered. Data collection was done with SAVAC, an electronic prescription system. Statistical analysis was performed using SPSS Statistics V.22. Categorical variables are shown as percentages and quantitative variables as mean (SD).

Results 64 patients (27.8% BT) were included: 28 (43.8%) were men and mean age was 43.7 (SD 16.3) years. 26 (40.6%) patients had received previous BT, most of them with an anti-TNF (53.8%). Only 11 (17.2%) patients switched from the original to the biosimilar drug. Distribution by drug was: 27 (42.2%) infliximab, 21 (32.8%) etanercept and 16 (25.0%) adalimumab. Distribution by medical speciality was: 34 (53.1%) dermatology, 26 (40.6%) rheumatology and 4 (6.3%) cardiology.

31 (48.4%) patients stopped or changed treatment: 13 (41.9%) infliximab, 12 (38.7%) etanercept and 6 (19.4%) adalimumab. Reasons were: 14 (45.2%) adverse effects, 14 (45.2%) inefficacy and 3 (9.6%) other reasons, mainly loss to follow-up. Persistence of treatment was 26 (SD 31.2) weeks. Adverse effects causing discontinuation of the biosimilar were: 3 (16.6%) cases of pain, 2 (11.1%) infections, 2 (11.1%) hypersensitivity reactions, 2 (11.1%) headache, 1 (5.6%) dyspnoea, 1 (5.6%) swelling, 1 (5.6%) asthenia, 1 (5.6%) diarrhea, 1 (5.6%) arthralgia, 1 (5.6%) skin lesions, 1 (5.6%) pruritus and 1 (5.6%) lupus drug induced.

33 (51.6%) treatments remained active: 15 (45.4%) infliximab, 9 (27.3%) adalimumab and 9 (27.3%) etanercept. Persistence of treatment was 55 (SD 39.6) weeks. 27 (81.8%) patients were in remission, 3 (9.1%) presented low activity and 3 (9.1%) moderate activity.

Conclusion and relevance Patients that changed or stopped taking a biosimilar had an average treatment of 6 months. The most common reasons were adverse effects and inefficacy. Regarding adverse effects, 50% were subjective symptoms. A possible nocebo effect could not be discarded. Patients who continued with a biosimilar had a persistence of more than 1 year.

References and/or acknowledgements

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