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STUDY OF SERUM CONCENTRATIONS OF SUBCUTANEOUS INFLIXIMAB IN INFLAMATORY BOWEL DISEASE AND THEIR CORRELATION WITH ANALYTIC RESPONSE

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BACKGROUND AND IMPORTANCE

Subcutaneous infliximab (SC-IFX) serum concentrations (Css-IFX) needed for a response in patients with inflammatory bowel disease (IBD) are not yet well defined.

AIM AND OBJECTIVES

Describing our patients population with IBD treated with subcutaneous infliximab, and relate their serum concentrations to analytic-response.

MATERIALS AND METHODS

An observational retrospective study was carried out, that included IBD patients treated with SC-IFX and with Css-IFX analyzed.
Duration: **3 years** (from 09/2021 to 09/2024)

Variables
- Age   - Sex   - Weight
- Diagnosis [Crohn´s disease (EC) or ulcerative colitis (CU)]
- Css-IFX
- Antibodies against infliximab (AC-IFX)
- Fecal calprotectin (FC)
- Reactive C protein (RCP)
- Analytic response in the first three laboratory tests (LT)

Three groups were stablished according to Css-IFX:
- G1 (< 10 µg/mL)
- G2 (10 – 20 µg/mL)
- G3 (> 20 µg/mL)

Defined as:
- FC < 100 µg/g
- RCP < 5 mg/L

Statistics*

Quantitative variables:
- mean±SD (normal distribution)
- Median±IQR (non normal distribution)

Qualitative variables: frequencies

Differences G1 vs G2 vs G3:
- Student´s t (quantitative variables)
- Fisher´s exact test (qualitative variables)

Linear correlation: Mantel-Haenszel test for trend.

*Done with R statistical programming.

RESULTS

63 patients were included

Laboratory tests were taken at:
- Week 13.3 (9.8-16.4) → LT1
- Week 28.1 (24.6-35.6) → LT2
- Week 54.6 (48.6-59.4) → LT3

Variables	Result
Age (years)	47 (39 – 55)
Sex (feminine)	27 (42.9%)
Weight (kg)	75.4 ± 17.8
Diagnosis CU vs EC	19 (30.2%) vs 44 (69.8%)

Variables		LT1	LT2	LT3
N (number of patients)		63	49	39
Missing patients		6	5	4
Css-IFX (µg/mL)		16.9 ± 8.4	17.6 ± 8.5	15.8 ± 8.5
AC-IFX		2 (3.2%)	1 (2.0%)	2 (5.1%)
FC (µg/g)		1,148.0 ± 3,785.7	12,886.3 ± 76,766.0	567.5 ± 1,353.3
RCP (mg/L)		6.1 ± 10.8	5.2 ± 6.7	5.3 ± 9.5
Analytic response (global)		23 (40.4%)	17 (38.6%)	16 (45.7%)
Analytic response (by groups)	G1 (< 10 µg/mL)	2/13 (15.4%)	3/8 (37.5%)	2/7 (28.6%)
	G2 (10 – 20 µg/mL)	6/16 (27.3%)	6/21 (28.6%)	10/19 (52.6%)
	G3 (> 20 µg/mL)	15/22 (68.2%)	8/15 (53.3%)	4/9 (44.4%)
Differences G1 vs G2 vs G3		**p = 0.003**	p = 0.359	p = 0.602
Linear correlation (response - Css-IFX)		**p = 0.001**	p = 0.319	p = 0.590

CONCLUSIONS AND RELEVANCE

Our study shows that a higher proportion of patients present analytic-response with levels above 10µg/mL. In the first measurement there were significant differences in the response between groups, with a greater proportion of patients with analytic-response at levels above 20µg/mL. However, these differences are not maintained thereafter. Further patients should be studied and the clinical and/or endoscopic response, as well as other variables influencing, should be evaluated in order to draw conclusions applicable to clinical practice.