ARTÍCULO ORIGINAL

Serum infliximab concentrations and body mass index in patients with inflammatory bowel disease

Relación entre el índice de masa corporal y las concentraciones séricas de infliximab en pacientes con enfermedad inflamatoria intestinal

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Conflict of interest
PGK has received consultancy and speaking honorarium from Abbvie, Johnson and Johnson, Sanofi, Pfizer and Takeda. He also received scientific grants from Pfizer and Takeda. All other authors have no conflicts of interest.

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ABSTRACT

Background: Inflammatory bowel diseases (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), are chronic conditions associated with healthcare burdens. Advanced therapies, such as infliximab (IFX), have improved disease outcomes. However, the role of body mass index (BMI) in influencing IFX serum concentrations and treatment response remains unclear. **Objective:** This study aimed to evaluate the association between BMI and IFX serum concentrations during different disease activity phases. **Materials and methods:** This cross-sectional observational report categorized patients into eutrophic (BMI < 24.9 kg/m²) and overweight/obese (BMI ≥ 25 kg/m²) groups. Serum IFX concentrations were measured, and disease activity was assessed using clinical, laboratory, endoscopic, and/or radiologic criteria. **Results:** The analysis included 102 patients (80 with CD, 22 with UC). The median serum IFX concentration in eutrophic CD patients was 3.84 µg/mL (1.66–8.82), while in overweight/obese patients was 6.00 µg/mL (1.90–10.34), with no significant difference (p = 0.353). Among the 22 patients with UC, the median serum IFX concentration in eutrophic patients was 6.28 µg/mL (0.860–13.66), compared to 4.23 µg/mL (2.33–12.91) in overweight/obese patients, with no significant difference (p = 0.920). No differences were found in IFX concentrations between patients in remission or active disease. **Conclusions:** this study did not confirm that BMI influences IFX concentrations. More studies are needed to explore the impact of BMI on IFX pharmacokinetics and therapeutic efficacy.
Keywords: *Inflammatory Bowel Disease; Body Mass Index; Infliximab (source: MeSH NLM).*

RESUMEN

Antecedentes: Las enfermedades inflamatorias intestinales (EII), que incluyen la enfermedad de Crohn (EC) y la colitis ulcerosa (CU), son afecciones crónicas asociadas a una elevada carga asistencial. Las terapias avanzadas, como el infliximab (IFX), han mejorado los desenlaces clínicos. Sin embargo, el papel del índice de masa corporal (IMC) en la influencia sobre las concentraciones séricas de IFX y la respuesta al tratamiento permanece incierto. **Objetivo:** Evaluar la asociación entre el IMC y las concentraciones séricas de IFX durante diferentes fases de actividad de la enfermedad. **Materiales y métodos:** Este estudio observacional transversal categorizó a los pacientes en dos grupos: eutróficos (IMC < 24,9 kg/m²) y con sobrepeso/obesidad (IMC ≥ 25 kg/m²). Se midieron las concentraciones séricas de IFX y la actividad de la enfermedad se evaluó mediante criterios clínicos, de laboratorio, endoscópicos y/o radiológicos. **Resultados:** El análisis incluyó a 102 pacientes (80 con EC y 22 con CU). La mediana de la concentración sérica de IFX en pacientes eutróficos con EC fue de 3,84 µg/mL (1,66–8,82), mientras que en los pacientes con sobrepeso/obesidad fue de 6,00 µg/mL (1,90–10,34), sin diferencia significativa (p = 0,353). Entre los 22 pacientes con CU, la mediana de la concentración sérica de IFX en pacientes eutróficos fue de 6,28 µg/mL (0,860–13,66), en comparación con 4,23 µg/mL (2,33–12,91) en los pacientes con sobrepeso/obesidad, también sin diferencia significativa (p = 0,920). No se observaron diferencias en las concentraciones de IFX entre pacientes en remisión o con enfermedad activa. **Conclusiones:** Este estudio no confirmó que el IMC influya en las concentraciones séricas de IFX. Se requieren más investigaciones para explorar el impacto del IMC en la farmacocinética y la eficacia terapéutica de IFX.
Palabras clave: *Enfermedades Inflamatorias del Intestino; Índice de Masa Corporal; Infliximab (fuente: DeCS Bireme).*

INTRODUCTION

Inflammatory bowel diseases (IBD), namely Crohn's disease (CD) and ulcerative colitis (UC), are chronic conditions associated with reduced quality of life and productive capacity [1]. Due to recurrent disease activity and progressive structural damage, IBD can significantly burden both public and private healthcare services [2].

The use of advanced therapies for the treatment of patients with moderate to severe IBD has brought significant benefits in recent decades, including a substantial reduction in hospitalization and surgery rates [3]. Anti-TNF (Tumor Necrosis Factor-alpha) agents typically comprise the first line of advanced therapy for both CD and UC. However, between 10% and 40% of patients may not respond to treatment (primary non-responders), and approximately 12% lose response over time, particularly with infliximab (IFX) [4].

Several mechanisms may be associated with IFX treatment failure, with immunogenicity, where antibodies form against the monoclonal antibody, being a primary factor. Other factors may also influence IFX clearance, including overweight and obesity. Drug clearance is influenced by the volume of distribution, which is dependent on the patient's weight. Additionally, excessive adipose tissue alters the pharmacokinetics of anti-TNF agents and exerts endocrine and immunological effects through the release of adipocytokines, which may contribute to the pathogenesis of various inflammatory conditions. Thus, excessive body weight may explain the failure of IFX therapy in some cases [5].

It appears that obesity negatively affects the response to immunosuppressants and anti-TNFs. However, the results of studies investigating the relationship between obesity, response to anti-TNFs, and autoimmune diseases remain inconsistent [6,7]. An analysis of three randomized controlled trials of IFX in dermatology and rheumatology found no statistically significant differences in response rates between different BMI groups [8]. In contrast, a prospective cohort study in patients with rheumatoid arthritis found that obese patients treated with IFX had lower clinical response rates [9]. A systematic review with meta-analysis found that obesity was associated with a 60% higher likelihood of losing response to anti-TNF agents compared to non-obese patients with rheumatoid arthritis, ankylosing spondylitis, and psoriasis. However, this finding was not confirmed in patients with IBD [10]. To date, few studies have been published on the potential influence of obesity or overweight on endoscopic remission in IBD. In a recent cohort study of patients receiving IFX, Singh *et al.* (2018) did not identify a lower rate of mucosal healing in obese patients after adjusting for covariates (CI, 0.12-2.35; p=0.31) [10]. A recent study also demonstrated that body composition parameters, such as subcutaneous adiposity index, visceral adiposity index and skeletal muscle mass index were identified as independent correlated factors of active CD, negatively impacted by visceral adiposity [11].

Identifying serum concentrations of IFX that are most closely associated with remission and disease activity across different BMI categories (eutrophic and overweight/obese) may help physicians optimize treatment in an individualized manner. In this context, the present study aimed to compare serum IFX concentrations in eutrophic and overweight/obese patients with inflammatory bowel disease during different phases of disease activity.

MATERIALS AND METHODS

This observational cross-sectional study included all consecutive adult patients with Crohn's disease (CD) or ulcerative colitis (UC) who were undergoing maintenance treatment with infliximab (IFX) at two referral centers in southern Brazil between August 2019 and September 2021. A non-random convenience sample was used.

Inclusion criteria were individuals over 18 years of age, diagnosed with CD or UC for at least 3 months, confirmed by clinical, endoscopic, radiological, and/or histological criteria. Patients must have been using IFX after the 14th week of treatment and followed the on-label induction regimen (5 mg/kg IV at weeks 0, 2, and 6), regardless of the dose used at the time of blood collection (patients with an optimized dose could be included). Patients were on IFX monotherapy or combination therapy with one of the following medications at the time of selection: aminosalicylates, antibiotics, prednisone, azathioprine, 6-mercaptopurine, or methotrexate.

Exclusion criteria included patients using IFX in combination with tacrolimus, cyclosporine, sirolimus, mycophenolate mofetil, another immunobiological agent, or tofacitinib; patients using total parenteral nutrition at the time of selection; individuals with intestinal stomas; and patients with insufficient data in their electronic medical records.

Eligible patients underwent clinical, laboratory, endoscopic, and/or imaging evaluations as part of routine outpatient monitoring at the discretion of their attending physician. Serum IFX concentrations were offered for collection. Clinical, laboratory, endoscopic, and/or radiological data from the patient's medical records were collected for the study. Data collected within a +/- 90-day interval from the time of serum IFX concentration collection were considered valid.

The following variables were evaluated: age, sex, BMI [weight (kg)/height (m)^2], smoking history, history of IBD-related surgeries, current and prior concomitant medications, disease duration, Montreal classification, and clinical activity indices for CD and UC. Clinical activity of CD was assessed using the Harvey-Bradshaw Index (HBI), with clinical remission defined as an HBI score ≤ 4 points [12]. Clinical activity of UC was assessed using the partial Mayo score, with clinical remission defined as a score ≤ 2 points [12].

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Laboratory markers of disease activity were assessed using C-reactive protein (CRP) levels and fecal calprotectin. Laboratory remission was defined as CRP below the assay's upper normal level and/or fecal calprotectin ≤ 250 µg/g [13]. Endoscopic CD activity was evaluated using colonoscopy results, with endoscopic remission defined as the complete absence of ulcers and inflammatory strictures in all segments of the colon and terminal ileum examined [12]. If any intestinal segments were not evaluated by colonoscopy, radiological examinations (computed tomography or magnetic resonance imaging) were used to assess CD activity. Radiological remission was defined as the absence of contrast enhancement according to radiologic criteria. The endoscopic activity of UC was assessed using the Mayo subscore, with endoscopic remission defined as a subscore of 0 or 1 [12]. Overall disease activity was defined by any criteria for active disease (clinical, laboratory, imaging, or endoscopic) for both CD and UC.

Serum IFX concentrations were collected up to 24 hours before each patient's next dose (trough level) and served as the study's main variable. Serum IFX concentrations were measured using the Promonitor® ELISA kit (Proteomika, Progenika Biopharma, Bizkaia, Spain) following the manufacturer's instructions. The detection limits of IFX ranged from 0.035 to 14.4 µg/mL [14], with absolute values used for correlation with outcomes (remission and disease activity).

Patients were categorized into two groups based on their BMI: eutrophic (BMI < 24.9) and overweight/obese (BMI ≥ 25). Median serum IFX concentrations were analyzed and compared between the groups, as well as between patients with CD and UC, and between those with active disease or remission. The study hypothesized that overweight/obese patients would have lower IFX concentrations compared to eutrophic patients.

Quantitative variables were analyzed using means and distribution patterns. Differences between the two groups were analyzed using parametric tests. The Student's t-test was applied for variables with normal distribution, while the Mann-Whitney test was used for variables without normal distribution. Qualitative variables were presented as percentages. The chi-square test was used to compare proportions between independent samples, and Fisher's exact test was applied when the sample size was less than 20.

Boxplot plots were generated to describe the variability in serum infliximab concentrations, as well as the activity and remission of CD and UC. The plots depicted median values, upper and lower quartiles, and minimum, maximum, and outlier values. A significance level of 5% was adopted for all statistical tests. Data were collected and stored in a Microsoft Excel spreadsheet, and IBM SPSS software (version 21.0) was used for statistical analysis and graph editing.

This research project (CAAE 12450919.8.1001.0020) was approved by the Research Ethics Committee of our Institution with approval number 3.499.556. All patients invited to participate were informed about the study's importance, objectives, expected results, and potential risks. After clarifying all questions and obtaining voluntary agreement, patients signed an Informed Consent Form authorizing their participation in the study in accordance with good clinical practice standards.

RESULTS

Out of the 112 patients receiving maintenance therapy with infliximab (IFX), 5 did not agree to undergo follow-up tests after signing the informed consent form. A total of 107 patients had serum IFX concentrations collected, with 5 excluded due to insufficient data in their medical records. The final analysis included 102 patients (80 with Crohn's disease (CD) and 22 with ulcerative colitis (UC)), of whom 55 (53.9%) had a BMI below 25 kg/m² (eutrophic), and 47 (46.1%) had a BMI ≥ 25 kg/m² (overweight/obese). The patient distribution of the study is illustrated in Figure 1.

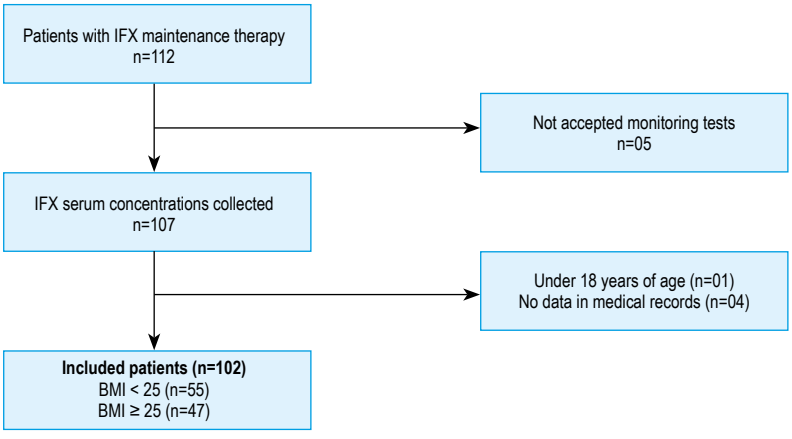

Figure 1. Flowchart with the distribution of patients included by study group.

Table 1 presents the baseline characteristics of the included patients. The groups were largely homogeneous across variables. However, a significant difference was observed in overall disease activity, present in 60% of eutrophic patients compared to 36.2% of overweight/obese patients (p = 0.016).

In the full cohort analysis (all IBD patients), there was no significant difference in serum IFX concentrations between the two groups. The median serum IFX concentration in the eutrophic group was slightly lower than in the overweight/obese group (5.71 µg/mL ± 4.84 vs. 6.47 µg/mL ± 4.74), but this difference was not statistically significant (p=0.964).

Among the 80 patients with CD, 47 (58.8%) were eutrophic, and 33 (41.3%) were overweight/obese. The median serum IFX concentration in eutrophic CD patients was 3.84 µg/mL (1.66-8.82), while in overweight/obese CD patients, it was 6.00 µg/mL (1.90-10.34), with no significant difference between the groups (p=0.353). Among the 22 patients with UC, 8 (36.4%) were eutrophic, and 14 (63.6%) were overweight/obese. The median serum IFX concentration in eutrophic UC patients was 6.28 µg/mL (0.860-13.66), compared to 4.23 µg/mL (2.33-12.91) in overweight/obese UC patients, with no significant difference (p=0.920). These results are illustrated in Figure 2.

Table 1. Baseline characteristics of patients.

	BMI ≤25 (n=55) Eutrophic	BMI > 25 (n=47) Overweight/obese	*p* value
Gender			
Male Female	32 (58.2%) 23 (41.8%)	20 (42.6) 27 (57.4)	0.11
Mean Age (years)	38.0 ± 13.0	43.1 ± 13.6	0.69
BMI (kg/m^2; mean ± SD)	22.29 ± 1.82	29.64 ± 4.21	<0.001
Serum IFX concentration in µg/mL (mean ± SD)	5.71 ± 4.84	6.47 ± 4.74	0.96
Disease duration (mean ± SD)	130.7 ± 121.7	138.4 ± 93.1	0.12
Montreal Crohn A A1 (<17years), n (%) A2 (17-40 years), n (%) A3 (>40 years), n (%)	 3 (6.4) 42 (89.4) 2 (4.2)	 3 (9.1) 24 (72.7) 6 (18.2)	0.10
Montreal Crohn L L1 (ileal), n (%) L2 (colonic), n (%) L3 (ileocolonic), n (%) L4 (upper GI), n (%)	 9 (19.1) 9 (19.1) 29 (61.7) 6 (12.8)	 5(15.2) 11 (33.3) 17 (51.5) 2 (6.1)	0.35
Montreal Crohn B B1 (inflammatory), n (%) B2 (stenotic), n (%) B3 (penetrating), n (%)	 26 (55.3) 17 (36.2) 4 (8.5)	 15 (45.5) 11 (33.3) 7 (21.2)	0.26
Montreal RCU (E) E1 (proctitis) n (%) E2 (left colitis), n (%) E3 (extensive colitis), n (%)	 1 (12.5) 1 (12.5) 6 (75)	 - 3 (21.4) 11 (78.6)	0.37
Smoking (n) %	5 (9.1)	6 (12.8)	0.57
Previous surgery (n) %	30 (54.5)	23 (48.9)	0,57
Combination Therapy n (%) No therapy, n (%) Azathioprine, n (%)	10 (18.2) 37 (67.3) 8 (14.5)	9 (19.1) 30 (63.8) 8 (17)	0.92
Optimized IFX dose n (%)	22 (40%)	17 (36.2)	0.64
Active disease, n (%)	33(60)	17 (36.2)	0.016
Colonoscopy, n (%)	51 (92.7)	45 (95.7)	0.519
Endoscopic activity, n (%)	21 (38.2)	12 (25.5)	0.135
Radiological activity, n (%)	7 (12.7)	4 (8.5)	0.69
Clinical activity, n (%)	12 (21.8)	5(10.6)	0.131
Laboratory activity, n (%)	14 (25.5)	8 (17)	0.218
Fecal calprotectin, n (%)	17 (30.9)	17 (36.2)	0.574
Calprotectin >250, n (%)	6 (31.6)	3 (16.7)	0.508
Elevated CRP, n (%)	9 (16.4)	5 (10.6)	0.200

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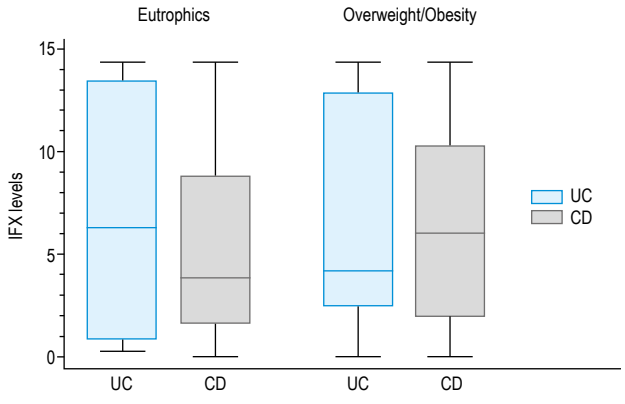

Figure 2. *Boxplot* depicting the relationship of median serum levels of infliximab in UC and CD, classified into different BMI ranges. Group 1: eutrophic. Group 2: overweight/obesity. Units in ug/ml.

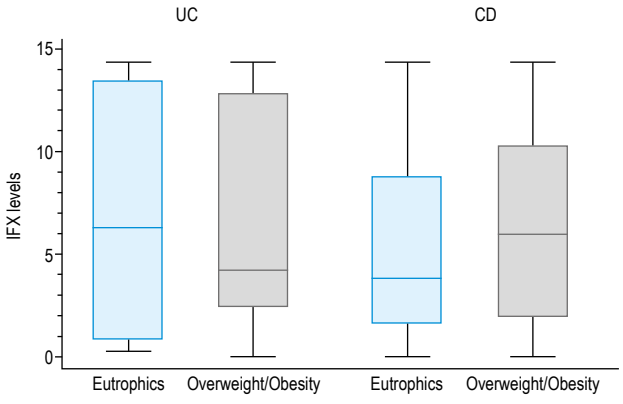

Figure 3. Boxplot depicting the relationship of median serum levels of infliximab observed by quartiles of patients with UC and CD, eutrophic, and overweight/obesity. Group 0: RCU. Group 1: DC. Units in ug/mL.

Of the 55 eutrophic patients, 8 (14.5%) had UC, and 47 (85.5%) had CD. Figure 3-A shows the comparison of median serum IFX concentrations in patients with UC (6.28 µg/mL [0.86-13.66]) and CD (3.84 µg/mL [1.66–8.82]), with no significant difference between these subgroups (p=0.734) within this BMI range. Of the 47 overweight/obese patients, 14 (29.8%) had UC, and 33 (70.2%) had CD. Figure 3-B shows the median serum IFX concentrations for patients with UC (4.23 µg/mL [2.33-12.91]) and CD (6.00 µg/mL [1.90-10.34]), with no significant difference between these subgroups (p=0.935).

Among the 47 eutrophic CD patients, disease activity was evaluated and serum IFX concentrations were compared. A total of 21 (44.7%) patients were in remission, with a median IFX concentration of 2.98 µg/mL (2.14-9.39), while 26 (55.3%) had active disease, with a median concentration of 4.00 µg/mL (1.31-8.61). There was no significant difference between these subgroups (p=0.991). Among the 8 eutrophic UC patients, 1 (12.5%) was in remission (with an IFX concentration of 12.97 µg/mL), while 7 (87.5%) had active disease, with a median concentration of 6.00 µg/mL (0.86-13.9), with no significant difference between these groups (p=0.750). These findings are illustrated in Figure 4.

Among the 33 overweight/obese CD patients, 20 (60.6%) were in remission, with a median IFX concentration of 7.20 µg/mL (3.83-10.87), and 13 (39.4%) had active disease, with a median concentration of 2.18 µg/mL (1.66-9.35), with no significant difference between the subgroups (p=0.157). Among the 14 overweight/obese UC patients, 10 (71.4%) were in remission, with a median IFX concentration of 3.20 µg/mL (2.28-8.79), and 4 (28.6%) had active disease, with a median concentration of 11.17 µg/mL (3.63-14.25), with no significant difference between these subgroups (p=0.188). These findings are illustrated in Figure 5.

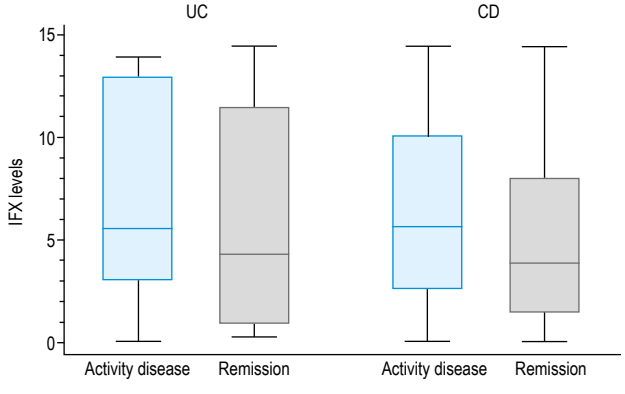

Figure 4. Boxplot depicting the relationship of median serum levels of infliximab observed by quartiles of eutrophic patients with UC and CD with disease activity or remission. Group 1: no activity. Group 2: with active disease. Units in ug/mL.

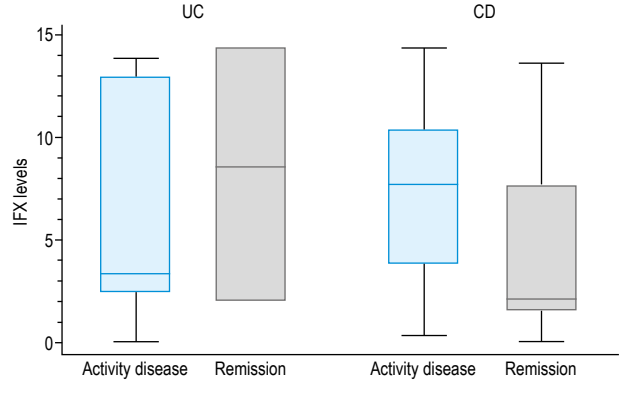

Figure 5. Boxplot depicting the variation in serum IFX levels observed by quartiles of patients with CD and UC, overweight/obese, with or without disease activity. Group 1: no activity. Group 2: with active disease. Units in ug/mL.

DISCUSSION

Our study demonstrated that there were no differences in infliximab (IFX) serum concentrations between eutrophic and overweight/obese patients with inflammatory bowel disease (IBD). Furthermore, no significant differences in IFX concentrations were observed between these BMI categories in both Crohn's disease (CD) and ulcerative colitis (UC) when analyzed separately. Additionally, no difference was found in IFX concentrations between patients in remission and those with active disease.

Several studies have highlighted a significant proportion of overweight/obese patients with IBD, with the incidence and prevalence of these diseases increasing globally [15]. Tumor necrosis factor-alpha (TNF-α) inhibitors, such as IFX, have become a cornerstone of treatment for IBD over the past decades, significantly altering the disease course and response to treatment. Obesity/overweight is emerging as a prevalent comorbidity in many chronic conditions [16]. The presence of greater amounts of adipose tissue could influence the response to treatment with anti-TNF agents [17]. Recent research indicates that adipose tissue produces inflammatory cytokines and functions as an immunologically active organ.

When comparing the baseline characteristics between study groups, most variables were comparable. The only significant difference was the presence of overall disease activity, observed in 59% of eutrophic patients, compared to 40% in overweight/obese patients (p=0.04). There is ongoing speculation in the literature that higher disease activity could be associated with lower serum IFX concentrations. However, a recent study by Bremer et al. (2023) found no difference in IFX concentrations between patients with and without overall disease activity [18]. Specifically, in patients with luminal CD, the mean IFX concentrations in remission vs. active disease were 6.41±4.75 µg/mL vs. 5.35±4.53 µg/mL, respectively (p=0.691). Differences in clinical activity were observed only between remission and active disease (6.32±4.70 µg/mL vs. 3.21±3.33 µg/mL, respectively, p=0.042) [18].

Our study hypothesized that serum IFX concentrations would vary between patients with different BMI categories. However, no such difference was found. This may be explained by several factors. First, the study may have included a limited number of patients to detect significant differences. Additionally, the mean BMI in the overweight/obese group (29.07 ± 4.24 kg/m²) was not as high as expected, with most classified as overweight rather than obese. This could have limited the expected differences.

Serum IFX levels measured just before the next infusion (trough levels) and antibodies to IFX are increasingly used in clinical practice for therapeutic drug monitoring (TDM) [19]. In maintenance therapy, IFX concentrations may correlate with disease activity or remission. While patients with higher BMI may experience higher rates of loss of response to the drug due to lower serum concentrations, there is limited data on this difference in the literature. Our results, however, showed that eutrophic patients had a higher proportion of disease activity, contradicting the literature's suggestion of lower levels, higher disease activity, and higher BMI being correlated. In this study, no differences in IFX concentrations were found between patients with or without disease activity, irrespective of BMI range.

Given the limitations of this cross-sectional observational study, it is difficult to observe longitudinal changes in IFX concentrations or patient outcomes. Monitoring IFX levels may help adjust doses and optimize treatment in cases of secondary loss of response. Further research is needed to better understand the relationship between obesity/overweight and IFX concentrations, particularly in patients with IBD [20].

Some studies have suggested that overweight/obese CD patients may require a more aggressive therapeutic strategy to avoid non-response or loss of response. The increasing prevalence of obesity worldwide, particularly in Western countries, emphasizes the importance of these findings [21]. For example, a North American study found that higher BMI was associated with an increased risk of CD flare-ups, such as IFX dose escalation, CT scans, IFX discontinuation, hospitalization, or surgery [5]. Although the study was limited by its heterogeneous population and long follow-up duration (3 years), its findings suggest that BMI changes over time might alter the relationship between IFX and patient outcomes.

Our study, however, did not confirm that BMI ≥ 25 kg/m² was a predictive factor for IFX optimization, likely due to the relatively small number of patients and its cross-sectional nature. In contrast, longitudinal studies such as the one by Guerbau et al. (2017) have shown that overweight/obese CD patients may benefit from closer monitoring of response and remission after IFX initiation [5]. Longitudinal studies are needed to further explore how higher BMI might influence IFX loss rates and whether serum concentrations could be a useful measurement tool.

Despite the recent interest in the possible influence of BMI in the efficacy of anti-TNF agents in the management of IBD, there is still scarce evidence in the international literature which may drive solid conclusions. In a recent retrospective analysis of 179 patients with CD, Fonseca et al. demonstrated in a multivariate analysis that secondary loss of response in patients with IFX with BMI ≥25 had a relative risk of 1.04 [CI 0.60-1.80 (p=0.891)] compared to patients with BMI < 25. Being overweight or obese led to a risk of 1.50 for loss of response to ADA at 54-week time point [CI 0.60-3.74 (p=0.0387)] [17]. These data, in accordance with our results, despite not being based on IFX concentrations, also showed a similar impact of BMI on treatment outcomes between eutrophic and overweight patients and warrant further research on this relation. Detailed analyses with other body composition variables such as muscle mass and visceral adiposity and their possible impact in treatment efficacy with IFX are also awaited [22].

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This study had limitations, including the small sample size, especially in the UC group, and the retrospective, observational nature of the data collection. Most patients with BMI ≥ 25 kg/m² were overweight, not obese, which may have influenced the results. Nevertheless, this is one of the first studies to investigate the potential differences in IFX serum concentrations across different BMI categories in IBD patients.

In conclusion, no differences were found in serum IFX concentrations between eutrophic and overweight/obese patients with IBD. There were also no differences between the two BMI categories in CD or UC when analyzed separately. The relationship between overweight/obesity, serum IFX concentrations, and disease activity remains an important topic for future research, with prospective longitudinal studies needed to clarify these potential associations.

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