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Impact of Medication Adherence Barriers on Disease Activity in Iraq Patients with Inflammatory Bowel Disease

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ABSTRACT

Background & Objective: Inflammatory bowel disease (IBD) management relies on biological therapies. However, poor medication adherence remains a challenge and linked to worsened outcomes. C-reactive protein (CRP) is a key marker of disease activity in IBD. This study investigated the relationship between adherence barriers and disease severity, measured by CRP, in Iraqi IBD patients.

Materials & Methods: A cross-sectional study enrolled 100 adult IBD patients on biological therapy (mostly on infliximab) for ≥6 months at a Gastroenterology and Hepatology teaching hospital in Baghdad province in the period from December 2024 to February 2025. Disease severity was assessed by determining serum CRP levels. Adherence barriers were evaluated using the Adherence Barriers Questionnaire, measuring four subscales: Intentional, Unintentional, Medication-related, and Healthcare system-related barriers (higher scores indicate greater barriers) and correlated with the sociodemographic data and the severity of the disease.

Results: Most sociodemographic factors showed no significant association with CRP levels or adherence barrier subscales. Exceptions included higher Healthcare system-related barriers in single vs. married patients (p=0.025), and significant associations between Unintentional barriers and lower education levels (p=0.003) and middle-income levels (p=0.009). Patients with elevated CRP exhibited significantly higher scores across all four adherence barrier subscales compared to those with normal CRP.

Conclusion: Significant associations demonstrated between elevated CRP related to disease activity and increased adherence barriers across all categories in Iraqi IBD patients. While sociodemographic factors had minimal overall influence, marital status, education, and income impacted specific barriers with minimal effect. Addressing these modifiable adherence barriers is essential for improving disease control in IBD management.

Keywords: Medication Adherence, C-Reactive Protein, Inflammatory Bowel Diseases, Sociodemographic Factors, Biological Therapy

1. Introduction

Inflammatory bowel disorders include chronic intestinal inflammation linked to dysbiosis in gut microbiota. Crohn's disease (CD) and ulcerative colitis (UC) are the most prevalent forms of inflammatory bowel disease and have garnered much attention due to their increasing incidence (1, 2). The clinical manifestation is diverse, with affected individuals commonly experience symptoms such as diarrhea, abdominal pain, rectal bleeding, and unintended weight loss (3).

Biologic drugs have become cornerstone of therapy for IBD, the United States (US) Food and Drug Administration (FDA) now approved the following therapeutic choice: Remicade (infliximab [IFX]), Humira (adalimumab [ADA]), Cimzia (certolizumab pegol [CZP]), Simponi (golimumab [GOL]), Tysabri (natalizumab [NAT]), Entyvio (vedolizumab [VDZ]) and Stelara (Ustekinumab [UST]] (4). Multiple routes of administration are available or being developed from biological therapy, among the available of biological therapy, patients prefer to self-administer of drug (5, 6).

Poor medication adherence poses a major challenge in the management of IBD and other diseases, which poor adherence in IBD potentially results in worsened disease activity, frequent relapses, reduced effectiveness of anti-TNF therapies, increased morbidity and mortality, elevated health care cost, functional impairment and potentially compromised quality of life (QOL) (7-9). High prevalence of non-adherence [up to 72%] has been documented across various IBD medication and healthcare systems (10). Adherence rates differ due to multitude of intricate factors, both modifiable and non-modifiable, which may stem from intentional and/or unintentional influences (11). Patients with chronic conditions reliant on prolonged treatment encounter greater challenges in maintaining consistent adherence (12).

Research has consistently demonstrated that maintenance therapy provides significant benefits including reducing the incidence of exacerbation, surgical intervention, hospital admission and a lower risk of developing colorectal cancer. These findings underscore the role of adherence to prescribed treatment (13-17).

Adherence to long-term pharmacotherapy is influenced by multifactorial barriers and the alteration of these factors throughout the course of the disease. The World Health Organization (WHO) has identified various factors linked to non-adherence: socioeconomic influences, health care system challenges, disease-related factors, treatment complexities and patient specific considerations (18). Non-adherence to treatment can be categorized based on patient intent, non-intentional occurs when patients intend to follow their prescribed regimen, but the patient unable to do because multiple factors such as forgetfulness, complexity of therapeutics protocol or financial constraints limited access to medication. Conversely, intentional non-adherence occurs when the patients consciously decide to discontinue or alter their therapeutic regimen based on personal belief (18, 19).

Several diagnostic and monitoring tests play an important role in assessing progression and disease activity such as C-reactive protein and another inflammatory marker (20, 21). Elevated CRP level in IBD patients is associated with clinical disease activity, endoscopic inflammation, severe histologic inflammation, and various other biomarkers of inflammation (22).

Inflammatory bowel disease patients' treatment adherence has been the subject of several earlier studies (23). But by determining the obstacles to adherence that patients encounter and measuring the severity of the disease using inflammatory markers, particularly C-reactive protein. This study seeks to investigate the relationship between adherence and disease severity in Iraqi patients. The goal of this study is to advance our understanding of patient management in IBD by shedding more light on the variables affecting adherence and their possible effects on the course of the illness.

In this study we hypothesized that higher adherence barrier scores would be significantly associated with elevated CRP levels, indicating worse IBD activity.

2. Materials and Methods

2.1 Study Design and Population

This study employed a cross-sectional design to assess adherence barriers and inflammatory markers in patients diagnosed with IBD. Data were gathered using structured interviews with patients and laboratory assessments at the Gastroenterology and Hepatology Teaching Hospital in Baghdad, Iraq, located within Medical City. In the present study 100 patients with IBD were included, using convenience sampling technique during the period from December 2024 to February 2025.

The study included adult patients (≥18 years) of either gender with a confirmed diagnosis of IBD who had been receiving biologic therapy (mostly on infliximab) for a minimum of six months, and who willingness to complete a questionnaire and provide informed consent. Conversely, individuals with severe intellectual impairments or mental disabilities that prevent informed consent or consistent adherence to treatment protocols were excluded from the study. Additional exclusion criteria included pregnancy and the presence of major comorbid conditions such as malignancies, advanced liver disease, end-stage renal failure, or severe cardiac dysfunction (NYHA class III or IV) that could potentially affect study outcomes.

2.2 Measurement Tools

Adherence barrier assessment: ABQ consisted of 16 different items organized into 4 subscales, the first includes five items referred to intentional adherence barriers, second subscale consist of four items that named unintentional adherence barriers, four items consist the third subscale; the medication related barriers, and the last subscale that referred as health care system-related barriers consist of three items. The responses were measured on a 4-point Likert scale: “strongly agree,” “generally agree,” “generally disagree,” and “strongly disagree,” with values assigned from 1 to 4, where a higher score indicated a greater perceived influence of a particular barrier on patient perceptions (12).

Blood samples were collected from each participant to measure inflammatory marker CRP to assess disease activity. Samples were processed in a standardized laboratory setting using the AFIAS CRP Test, objectively measured decrease disease activity was achieved if CRP < 5 mg/L (24).

2.3 Statistical analysis

The data were assessed for normality using appropriate tests (e.g., Shapiro-Wilk or Kolmogorov-Smirnov) and to assess whether the data distributed normally or not to choose the best statistical test for comparing two independent groups (independent t-test for normally distributed data and Mann-Whitney U test for the non-

normally distributed data) or more than two groups (ANOVA test for normally distributed data and Kruskal-Wall test for the non-normally distributed data). Continuous data are expressed as mean ± standard deviation (SD) for descriptive purposes in addition to median and interquartile ranges (IQRs) if the data were non-normally distributed. Chi square test was used to assess the association in the categorical variables (Sex, Place of residence, Marital status, education, etc.) while Spearman correlation was used to assess the association in the numerical variables. All statistical analyses were performed using SPSS software (IBM Corp., Armonk, NY, USA), considering a p-value of <0.05 as statistically significant differences.

3. Result

Results obtained in the present study showed to be non-normally distributed which necessitated the use of Mann-Whitney U test to compare the adherence in patients with negative CRP test with those with positive CRP test.

The Sociodemographic features of all patients subjected to the current study were demonstrated in table 1 which revealed that the patients with a positive CRP test were non-significantly differ in age from those of patients with negative CRP result. Moreover, the other categorical Sociodemographic features including Sex, Place of residence, Marital status, education, Occupational activity, income, exercise and medical visit showed to be non-significantly different in patients with either positive or negative CRP results.

Table 2 presents the descriptive statistics (minimum, maximum, interquartile range, and median) for each subscale of the Adherence Barriers Questionnaire (ABQ). The ABQ comprises four subscales: intentional barriers (score range: 1–20), unintentional barriers (1–16), medication-related barriers (1–16), and healthcare system-related barriers (1–12). Higher scores indicate greater perceived influence of the respective barrier domain.

The results revealed variability across subscale scores adherence barrier. The results demonstrated that patients showed a low median of intentional adherence barriers (less than 10 out of 20). Conversely, Unintentional adherence barriers were the only subscale of adherence barriers that showed a high score that exceeded the cut-off value of 8 out of 16 which indicates the presence of adherence barriers that affect the compliance of patients toward their treatment regimen. On the other hand, the median of the medication related barriers scores showed to be low (the score is 8 out of 16). Furthermore, health care system-related barriers scores showed a median of 6 out of 12 that indicate low health care system-related barriers.

Results demonstrated in Table 3 showed that the associations of the age with the subscales of adherence barriers were non-significant as it measured by Spearman correlation test. However, the effect of the other sociodemographic features on the adherence barriers were assessed by checking the difference in the values of adherence barriers subscales in relation to the sociodemographic features which revealed that the differences were non-significantly in the majority of features, except the significant differences in the following; health care system-related barriers in single patients comparing to married patients (p=0.025), unintentional adherence barriers in relation to the education levels (p=0.003) and the unintentional adherence barriers in relation to the income of the patients (p=0.009).

The results illustrated in table 4 that showed the difference in the adherence barriers subscales in patients with negative and positive CRP result were presented as mean, standard Deviation (SD), median, and IQRs. P-values illustrated in table 3 showed a significant difference in the adherence barriers subscales according to the CRP results. Patients with elevated CRP levels exhibited consistently higher scores across all adherence barrier subscales compared to those with normal CRP values. Specifically, the mean score for intentional adherence barriers was 9.27 ± 2.55 in the elevated CRP group versus 8.30 ± 2.24 in the normal CRP group ($p = 0.041$). For unintentional barriers, the elevated group scored 9.95 ± 2.50 compared to 8.52 ± 2.21 ($p = 0.007$). Medication-related barriers were also higher among patients with elevated CRP (8.76 ± 2.43 vs. 7.48 ± 2.63, $p = 0.030$), as were healthcare system-related barriers (5.84 ± 1.36 vs. 5.16 ± 1.59, $p = 0.033$). These findings underscore a statistically significant association between systemic inflammations and increased perceived barriers to medication adherence.

Figure 1 compares patients with negative versus positive CRP levels across four subscales: intentional, unintentional, medication-related, and health care system-related barriers. The boxplot highlights differences in median scores and interquartile ranges, demonstrating that patients with elevated CRP levels consistently reported higher perceived barriers, particularly in medication-related domains.

Table 1. Sociodemographic features of all patients subjected to the current study in association with CRP results.

Feature	Group	Mean ± Sd	Median ± IQRs	p-value
*Age (y)	CRP- negative	30.62 ± 10.15	28±16	0.769
	CRP- positive	25.59 ± 8.86	30±12	
Feature	**Group**	**CRP- negative (n)**	**CRP- positive (n)**	**p-value**
**Sex	Male (n)	36	25	0.302
	Female (n)	27	12	
**Place of residence	Rural (n)	8	4	0.779
	Urban (n)	55	33	
**Marital status	Single (n)	34	21	0.787
	Married (n)	29	16	
**Education	Primary	13	4	0.427
	Secondary	15	11	
	University	35	22	
**Occupational activity	Yes	21	9	0.343
	No	42	28	
**Income (IQD)	Less than 500,000	39	24	0.952
	500,000-1,000,000	17	9	
	More than 1,000,000	7	4	
**Exercise	No	43	21	0.371
	Less than 3 times per week	9	9	
	3 times per week	9	4	
	More than 3 times per week	3	2	
**Medical visit	Periodically	28	19	0.622
	if needed	34	18	
	Once a year	1	0	

* Independent-Samples Mann-Whitney U Test

** Chi square test

Table 2. Descriptive Statistics of Adherence Barrier Subscales.

	N	Minimum	Maximum	IQR	Median
Intentional adherence barriers	100	5.00	16.00	7.000-10.000	8.500
Unintentional adherence barriers	100	4.00	16.00	7.000-11.000	9.000
Medication related barriers	100	4.00	14.00	6.000-10.000	8.000
Health care system-related barriers	100	3.00	9.00	4.000-6.750	6.000
Sum Adherence barrier	100	16.00	44.00	26.00-36.00	31.000

IQR: interquartile range, **N**: Number

Table 3. Sociodemographic features of all patients subjected to the current study in association with adherence barrier.

Feature	Group	Intentional adherence barriers	Unintentional adherence barriers	Medication related barriers	Health care system-related barriers
*** Age (y)**	r	-0.111	0.103	-0.041	-0.108
	p	0.273	0.306	0.685	0.283
**** Sex**	Male (Median ± IQRs)	8±2.5	9±3	8±4	6±3
	Female (Median ± IQRs)	9±3	10±4	9±4	6±2
	p	0.912	0.661	0.251	0.803
**** Place of residence**	Rural (Median ± IQRs)	8±3.75	9.5±3	5.75±5.75	5.5±3.75
	Urban (Median ± IQRs)	9±3	9±4	8±4	6±2.75
	p	0.281	0.507	0.058	0.516
**** Marital status**	Single (Median ± IQRs)	9±3	8±4	8±4	6±2
	Married (Median ± IQRs)	8±4	9±4	8±4	5±2
	p	0.264	0.508	0.872	0.025#
***** Education**	Primary (Median ± IQRs)	9±2	9±3	8±4.5	6±1
	Secondary (Median ± IQRs)	8.5±4.5	11±5	7±6	5.5±3
	University (Median ± IQRs)	8±3	8±3	8±3	5±3
	p	0.896	0.003#	0.591	0.976
****Occupational activity**	Yes	8±5.25	9±3.25	8±3	5±3.25
	No	9±2	9±4	8±4	6±1.25
	p	0.400	0.843	0.412	0.237

***** Income (IQD)**	Less than 500,000	9±2	10±4	8±4	6±2
	500,00-1,000,000	8±3	7.5±2	7±3	5±2
	More than 1,000,000	8±7	9±4	9±2	5±3
	p	0.311	0.009#	0.265	0.074
***** Exercise**	No	8±3.75	9±4	7.5±4	6±2
	Less than 3 times per week	9±2.5	9.5±3.25	9.5±4.25	6±2.25
	3 times per week	10±3.5	7±4	8±5.5	6±3.5
	More than 3 times per week	10±3.5	8±4.5	7±5.5	6±2.5
	p	0.315	0.687	0.243	0.700
***** Medical visit**	Periodically	9±2	9±4	9±4	6±2
	if needed	8±5	9±3.75	7.5±4	5±3
	p	0.735	0.557	0.507	0.300

* Spearman correlation; r: Spearman correlation coefficient, p: significance.

** Independent-Samples Mann-Whitney U Test

*** Independent-Samples Kruskal-Wall

Significant at $p<0.05$

Table 4. The difference in the values of Adherence barriers subscales in association with CRP results.

Adherence barriers subscales	CRP	N	Mean	SD	Median	IQRs	p-value
Intentional adherence barriers	Negative	63	8.3016	2.24064	8	3	0.041
	positive	37	9.2703	2.54568	10	3.5	
Unintentional adherence barriers	Negative	63	8.5238	2.21328	8	3	0.007
	positive	37	9.9459	2.50495	10	4	
Medication related barriers	Negative	63	7.4762	2.63266	7	5	0.03
	positive	37	8.7568	2.43134	9	10	
Health care system-related barriers	Negative	63	5.1587	1.58833	5	2	0.033
	positive	37	5.8378	1.36450	6	2	

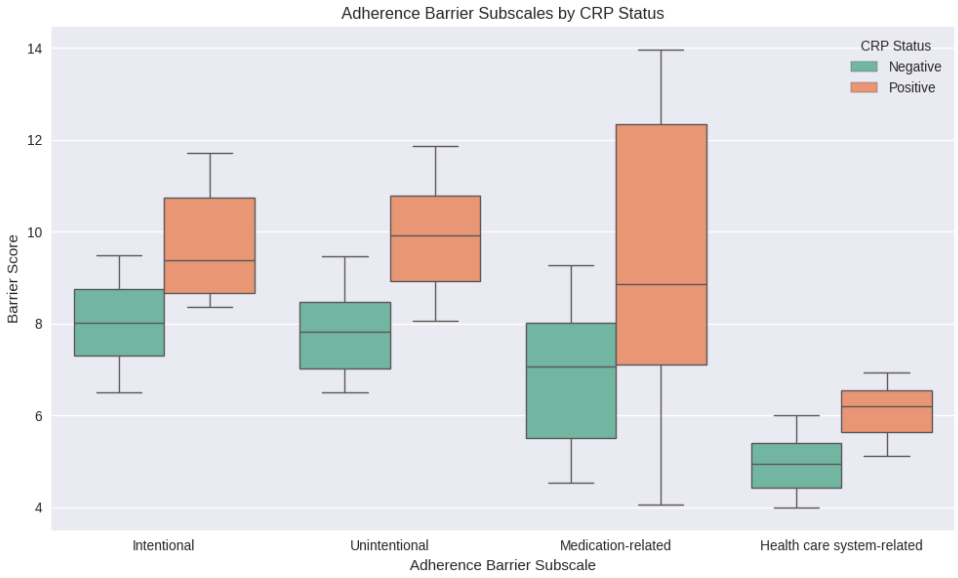

Figure 1. Boxplot of Adherence Barrier Subscales Stratified by CRP Status (**Prepared by Authors, 2025**).

4. Discussion

The present study aimed to assess barriers to adherence in relation to CRP results, which generally indicate the presence of inflammation **(25)**. To achieve this, we examined the association between sociodemographic characteristics and CRP test outcomes to ensure that no such factors influenced CRP levels. This was supported by the absence of significant differences in sociodemographic features between patients with negative and positive CRP results.

Excluding the effect of sociodemographic features on the CRP levels facilitates the assessment of the patients' adherence toward their biological treatments that revolutionarily transformed the management of IBD, enabling more patients to attain remission from active disease **(26, 27)**. However, real world adherence to therapy remains a significant challenge, often limiting the potential for optimal therapeutic outcome **(28)**. The adherence was assessed as a functional of the CRP results that considered as a marker for the assessment of IBD severity in several medical centers **(29)**.

As we concluded before, the sociodemographic features didn't affect the severity of the IBD according to the present research's results. Additionally, the results showed only few significant associations between demographic features and adherence barrier subscales which include the difference in the score of health care system-related barriers between married and single patients in that the single patients showed a higher score in comparison with married patients, and this subscale include three questions that elucidate the trustfulness of patient in his medical caregiver. This finding means that the adherence of married patients to their treatment and health care provided is higher than that of single patients which are parallel to the previous studies which reported that the married patients were more likely to be adherent to their medications **(30, 31)**. In contrary, the other subscales showed to be non-significantly associated with the marital status which is agreed with another study conducted in Iraq **(32)**.

The possible explanation for the role of marital status in improving the adherence to treatment originates from the opinion of investigators who have suggested that spouses can improve adherence by providing practical support. Previous study reaches a conclusion that the presence of a spouse or other caregiver can affect positively the adherence of patients to their treatment which is obtained through the direct supervision on the administration of medications. Patients seem to struggle with adhering to their medicine regimen, attending physician appointments, and following their medical plan without the support of family members **(31)**.

Additionally, unintentional adherence barriers showed to be significantly affected by the level of education and the income. The patients with the highest education showed the lowest score for unintentional adherence barriers, which is owed to their knowledge that originates from their scientific background that lets them remember their treatments and understand the whole situation regarding to the disease in manner better than that for the patients with a lower education level. The association between education and adherence to treatment was reported in several previous articles and this finding necessitates the focus on the patients with low education to improve their adherence toward their treatment **(33, 34)**. Furthermore, the patients in the present study were classified according to their income into 3 groups: low, middle and high-income patients, and the study showed that the patients with the middle level of income showed the lowest score of unintentional adherence barriers, which might be explained in two ways. The first way is that the patients with a low income also have a lower education level that affects their adherence, as mentioned

before, and the second way suggested that patients with a high income have heavier duties that affect their adherence to the treatment regimen. Prior research indicated that poor income may influence adherence due to inconsistent primary healthcare access, inability to afford medications, lack of transportation, and familial dysfunction (34, 35).

In our study, CRP levels, which are regarded as a marker for assessing the activity of IBD, were determined in relation to the intentional adherence barriers, unintentional adherence barriers, medication-related barriers and health care system-related barriers, which showed significant impact on IBD disease severity as a function of CRP levels.

In terms of intentional adherence barriers, patients face multiple challenges in terms of adherence to biological therapy, where belief and perception influence the efficiency and safety of the drug some patient belief that adherence to treatment as prescribed by a physician does not impact the improvement of the disease and decrease complications. There is a prevalent perception that all drugs have a negative impact on patient health, and this leads to avoiding medication necessary to control disease activity (36-38).

Patients frequently fail to seek strategies to overcome this obstacle and improve their adherence, which exacerbates the issue and increases the risk of disease-related consequences. These findings are also aligned with several research which reported that considering the patient's beliefs regarding the given drug has been identified as a crucial element influencing adherence, research demonstrated that possessing good attitudes about treatments is essential for intentional adherence (39, 40).

Regarding unintentional adherence barriers, many patients frequently miss daily tasks. Consequently, they forget their regular prescriptions and cannot remember the name of the therapy. This subscale might be owned to the educational level or the financial status of the patients which necessitate to help ensure adherence. The lack of assistance may hinder their capacity to adhere to the therapeutic treatment regimen consistently, resulting in diminished health outcomes and increased complications as demonstrated in this study in alignment with previous studies (23, 41-43).

As for medication-related barriers, patients have obstacles to maintaining adherence due to difficulties in managing their therapeutic schedule and the condition related to medication intake and because of fear of adverse effects, some patients discontinue treatment without consulting a specialist physician when adverse effects arise (11, 23).

Another subscale of the adherence barrier is the healthcare-related barrier, which is related to patients' understanding of the medical guidance and information from a physician, pharmacist, or nurse and their lack of trust in healthcare providers. Regarding this subscale, basic examination fees may be considered one of the greatest burdens for patients that affect their adherence to their treatments (41, 44, 45). The previous studies suggested that the medication- and healthcare-related barrier can be eliminated by discussing all patients' concerns about medications that obtained by a good communication with the patients (46).

This study found a significant association between increasing barriers to adherence and increasing disease severity as assessed by the inflammatory marker CRP. This result appears that adherence barriers and disease activity have a bidirectional relationship. Patients with higher disease activity may face additional difficulties that worsen adherence problems. For example, aggravated symptoms might cause psychological discomfort, including higher degrees of anxiety or depression, which would then reduce their capacity to follow treatment advice (47, 48).

Apart from personal patient considerations, systematic problems could also be involved. Structural factors such as limited access to comprehensive healthcare services, poor communication between patients and providers, and socioeconomic limitations could exacerbate disease activity. Such elements emphasize the need for a comprehensive intervention plan transcending clinical management (23). Interventions combining patient education, treatment protocol simplification, improved support systems, and techniques to overcome socioeconomic challenges could help to lower disease activity by means of adherence barrier removal (41, 49).

These results have rather important consequences. Clinicians should be aware that inadequate disease outcomes could be partly a result of underlying adherence difficulties (38). By means of focused interventions, removing these obstacles might help to improve general disease control as well as adherence (50). Future studies should concentrate on creating and assessing complete intervention models in a longitudinal framework to untangle the causal dynamics between adherence constraints and disease activity, so opening the path for more customized and successful patient management strategies.

This study has certain limitations. The use of convenience sampling and recruitment from a single center. Nevertheless, the results offer valuable clinical insights into the association between inflammatory status and treatment adherence in patients with IBD. The observed correlations between CRP levels and multiple adherence barrier domains highlight the importance of targeted interventions. Clinicians should account for psychosocial and systemic factors when assessing adherence, and healthcare systems, particularly in resource-constrained settings like Iraq, should emphasize patient education, trust-building, and improved access to biologic therapies to enhance treatment outcomes.

5. Conclusion

This study demonstrates a significant association between increased medication adherence barriers and

elevated disease activity in Iraqi patients with IBD. These findings underscore that adherence challenges in IBD are multifaceted and closely linked to inflammatory burden. The bidirectional relationship was also demonstrated in that active disease heightens adherence barriers, and poor adherence exacerbates inflammation which necessitates the need for proactive, individualized management. Interventions addressing modifiable barriers (e.g., patient education, regimen simplification, psychosocial support, and financial assistance) are critical to improving adherence, reducing disease activity, and enhancing long-term outcomes in this population.

6. Declarations

6.1 Acknowledgments

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6.2 Ethical Considerations

The study was approved by the University of Baghdad-College of Pharmacy Research Ethics Committee with an approval number REC06202478H.

6.3 Authors' Contributions

Conceptualization, Hasan A. Owayez and Ali L. Jasim; methodology, Hasan A. Owayez; software, Hasan A. Owayez; validation, Hasan A. Owayez and Ali L. Jasim; formal analysis, Hasan A. Owayez; investigation, Hasan A. Owayez; resources, Ahmed A. Kassid; data curation, Hasan A. Owayez; writing—original draft preparation, Hasan A. Owayez; writing—review and editing, Ahmed A. Kassid; visualization, Hasan A. Owayez; supervision, Ali L. Jasim; project administration, Hasan A. Owayez. All authors reviewed, edited, and approved the final version of the manuscript.

6.4 Conflict of Interest

The authors declare no conflict of interest.

6.5 Fund or Financial Support

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

6.6 Using Artificial Intelligence Tools (AI Tools)

The authors were not utilized AI Tools.

7. Publisher's Note

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