COMPARATIVE ANALYSIS BETWEEN ORIGINATOR AND BIOSIMILAR INFLIXIMAB ACCORDING TO TROUGH LEVELS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background

The introduction of Biosimilar Infliximab (IFX-B) has led to a decrease in the costs of patients with inflammatory bowel disease (IBD). The molecular complexity in the manufacture of biological drugs makes it difficult to verify the similarity between the different drugs. Infliximab (IFX) therapeutic drug monitoring allows for objective decision making in patients with IBD.

Objective

To compare the percentage of patients in therapeutic IFX concentrations, between Originator Infliximab (IFX-O) versus IFX-B, as well as the prevalence of immunogenicity between both.

Material and method

- Retrospective observational study (March 2017- September 2018).
- **Patients** with **IBD** who received maintenance therapy with **IFX** and underwent pharmacokinetic monitoring.
- The **variables** studied were:
  - Sex, age, diagnosis
  - Type of drug (IFX-O or IFX-B)
  - Number of serum samples collected
  - Serum trough levels infliximab
  - Presences of antibodies.

- Blood extraction was performed in trough levels and determined by sandwich ELISA (Promonitor®).
- IFX therapeutic range was defined between 3-10 mcg/mL.
- We used X^2 test to compare the association between categorical variables and t-student for quantitative variables. All tests we performed using SPSS v.23.0.

Results

- We included **70** patients
  - 65.7% were men
  - Mean age was 41.8 (DE: 14.8) years
  - 74.4% had Crohn's disease

→ Type of IFX/patient:

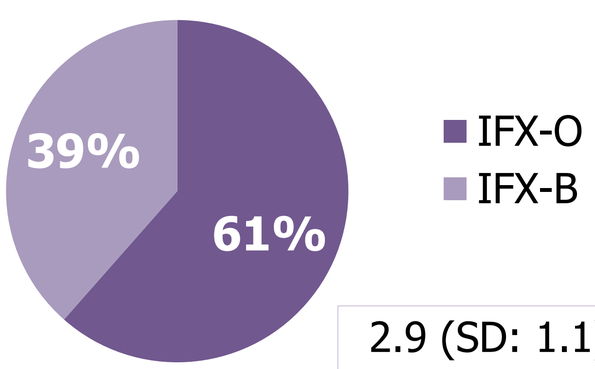
49.3% IFX-O
50.7% IFX-B

- Mean serum **trough levels**
  - IFX-O: **7.2** (SD:4.5) mcg/mL
  - IFX-B: **8.3** (SD: 7.8) mcg/mL

  } **p= 0.790**

Therapeutic range: 61.9% IFX-O
47.8% IFX-B } **p=0.137**

174 Serum Samples Analyzed



2.9 (SD: 1.1) and 1.8 (SD:1.0) samples per patient of IFX-O and IFX-B respectively.

- **Immunogenicity**: **13.1%** patients presented antibodies anti-IFX (11.6% IFX-O and 15.4% IFX-B, **p = 0.43**)

Conclusion

1. In our study there was no significant difference in the mean concentration of drug between IFX-O and IFX-B, and neither in immunogenicity, being IFX-B a **cost-effective alternative** to the originator product.
2. Pharmacokinetic **monitoring** represents a fundamental mainstay in the **optimization** of these treatments.

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