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


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**Background and Objective**

- 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 (UC).
- 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.

**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.

**Results**

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

**Clinical outcomes**

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<th>Prior to the switch</th>
<th>Immediately after</th>
<th>8 months after</th>
<th>2 years after the switch</th>
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<tbody>
<tr>
<td>BR</td>
<td>95%</td>
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<td>88%</td>
<td>92%</td>
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<tr>
<td>CR</td>
<td>93%</td>
<td>93%</td>
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<td>97%</td>
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<tr>
<td>ER</td>
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**Pharmacokinetic parameters**


**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.

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