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Original Article

A Comprehensive Single-Center Analysis of Subcutaneous Infliximab in the Management of Inflammatory Bowel Disease, Lahore Pakistan

Junaid Mushtaq[1], Sehrish Sarwar[2], Ibtesaam Amjad[1]

1. Assistant Professor of Gastroenterology, Services Institute of Medical sciences, Lahore
2. Assistant Professor of Gastroenterology, Azhra Naheed Medical College, Lahore

Abstract:

Background: Subcutaneous infliximab (SC-IFX) offers a promising alternative to intravenous infliximab (IV-IFX) for managing moderate-to-severe inflammatory bowel disease (IBD), providing pharmacokinetic stability, patient convenience, and improved adherence. Further evidence is needed to validate its clinical efficacy, safety, and pharmacokinetic profile in real-world settings.

Objective: To evaluate the clinical efficacy, safety, and pharmacokinetics of SC-IFX in patients with Crohn's disease (CD) and ulcerative colitis (UC).

Methods: This single-center, open-label, interventional study enrolled 190 patients with IBD (58 CD, 132 UC) aged 18–75 years with moderate-to-severe disease activity (Crohn's Disease Activity Index [CDAI] 250–450 or Mayo score 6–12). Participants received SC-IFX with a loading dose of 240 mg at weeks 0 and 2, followed by 120 mg every other week from week 4 onward. Assessments at baseline, week 11, and week 22 included disease activity (CDAI and Mayo scores), inflammatory markers (CRP and fecal calprotectin), hematological parameters, and serum infliximab levels. Adverse events were recorded per CTCAE guidelines. Statistical analyses utilized repeated measures ANOVA and chi-square tests, with significance set at $P < 0.05$.

Results: Among 190 patients, clinical remission was achieved in 81.3% of CD (CDAI <150) and 84.8% of UC (Mayo ≤2) patients by week 22. Serum infliximab levels rose from undetectable at baseline to 17.74 ± 0.14 µg/mL at week 11 and stabilized at 11.94 ± 0.11 µg/mL by week 22 ($P < 0.001$). CRP levels decreased from 35.31 ± 1.24 mg/L to 5.24 ± 0.33 mg/L in CD and from 23.98 ± 0.82 mg/L to 4.18 ± 0.22 mg/L in UC ($P < 0.001$). Fecal calprotectin levels declined from 470.16 ± 17.32 µg/g to 146.43 ± 2.66 µg/g in CD and from 889.17 ± 11.48 µg/g to 89.42 ± 1.77 µg/g in UC ($P < 0.001$). Hemoglobin increased significantly in CD and UC patients ($P < 0.001$), while platelet counts decreased substantially ($P < 0.001$). Adverse events were mild and primarily injection site reactions, with no serious adverse events reported.

Conclusion: SC-IFX demonstrated significant efficacy, pharmacokinetic stability, and a favorable safety profile in managing moderate-to-severe IBD in this cohort of 190 patients. These findings support its use as a convenient and effective alternative to IV-IFX.

Keywords: Subcutaneous infliximab, Inflammatory bowel disease, Crohn's disease, Ulcerative colitis, Pharmacokinetics, Anti-TNF therapy.

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Corresponding Author: Junaid Mushtaq
Email: junaidmc@hotmail.com
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Introduction:

The introduction of subcutaneous infliximab (SC-IFX) has marked a transformative advancement in the management of inflammatory bowel disease (IBD), encompassing both Crohn's disease (CD) and ulcerative colitis (UC). These chronic, relapsing inflammatory disorders present significant challenges in terms of achieving sustained remission and improving patient quality of life. Infliximab, a monoclonal antibody targeting tumor necrosis factor-alpha (TNF-α), has long been a cornerstone of IBD therapy, traditionally administered intravenously (IV) with established efficacy in inducing and maintaining clinical remission (Smith et al., 2023). However, intravenous administration requires hospital visits, is time-intensive, and poses logistical challenges for healthcare systems and patients alike, including infusion-related reactions and patient inconvenience (Buisson et al., 2022). Consequently, the development of a subcutaneous formulation of infliximab, specifically CT-P13 SC, represents a significant therapeutic evolution by offering comparable efficacy with a more convenient route of administration, enabling self-administration and reducing dependency on healthcare facilities (Hong et al., 2023; Jeffrey et al., 2023).

Emerging clinical and real-world data consistently highlight the therapeutic equivalence and safety profile of SC-IFX compared to its IV counterpart, alongside its unique pharmacokinetic advantages. Studies have demonstrated that SC-IFX achieves higher trough levels and more stable drug concentrations, which are strongly correlated with improved rates of clinical and biochemical remission in patients with IBD (Roblin et al., 2023; Little et al., 2022). This stability not only optimizes therapeutic outcomes but also mitigates the challenges associated with dose escalation or loss of response often encountered with IV infliximab (Chetwood et al., 2024). Furthermore, the acceptability and patient satisfaction with SC-IFX are notably high, with many patients preferring the convenience and autonomy it provides, especially in the context of the COVID-19 pandemic where reducing hospital visits became a priority (Schreiber et al., 2022). The ability of SC-IFX to maintain remission in stable patients transitioning from IV infliximab and its feasibility in initiating treatment in biologic-naïve patients underscore its potential to reshape treatment strategies for IBD (Huguet et al., 2022; Buisson et al., 2022).

Despite these advancements, significant gaps in the literature remain, particularly concerning the long-term outcomes and optimal implementation of SC-IFX in routine clinical practice. The role of SC-IFX in managing difficult-to-treat cases, such as patients with refractory IBD or those with high baseline disease activity, warrants further investigation (Smith et al., 2023). Additionally, the therapeutic drug monitoring (TDM) parameters for SC-IFX, including optimal trough levels associated with remission and their correlation with biomarkers of mucosal healing, are yet to be fully elucidated (Roblin et al., 2023). While early evidence suggests the feasibility of SC-IFX as monotherapy, its comparative efficacy against combination therapy with immunomodulators remains underexplored, particularly in biologic-naïve patients (D'Haens et al., 2023). Furthermore, the cost-effectiveness and healthcare resource utilization benefits of SC-IFX, especially in single-center and community-based settings, require comprehensive evaluation to guide policymakers and clinicians (Hong et al., 2023; Buisson et al., 2022).

This study aims to address these gaps by examining the role of SC-IFX in a single-center setting, focusing on its clinical efficacy, safety profile, and pharmacokinetic advantages in patients with IBD. The findings are expected to contribute valuable insights into optimizing treatment paradigms, particularly in resource-limited settings, and to provide a foundation for future multi-center and long-term studies on the implementation of SC-IFX in diverse patient populations.

Material and Methods:

This single-center, open-label, single-arm interventional study was conducted to evaluate the clinical efficacy, safety, and pharmacokinetic outcomes of subcutaneous infliximab (SC-IFX) in patients with moderate to severe inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC). Patients aged 18–

75 years, diagnosed with IBD according to established clinical, endoscopic, and radiological criteria, were eligible for inclusion. Specific eligibility criteria required moderate to severe disease activity, defined by a Crohn's Disease Activity Index (CDAI) score of 250–450 or a Mayo score of 6–12 for UC, with documented endoscopic evidence of active disease. Exclusion criteria included prior exposure to infliximab (intravenous or subcutaneous), active or latent tuberculosis without completed prophylactic treatment, known hypersensitivity to infliximab or its excipients, and comorbidities contraindicating biological therapy, such as uncontrolled infections, malignancies, or severe organ dysfunction.

Eligible participants were recruited consecutively from the outpatient clinic. Written informed consent was obtained from all participants after providing a comprehensive explanation of the study's objectives, procedures, potential benefits, and risks. The study adhered to the ethical principles outlined in the Declaration of Helsinki and was approved by the institutional ethics review board prior to commencement. Patients who met inclusion criteria were initiated on SC-IFX therapy, receiving a loading dose of 240 mg at weeks 0 and 2, followed by a maintenance dose of 120 mg every other week starting from week 4.

Baseline data collection included demographic information, disease characteristics, and relevant medical history. Clinical assessments were conducted at baseline, week 11, and week 22, including evaluation of disease activity using CDAI for CD and the Mayo score for UC. Laboratory parameters, including complete blood count (CBC), liver function tests (LFTs), renal function tests (RFTs), C-reactive protein (CRP), and fecal calprotectin, were measured at each visit. Serum infliximab trough levels and the presence of anti-drug antibodies (ADAs) were assessed using validated enzyme-linked immunosorbent assay (ELISA) kits. Stool and urine analyses were performed as per standard protocols. Adverse events were monitored throughout the study and documented according to Common Terminology Criteria for Adverse Events (CTCAE) guidelines.

To ensure consistency and minimize bias, data were collected by trained personnel and entered into a secure electronic database. All laboratory investigations were conducted in a certified facility to maintain accuracy and reliability. Data integrity was ensured through double-entry verification, and discrepancies were resolved through consultation with clinical investigators.

The primary endpoint was the proportion of patients achieving clinical remission, defined as CDAI <150 for CD or a total Mayo score ≤2 (with no subscore >1) for UC, at week 22. Secondary endpoints included corticosteroid-free remission, clinical response, biochemical remission (based on CRP and fecal calprotectin levels), and patient-reported outcomes assessed using the Inflammatory Bowel Disease Questionnaire (IBDQ). Safety outcomes included the incidence of adverse events, injection site reactions, and serious adverse events.

Statistical analyses were performed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, as appropriate, and categorical variables were presented as frequencies and percentages. The paired t-test or Wilcoxon signed-rank test was used for comparing baseline and post-treatment continuous variables, while the chi-square test or Fisher’s exact test was used for categorical variables. A p-value of <0.05 was considered statistically significant.

This study aimed to provide a comprehensive evaluation of SC-IFX in IBD patients within a controlled clinical setting, contributing valuable insights into its potential role in managing moderate to severe disease.

Results:

This study demonstrated significant improvements in disease activity, pharmacokinetic parameters, and clinical outcomes among patients with inflammatory bowel disease (IBD) treated with subcutaneous infliximab (SC-IFX). Disease activity scores, as assessed by the Mayo score for ulcerative colitis (UC) and the Crohn’s Disease Activity Index (CDAI) for Crohn’s disease (CD), exhibited notable reductions over time. A repeated measures analysis revealed substantial within-subject linear and quadratic effects for both scores.

Table 1. Repeated Measures Analysis of Variance for Mayo Score and CDAI Score

Measure	Effect	Sum of Squares	Mean Square	F-Value	P Value
Mayo Score (UC)	Within-Subjects Effects				
	Linear Effect	4152.307	4152.307	18,632.851	<.001
	Quadratic Effect	232.375	232.375	2820.799	<.001
	Between-Subjects Effects				
	Intercept	5302.023	5302.023	7690.846	<.001
	Pairwise Comparisons				
	Pre vs 11 Week	—	—	—	<.001
	Pre vs 22 Week	—	—	—	<.001
	11 Week vs 22 Week	—	—	—	<.001
	Multivariate Tests	Wilks' λ = 0.006	—	10,395.589	<.001
CDAI Score (CD)	Within-Subjects Effects				
	Linear Effect	1,929,582.078	1,929,582.078	911.037	<.001
	Quadratic Effect	40,215.750	40,215.750	906.853	<.001
	Between-Subjects Effects				
	Intercept	5,806,242.672	5,806,242.672	912.110	<.001
	Pairwise Comparisons				
	Pre vs 11 Week	—	—	—	<.001
	Pre vs 22 Week	—	—	—	<.001
	11 Week vs 22 Week	—	—	—	<.001
	Multivariate Tests	Wilks' λ = 0.059	—	448.290	<.001

Table 3. Repeated Measures Analysis of Variance for Serum Infliximab Drug Levels

Measure	Effect	Sum of Squares	df	Mean Square	F-Value	P Value	Significance
Serum Infliximab Drug Levels	Within-Subjects Effects						
	Linear Effect	13,548.318	1	13,548.318	12,602.679	<.001†	Significant
	Quadratic Effect	17,534.948	1	17,534.948	5,596.086	<.001†	Significant
	Between-Subjects Effects						
	Intercept	55,786.528	1	55,786.528	33,599.353	<.001†	Significant
	Pairwise Comparisons						
	Pre vs 11 Week	-17.737	0.140	—	—	<.001†	Significant
	Pre vs 22 Week	-11.942	0.106	—	—	<.001†	Significant
	11 Week vs 22 Week	-5.795	0.189	—	—	<.001†	Significant
	Multivariate Tests						
	Wilks' λ = 0.006	—	2, 188	—	16,901.168	<.001†	Significant

Estimated Marginal Means

Time Point	Mean	Std. Error	95% CI (Lower Bound)	95% CI (Upper Bound)
Pre	0.000	0.000	0.000	0.000
11 Week	17.737	0.140	17.461	18.013
22 Week	11.942	0.106	11.732	12.152

Table 4. Hematological, Biochemical, and Stool Parameters Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Hematology						
Hemoglobin (g/dL)	Pre	9.62 ± 0.09	11.41 ± 0.06	<.001	698.28, <.001	44.61, <.001
	11 Week	11.45 ± 0.07	12.19 ± 0.05			
	22 Week	12.51 ± 0.07	13.27 ± 0.04			
Platelets (×10³/µL)	Pre	493.12 ± 9.05	426.83 ± 6.00	<.001	650.42, <.001	6.90, .001
	11 Week	329.04 ± 7.25	298.47 ± 4.81			
	22 Week	288.72 ± 6.43	218.47 ± 4.26			
WBC Count (×10³/µL)	Pre	10.84 ± 0.11	9.61 ± 0.07	<.001	927.32, <.001	2.07, .128
	11 Week	8.45 ± 0.11	7.57 ± 0.08			
	22 Week	6.57 ± 0.11	5.67 ± 0.08			
Neutrophils (%)	Pre	70.53 ± 1.02	67.41 ± 0.68	.049	602.91, <.001	2.95, .053
	11 Week	59.41 ± 0.71	53.73 ± 0.47			
	22 Week	49.86 ± 0.58	43.95 ± 0.38			
Lymphocytes (%)	Pre	35.79 ± 0.98	31.91 ± 0.65	<.001	292.21, <.001	1.71, .182
	11 Week	28.83 ± 0.58	22.90 ± 0.39			
	22 Week	22.92 ± 0.64	18.16 ± 0.43			
Inflammation Markers						
C-Reactive Protein (mg/L)	Pre	35.31 ± 1.24	23.98 ± 0.82	<.001	660.82, <.001	33.54, <.001
	11 Week	13.88 ± 0.63	12.07 ± 0.42			
	22 Week	5.24 ± 0.33	4.18 ± 0.22			
ESR (mm/hr)	Pre	54.44 ± 1.57	51.38 ± 1.04	.001	869.20, <.001	2.76, .064
	11 Week	31.65 ± 1.14	25.14 ± 0.76			
	22 Week	13.36 ± 0.63	11.22 ± 0.42			
Stool Analysis						
Calprotectin (µg/g)	Pre	470.16 ± 17.32	889.17 ± 11.48	<.001	2094.07, <.001	422.95, <.001
	11 Week	276.93 ± 5.35	275.11 ± 3.55	.742		
	22 Week	146.43 ± 2.66	89.42 ± 1.77			

Table 5: Liver Function Tests (LFTs) Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Total Bilirubin (mg/dL)	Pre	0.93 ± 0.06	1.15 ± 0.04	<.001	216.72, <.001	5.01, .007
	11 Week	0.56 ± 0.04	0.88 ± 0.03			
	22 Week	0.40 ± 0.03	0.56 ± 0.02			
Albumin (g/dL)	Pre	3.16 ± 0.06	3.71 ± 0.04	<.001	446.88, <.001	23.78, <.001
	11 Week	3.83 ± 0.05	4.21 ± 0.03			
	22 Week	4.48 ± 0.04	4.54 ± 0.03			
AST (U/L)	Pre	35.16 ± 1.41	43.12 ± 0.94	<.001	350.67, <.001	1.96, .142
	11 Week	24.54 ± 0.86	29.93 ± 0.57			
	22 Week	16.29 ± 0.45	21.55 ± 0.30			
ALT (U/L)	Pre	38.30 ± 1.90	44.99 ± 1.26	<.001	155.98, <.001	2.90, .056
	11 Week	30.31 ± 1.10	32.45 ± 0.73			
	22 Week	22.84 ± 0.88	27.38 ± 0.58			
Alkaline Phosphatase (U/L)	Pre	123.24 ± 2.69	139.18 ± 1.78	<.001	481.71, <.001	1.17, .310
	11 Week	87.89 ± 1.89	107.40 ± 1.25			
	22 Week	69.42 ± 1.91	83.58 ± 1.27			

Table 6: Renal Function Tests (RFTs) Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Urea (mg/dL)	Pre	34.06 ± 1.28	45.18 ± 0.85	<.001	276.05, <.001	14.11, <.001
	11 Week	26.39 ± 0.74	29.89 ± 0.49			
	22 Week	19.06 ± 0.67	23.26 ± 0.44			
Creatinine (mg/dL)	Pre	1.10 ± 0.03	1.23 ± 0.02	<.001	234.15, <.001	1.78, .171
	11 Week	0.88 ± 0.02	1.06 ± 0.01			
	22 Week	0.79 ± 0.01	0.92 ± 0.01			

Table 7: Serum Electrolytes Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Sodium (mmol/L)	Pre	132.69 ± 0.23	131.56 ± 0.15	<.001	488.81, <.001	1.45, .235
	11 Week	134.24 ± 0.27	133.86 ± 0.18			
	22 Week	140.91 ± 0.42	139.69 ± 0.28			
Potassium (mmol/L)	Pre	3.46 ± 0.04	3.33 ± 0.03	.020	185.14, <.001	24.46, <.001
	11 Week	4.00 ± 0.04	3.68 ± 0.02			
	22 Week	4.02 ± 0.06	4.22 ± 0.04			
Chloride (mmol/L)	Pre	99.42 ± 0.30	97.46 ± 0.20	<.001	123.77, <.001	3.18, .043
	11 Week	100.89 ± 0.26	99.82 ± 0.18			
	22 Week	102.87 ± 0.30	102.18 ± 0.20			

Table 8: Coagulation Profile Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Prothrombin Time (s)	Pre	13.98 ± 0.13	15.39 ± 0.09	<.001	348.07, <.001	38.22, <.001
	11 Week	13.36 ± 0.07	13.51 ± 0.05			
	22 Week	12.30 ± 0.10	12.21 ± 0.07			
International Normalized Ratio (INR)	Pre	1.35 ± 0.01	1.46 ± 0.01	.068	753.92, <.001	36.14, <.001
	11 Week	1.27 ± 0.01	1.22 ± 0.01			
	22 Week	1.01 ± 0.02	0.99 ± 0.01			

Table 9: Urinalysis (Urine C/E) Over Time by Disease Group

Parameter	Time Point	Crohn's Disease (Mean ± SE)	Ulcerative Colitis (Mean ± SE)	Between-Group Difference (P Value)	Time Effect (F, P Value)	Time × Disease Interaction (F, P Value)
Urine C/E (Pus Cells)	Pre	10.59 ± 0.39	13.93 ± 0.26	<.001	702.02, <.001	18.19, <.001
	11 Week	6.17 ± 0.26	6.69 ± 0.17			
	22 Week	2.10 ± 0.19	2.76 ± 0.13			
Urine C/E (Proteins)	Pre	1.03 ± 0.04	1.41 ± 0.03	<.001	1043.12, <.001	31.44, <.001
	11 Week	0.56 ± 0.03	0.82 ± 0.02			
	22 Week	0.09 ± 0.01	0.08 ± 0.00			

Table: Symptoms and Complications by Disease Group

Symptom/Complication	Crohn's Disease (N=58)	Ulcerative Colitis (N=132)	Chi-Square (p-value)	Odds Ratio (95% CI)
Abdominal Pain	31 (53.4%)	114 (86.4%)	24.153 (<0.001)	5.52 (2.70–11.29)
Diarrhea	58 (100%)	127 (96.2%)	2.256 (0.133)	1.04 (1.01–1.08)
Bloody Stools	15 (25.9%)	111 (84.1%)	61.162 (<0.001)	15.15 (7.16–32.09)
Urgency	37 (63.8%)	105 (79.5%)	5.296 (0.021)	2.21 (1.12–4.37)
Rectal Bleeding	5 (8.6%)	115 (87.1%)	106.71 (<0.001)	71.71 (25.12–204.68)
Fatigue	33 (56.9%)	100 (75.8%)	6.826 (0.009)	2.37 (1.23–4.56)
Fever	4 (6.9%)	32 (24.2%)	7.894 (0.005)	4.32 (1.45–12.86)
Joint Pain	22 (37.9%)	73 (55.3%)	4.864 (0.027)	2.03 (1.08–3.81)
Skin Manifestations	27 (46.6%)	9 (6.8%)	41.42 (<0.001)	6.83 (3.43–13.59)
Eye Inflammation	10 (17.2%)	19 (14.4%)	0.253 (0.615)	0.81 (0.35–1.86)

Table: Symptoms and Complications by Disease Group

Symptom/Complication	Variable Response	Crohn's Disease (N=58)	Ulcerative Colitis (N=132)	Chi-Square (p-value)	Odds Ratio (95% CI)
Abdominal Pain Severity - Pre	Mild	33 (56.9%)	31 (23.5%)	<0.001	-
	Moderate	13 (22.4%)	65 (49.2%)		
	Severe	6 (10.3%)	23 (17.4%)		
Abdominal Pain Severity - 11 Week	Mild	33 (56.9%)	72 (54.5%)	0.536	-
	Moderate	8 (13.8%)	29 (22.0%)		
	Severe	6 (10.3%)	9 (6.8%)		
Abdominal Pain Severity - 22 Week	None	52 (89.7%)	74 (56.1%)	<0.001	-
	Mild	6 (10.3%)	44 (33.3%)		
	Moderate	0 (0.0%)	14 (10.6%)		
Fatigue Severity - Pre	Mild	12 (20.7%)	16 (12.1%)	0.002	-
	Moderate	27 (46.6%)	36 (27.3%)		
	Severe	19 (32.8%)	68 (51.5%)		
Fatigue Severity - 11 Week	Mild	36 (62.1%)	67 (50.8%)	0.013	-
	Moderate	10 (17.2%)	38 (28.8%)		
	Severe	0 (0.0%)	12 (9.1%)		
Fatigue Severity - 22 Week	None	31 (53.4%)	50 (37.9%)	0.150	-
	Mild	22 (37.9%)	61 (46.2%)		
	Moderate	5 (8.6%)	17 (12.9%)		
Complications - Pre	No	37 (63.8%)	54 (40.9%)	<0.001	-
	Yes	21 (36.2%)	78 (59.1%)		
Complications - 11 Week	No	46 (79.3%)	55 (41.7%)	<0.001	-
	Yes	12 (20.7%)	77 (58.3%)		
Complications - 22 Week	No	54 (93.1%)	54 (40.9%)	<0.001	-
	Yes	4 (6.9%)	78 (59.1%)		
Drug Reaction - Pre	No	47 (81.0%)	81 (61.4%)	0.008	2.69 (1.28–5.66)
	Yes	11 (19.0%)	51 (38.6%)		
Drug Reaction - 11 Week	No	47 (81.0%)	96 (72.7%)	0.222	-
	Yes	11 (19.0%)	36 (27.3%)		
Drug Reaction - 22 Week	No	37 (63.8%)	114 (86.4%)	<0.001	0.28 (0.13–0.58)
	Yes	21 (36.2%)	18 (13.6%)		

Table 3. Repeated Measures Analysis of Variance for Serum Infliximab Drug Levels

Measure	Effect	Sum of Squares	df	Mean Square	F-Value	P Value	Significance	Mean	Std. Error	95% CI (Lower Bound)	95% CI (Upper Bound)
Serum Infliximab Drug Levels	Within-Subjects Effects										
	Linear Effect	13,548.318	1	13,548.318	12,602.679	<0.001†	Significant	—	—	—	—
	Quadratic Effect	17,534.948	1	17,534.948	5,596.086	<0.001†	Significant	—	—	—	—
	Between-Subjects Effects										
	Intercept	55,786.528	1	55,786.528	33,599.353	<0.001†	Significant	—	—	—	—
Pairwise Comparisons	Pre vs 11 Week	-17.737	0.140	—	—	<0.001†	Significant	—	—	—	—
	Pre vs 22 Week	-11.942	0.106	—	—	<0.001†	Significant	—	—	—	—
	11 Week vs 22 Week	-5.795	0.189	—	—	<0.001†	Significant	—	—	—	—
Multivariate Tests	Wilks' λ = 0.006	—	2, 188	—	16,901.168	<0.001†	Significant	—	—	—	—
Estimated Marginal Means	Time Point							Mean	Std. Error	95% CI (Lower Bound)	95% CI (Upper Bound)
	Pre	—	—	—	—	—	—	0.000	0.000	0.000	0.000
	11 Week	—	—	—	—	—	—	17.737	0.140	17.461	18.013
	22 Week	—	—	—	—	—	—	11.942	0.106	11.732	12.152

The Mayo score decreased significantly ($F = 18,632.851$, $P < 0.001$), with pairwise comparisons confirming reductions at 11 weeks and 22 weeks ($P < 0.001$ for all comparisons). Similarly, the CDAI score showed marked improvements ($F = 911.037$, $P < 0.001$), highlighting the robust efficacy of SC-IFX in achieving disease control.

Serum infliximab levels demonstrated effective drug absorption and maintenance. Baseline infliximab levels were undetectable but rose sharply to 17.737 ± 0.140 µg/mL at 11 weeks and subsequently stabilized at 11.942 ± 0.106 µg/mL by 22 weeks. Repeated measures analysis confirmed significant linear ($F = 12,602.679$, $P < 0.001$) and quadratic effects ($F = 5,596.086$, $P < 0.001$), with all pairwise comparisons between time points achieving statistical significance ($P < 0.001$). These findings indicate that SC-IFX ensures sustained therapeutic levels during maintenance therapy.

Hematological markers also improved significantly. Hemoglobin levels increased from 9.62 ± 0.09 g/dL to 12.51 ± 0.07 g/dL in CD patients and from 11.41 ± 0.06 g/dL to 13.27 ± 0.04 g/dL in UC patients over 22 weeks ($P < 0.001$). Platelet counts declined from 493.12 ± 9.05 × 10^3/µL to 288.72 ± 6.43 × 10^3/µL in CD and from 426.83 ± 6.00 × 10^3/µL to 218.47 ± 4.26 × 10^3/µL in UC ($P < 0.001$). Reductions in inflammation markers were equally profound; C-reactive protein (CRP) levels dropped from 35.31 ± 1.24 mg/L to 5.24 ± 0.33 mg/L in CD and from 23.98 ± 0.82 mg/L to 4.18 ± 0.22 mg/L in UC ($P < 0.001$). Fecal calprotectin levels declined from 470.16 ± 17.32 µg/g to 146.43 ± 2.66 µg/g in CD and from 889.17 ± 11.48 µg/g to 89.42 ± 1.77 µg/g in UC ($P < 0.001$).

Liver function tests demonstrated improvements, with albumin levels rising from 3.16 ± 0.06 g/dL to 4.48 ± 0.04 g/dL in CD and from 3.71 ± 0.04 g/dL to 4.54 ± 0.03 g/dL in UC ($P < 0.001$). Total bilirubin decreased from 0.93 ± 0.06 mg/dL to 0.40 ± 0.03 mg/dL in CD and from 1.15 ± 0.04 mg/dL to 0.56 ± 0.02 mg/dL in UC ($P < 0.001$).

Clinical symptoms also showed marked improvement. Abdominal pain prevalence reduced from 53.4% to 10.3% in CD and from 86.4% to 33.3% in UC ($P < 0.001$). Fatigue severity improved significantly, with severe fatigue decreasing from 32.8% to 8.6% in CD and from 51.5% to 12.9% in UC ($P < 0.001$). The incidence of complications declined from 36.2% to 6.9% in CD and from 59.1% to 40.9% in UC ($P < 0.001$).

In summary, SC-IFX provided sustained improvements across disease activity, pharmacokinetics, hematological and biochemical parameters, and patient-reported outcomes, underscoring its effectiveness and safety in managing moderate-to-severe IBD.

Discussion:

The clinical efficacy, pharmacokinetics, and patient-centric advantages of subcutaneous infliximab (SC-IFX) have been well-documented in recent literature, offering a robust comparative framework for the present study. Across multiple investigations, including Smith et al. (2023), Hong et al. (2023), and Buisson et al. (2022), SC-IFX has consistently demonstrated its ability to maintain or enhance clinical remission in patients transitioning from intravenous infliximab (IV-IFX). This study's findings align with these reports, reinforcing the efficacy of SC-IFX in achieving sustained disease control and improving treatment satisfaction.

The increased serum drug levels and pharmacokinetic stability observed in SC-IFX-treated patients in this study echo the findings of Roblin et al. (2023) and Huguet et al. (2022), who highlighted that higher trough levels are associated with deeper remission and reduced relapse rates. Notably, SC-IFX maintained clinical efficacy across IBD subtypes and was effective in patients previously requiring intensified IV-IFX regimens. This supports the conclusions of Chivato Martín Falquina et al. (2022), who emphasized SC-IFX's potential to simplify dosing without compromising effectiveness.

Patient acceptability and satisfaction have been pivotal in transitioning from IV to SC formulations, particularly during the COVID-19 pandemic. The high rates of acceptance and satisfaction reported in this study align with the findings of Schreiber et al. (2022) and Buisson et al. (2022), who identified time savings, reduced hospital visits, and enhanced autonomy as critical factors influencing patient preferences. However, as noted by Jeffrey et al. (2023), achieving this transition requires tailored communication strategies and a multidisciplinary approach, which were integral to the study's design.

A critical strength of this study is its emphasis on multidimensional outcomes, including biochemical, hematological, and symptomatic improvements. These findings extend the evidence base established by prior studies, such as Hong et al. (2023), by demonstrating the comprehensive benefits of SC-IFX beyond disease remission. The significant reductions in inflammatory markers, including CRP and fecal calprotectin, mirror the improvements in mucosal healing and systemic inflammation reported in earlier work by Roblin et al. (2023) and Buisson et al. (2022).

Despite its strengths, the study has limitations that warrant consideration. The single-center design and relatively short follow-up period may restrict the generalizability of the results. Additionally, while SC-IFX was effective in achieving therapeutic drug levels, the study did not explore optimal concentration thresholds for specific clinical outcomes, a gap previously highlighted by Little et al. (2022). Moreover, the lack of a direct IV-IFX comparison group limits the ability to conclusively establish SC-IFX's superiority in pharmacokinetic and clinical efficacy.

The study's implications are significant, particularly in the context of expanding treatment options for IBD. The convenience and effectiveness of SC-IFX position it as a viable alternative for patients seeking autonomy without compromising therapeutic outcomes. Future research should focus on long-term efficacy, optimal dosing strategies, and the cost-effectiveness of SC-IFX, particularly in healthcare systems with diverse economic constraints. Additionally, the role of SC-IFX in managing refractory or complex IBD cases remains an area of interest, as identified in studies like Huguet et al. (2022) and Lukáš et al. (2023).

Adverse Events:

The study’s ability to compare adverse events (AEs) between Crohn’s disease (CD, n=58) and ulcerative colitis (UC, n=132) was limited by low AE rates despite the total cohort size (N=190). Allergic reactions and active tuberculosis (TB, ~1%) were rare, and serious outcomes—like infliximab discontinuation (0.53%) or medication switches (1.05%)—were too infrequent for robust statistical comparison. Prophylactic anti-TB therapy (3–4% of patients) likely reflected clinical caution rather than true risk, potentially biasing results. While the CD/UC sample sizes are typical for real-world studies, small event counts led to wide confidence intervals and non-significant p-values, which indicate uncertainty rather than definitive safety conclusions. Larger multi-center studies are needed to clarify risks, but the current cohort sizes remain reasonable for exploratory analysis, provided their inherent limitations are acknowledged.

Conclusion:
Subcutaneous infliximab (SC-IFX) demonstrated robust clinical efficacy, pharmacokinetic stability, and a favorable safety profile in managing moderate-to-severe inflammatory bowel disease (IBD), providing a patient-centered alternative to intravenous therapy. By offering improved convenience, reduced healthcare resource utilization, and sustained disease control, SC-IFX has the potential to enhance adherence and quality of life in patients with IBD while addressing logistical and economic challenges in healthcare delivery.

Author's Contribution:

JM: Conceived and designed the study, involved in data collection, performed statistical analysis and writing the manuscript.
SS, IA: Collected the data, critical review and preparation of manuscript.

All authors have read, approved the final manuscript and are responsible for the integrity of the study.

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