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PHARMACOKINETIC MONITORING OF SUBCUTANEOUS INFLIXIMAB IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

M. CHOVI TRULL[1], M. GIL CANDEL[1], M.R. MARQUÉS MIÑANA[1], L. ESCOBAR HERNÁNDEZ[1], N. FERRANDIS SALES[1], B. ARNAU BLASCO[1], M. RODENAS ROVIRA[1], A. SOLANA ALTABELLA[1], M. MARTIN CEREZUELA[1], J. GARCIA PELLICER[1], J.L. POVEDA ANDRÉS[2]

[1]Hospital Universitari i Politècnic La Fe, Pharmacy department, Valencia. [2] Hospital Universitari i Politècnic La Fe, Management department, Valencia.

corresponding author: **mariach22ch@gmail.com*

BACKGROUND AND OBJECTIVES

Subcutaneous infliximab (SC-IFX)

Inflammatory bowel disease (IBD)

stable drug concentration → CUT OFF? → **treatment effectivenes** and **safety**

- To analyze the **variability** of trough concentration (Cmin) of SC-IFX
- To establish a **cutoff** to achieve clinical response (CR), biochemical remission (RemBq) and clinical remission (RemC) during the maintenance phase in **IBD patients.**

MATERIAL AND METHODS

Study design

- Ambispective
- Observational
- Single center
- January 2020 - June 2024

- Data: electronic prescription program (**Abucasis**/MDIS program)
- Variables:

Demographic data
- Sex
- Age
- Weight

Diagnosis
- Crohn disease (CD)
- Ulcerative colitis (UC)

Pharmacoterapeutic data
- Cmin (3rd,6th,12th months)
- Previous biological therapy

Biochemical parameters
- Albumin (ALB)
- Fecal calprotectin (FCP)
- C-reactive protein (CRP)

Clinical score
- Partial-Mayo Score (MS): UC
- Harvey-Bradshaw (HB): CU

- Results expression: percentage, and median [interquartile range(IQR)].

RESULTS

	PATIENTS
n	52
IBD	CD (n=42)
	UC (n=10)
Age	45.0 [34.0 - 56.0]
Weight	70.0 [62.0-83.0]
Prior biologic treatment	n = 8

Table 1. Patient's characteristics.

Pharmacokinetic parameters (median [IQR])	3rd	6th	12th	p_value
Cmin (µg/mL)	15.1 [10.4-19.4]	13.7 [10.0-16.7]	14.3 [10.2-17.4]	0.226

Table 2. Pharmacokinetic parameters.

SC- IFX cut off

CR	3rd	12th
Cmin (µg/mL)	13.5	13.7
AUC [95%CI] p_value	0.90 [0.82-0.98] p=0.024	0.77 [0.61-0.93] p= 0.020
S	0.83	0.68
E	0.87	0.88

RemBq	3rd
Cmin (µg/mL)	16.8
AUC [95%CI] p_value	0.76 [0.63-0.90] p= 0.070
S	0.53
E	0.92

Biochemical parameters (median [IQR])	3rd	6th	12th
ALB (g/dL)	4.4 [4.2-4.6]	4.4 [4.2-4.5]	4.4 [4.3-4.7]
FCP (µg/g)	58.0 [30.5-199.4]	105.2 [37.4 -265.1]	75.6 [32.3-316.2]
CRP (mg/L)	1.3 [1.0-3.3]	1.5 [1.0-3.1]	1.4 [1.0-3.0]

Table 3. Biochemical parameters.

S: sensitivity, E: specificity

CONCLUSIONS AND RELEVANCE

- **SC-IFLX Cmin** remained stable over the follow-up period. A **cutoff** for CR was identified at **13.5 µg/mL** and **13.7 µg/mL**, and a cutoff of **16.8 µg/mL** for RemBq.
- Further studies are required to confirm these findings and establish an optimal cutoff that ensures favorable clinical outcomes.

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