Clinical and pharmacokinetic results after the switch to infliximab biosimilar in inflammatory bowel disease: 2 years of real-life experience

Martín-Gutiérrez N[1], Sánchez-Hernández JG[1], Rebollo-Díaz N[1], Fernández-Pordomingo A[2], Muñoz-Núñez JF[2], Recarey –Gerpe V[1], Otero-López MJ[1].

[1] Pharmacy Service, [2] Gastroenterology Service, Hospital Universitario de Salamanca.

NP-010

Background and Objetive

- Debate on the use of biosimilars focuses on the therapeutic efficacy and safety of switching between biosimilars and their reference products.
- The objective was to determine the clinical results and pharmacokinetic (PK) behavior of switching from originator infliximab to biosimilar (CT-P13) in patients with inflammatory bowel disease (IBD) over 2 years.

Material and Methods

Study subjects

- Adult patients diagnosed of Crohn's disease (CD) or ulcerative colitis (CU).
- Treated with originator infliximab (Remicade®) and changed to CT-P13.

Data Collection

- Demographic.
- Clinical Response: Harvey Bradshaw (HB) and Mayo partial (iMP) index
- Biochemical biomarkers: fecal calprotectin (FC).
- Endoscopic findings.

PK analysis

- IFX serum concentrations
- ELISA technique.
- PK parameters: Clearance (CL) and volume of distribution (Vd) estimated by population Pk model[1]

Clinical outcomes

- Biochemical remission (BR): FC < 100 mg/Kg.
- Clinical remission (CR): HB<5 (CD) and iMp <3 (CU).
- Endoscopic remission (ER): Mucosa healing with absence of ultrasound activity.

Chronological evaluation of PK parameters and response outcomes:

Prior to the switch → Immediatly after → 8 months after → 2 years after the switch

Statistical analysis:

- Repeated measures ANOVA test to compare PK parameters.
- Percentage of patients who reached the response outcomes.

Results

Demographics

- **Patients (n=42):** 55% women.
- **Age:** 42 [18-70] years.
- **Pathology:** 10 UC and 32 CD

Clinical outcomes

	Prior to the switch	Immediatly after	8 months after	2 years after the switch
BR	95%	95%	88%	92%
CR	93%	93%	93%	97%
ER	93%	93%	88%	92%

Reference: 1. Sánchez-Hernández, et al. A 3-year prospective study of a multidisciplinary early proactive therapeutic drug monitoring programme of infliximab treatments in inflammatory bowel disease. Br J Clin Pharmacol. 2020;1– 11.

Pharmacokinetic parameters

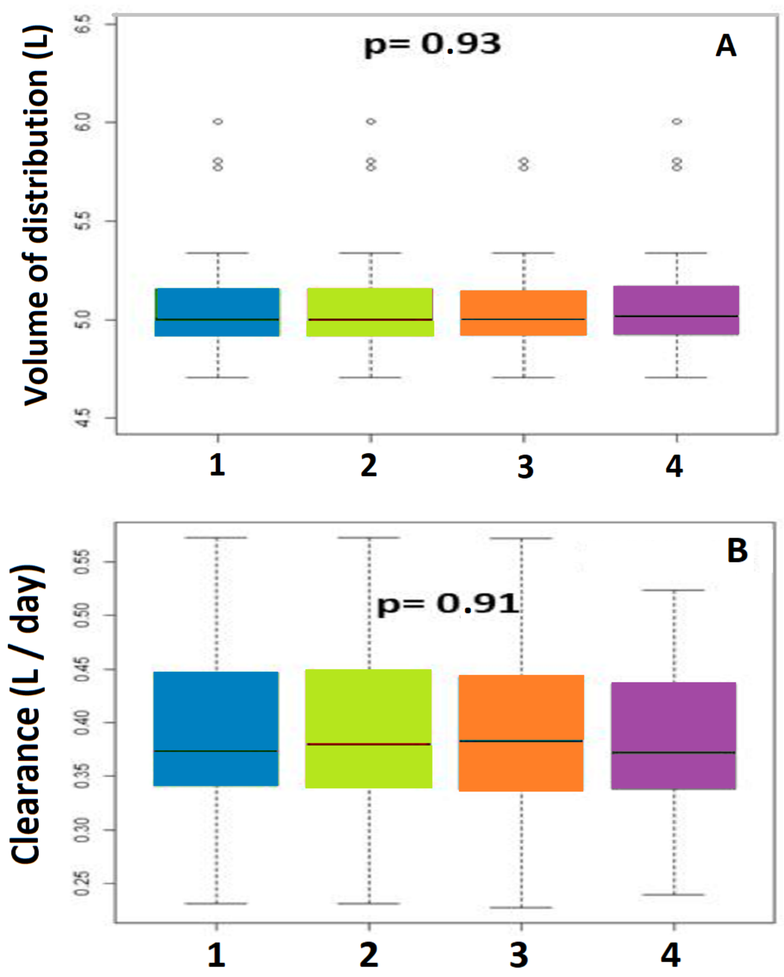

Figure 1. Box plot of PK parameters: volumen of distribution (A) and clearance (B) in four temporal sections: prior to the switch (1), inmediatly after (2), eight months later (3) and two years later (4).

Conclusion

After switching from infliximab originator to biosimilar in a real cohort of IBD patients, no changes in clinical outcomes or pharmacokinetic behavior were observed over 2 years, which supports the switch in clinical practice.

Contact us:
jgermansanchez@saludcastillayleon.es

https://www.eahp.eu/25-NP-010