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Original article

Compliance to Drug Therapy in Inflammatory Bowel Diseases: A Monocentric Experience

Aouroud Hala *[1], Adil Ait Errami [1], Nayala Hanane Essaidi [1], FZ. Lairani [1], O. Nacir [1], Sofia Oubaha [2], Zouhour Samlani [1], Khadija Krati [1]

[1]Department of Gastro-enterology and Hepatology, University Mohamed VI Hospital, Marrakesh, Morocco.
[2]Department of Physiology, Faculty of Medicine and Pharmacy, Marrakesh, Morocco.

*Corresponding author: Hala Aouroud; *aouroudhala@gmail.com*

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Abstract

Poor therapeutic compliance in inflammatory bowel diseases (IBD) has a negative impact on treatment efficacy and patients' quality of life. Addressing this issue requires an understanding of the factors involved, which include patient-related factors, socioeconomic conditions, treatment, and healthcare system factors. The aim of this study was to identify the factors responsible for poor therapeutic compliance in patients with IBD in our context. We conducted a prospective study involving 120 patients with IBD over a 10-month period. Data was collected using two questionnaires: one general questionnaire exploring factors influencing compliance and another specific one (Morisky Score) assessing the level of compliance. Of the 120 patients included, the average age was 39.66 years, with a female predominance. Crohn's disease was the most common pathology (71.7%), and 75% of patients were adherent to treatment. Lack of means was the most common reason for treatment abandonment. Bivariate analysis revealed a significant correlation between compliance, gender, monthly income, number of hospitalizations, number of daily doses, cost, perception of treatment importance, access to the treating physician, and mode of communication. Therefore, improving therapeutic compliance requires continuous support from healthcare professionals and the healthcare system, as well as responsible patients.

Keywords: ***Systemic Lupus Erythematosus, jaundice, hepatic involvement, Therapeutic compliance, inflammatory bowel diseases, therapeutic adherence, improvement***

Introduction

Inflammatory bowel diseases (IBD) include Crohn's disease, ulcerative colitis, and indeterminate colitis. The precise etiology remains unknown and is believed to be multifactorial according to the literature. Maintaining disease remission requires good patient therapeutic compliance, defined as the "agreement between a person's behavior, medication intake, adherence to a diet, or modification of behavior and a healthcare provider's recommendations." This includes not only adherence to medications but also adherence to associated diets and lifestyles. Solving the problem of non-compliance with treatment would be more effective than any new biomedical advancement. Therefore, its evaluation is of great importance. The World Health Organization (WHO) highlights non-compliance as a "striking problem" that continues to grow, as evidenced by the increasing number of publications on this topic. This study aims to explore the issue of therapeutic compliance, which has been relatively unaddressed in Morocco, and shed light on therapeutic compliance in IBD patients treated at the Mohamed VI University Hospital in Marrakech. We will attempt to apply a tool to measure therapeutic compliance in our study, explore possible correlations between therapeutic compliance in IBD patients and factors influencing this condition, and finally discuss some actions that can improve therapeutic compliance.

Methods

We conducted a prospective descriptive and cross-sectional analytical study over a period of 10 months (April 2021 - January 2022). The study population was recruited from the gastroenterology department at Mohamed VI University Hospital in Marrakech (day hospital, outpatient clinic, and inpatient department). The target population consisted of patients with IBD. We excluded patients under 17 years of age, those who stopped treatment following medical advice, those diagnosed within the past year, and those experiencing a flare-up for less than a month. Each included patient was informed about the study by the investigating physician. After obtaining their consent, the patient was informed again about the study's objectives. The variables studied in our research included epidemiological data (age, sex, geographic origin, employment status, socioeconomic level, education level), personal and family history, disease history (type of IBD, years since diagnosis, associated events, number of flare-ups, consultations, colonoscopies, surgeries, complications), therapeutic measures, doctor-patient relationship, family-patient relationship, patient's psychological experience, Morisky 8-item adherence scale (the most widely used scale in the literature to evaluate therapeutic adherence), and reasons for treatment abandonment. Data entry was done using SPSS version 2.6 software and R language. The study included a

descriptive analysis with calculations of frequencies and percentages for qualitative variables and calculations of central tendencies (means and medians) and measures of dispersion (standard deviation) for quantitative variables. The study also included a bivariate analysis, which involved comparing percentages for qualitative variables and using the Pearson chi-squared test and Fisher's test for statistical significance (p-value set at $p < 0.05$).

Results

Out of a total of 200 questionnaires distributed, 120 were successfully returned, while 80 were excluded based on our inclusion and exclusion criteria. Participation was voluntary, and information was collected anonymously. Descriptive data: The average age of our sample was 39.66 years, with a range of 17 to 69 years. There was a female predominance, with a female-to-male ratio of 1.6. On the socioeconomic front, the majority of patients had low monthly income (less than 254 euros/month), accounting for 90% of the population. 38.3% of them were illiterate, while most educated patients had primary-level education (28.3%), and 85% had RAMED as their social coverage. Crohn's disease was the most commonly encountered type of disease, affecting 71.7% of the population, with a median follow-up time since diagnosis of 5.9 years. 63% of them had at least one flare-up per year, requiring hospitalization at least once a year for 14% of the population, while 93% of patients had consulted or been to the outpatient department at least twice in the past year. Regarding treatment, 40% of patients were on oral aminosalicylate derivatives, with only one case receiving them rectally. 22.53% were on thiopurines, 4.15% were receiving methotrexate, 1.66% were on cyclosporines, and 16% used biologic therapy either as monotherapy or combination therapy. The oral route was the most common mode of administration, often with three doses per day. The average cost of treatment ranged from 24 to 35 euros per month for 83.3% of the population. Twenty-five percent of the population rated the treatment's effectiveness at 8/10 on the effectiveness numeric scale, while 8.3% suggested no effectiveness, and 90% perceived their treatment as important. Over the past twelve months, 7.5% of patients received corticosteroid treatment without medical advice (self-medication). The majority of recruited patients found it easy to access their treating physician (83.3%), with only 2.2% stating that the telephone was the primary mode of communication. In our sample, 46.7% of patients were compliant, with 28.3% having moderate compliance, and the remaining 25% being non-compliant. For patients with moderate and low compliance, 29.17% of patients reported a lack of means as the reason for non-compliance. Regarding their psychological experience, 28.33% of patients suffered from anxiety, and 10.83% had depressive symptoms.

Analytical results: Bivariate analysis allowed us to study the correlation between various socio-demographic factors, history, disease-related factors, system-related factors, treatment-related factors, and therapeutic compliance in our patients. Bivariate analysis of qualitative variables: According to our results, there was a significant correlation between compliance and the following qualitative variables:

- Gender ($p = 0.005$)
- Monthly income ($p < 0.001$)
- Perception of treatment importance ($p < 0.001$)
- Accessibility to the treating physician ($p = 0.001$)
- Mode of communication ($p = 0.036$)
- Involvement of the family in treatment ($p < 0.001$)

There was no correlation between therapeutic compliance and:

- Marital status
- Social coverage
- Education level
- Occupation
- Place of residence
- History
- Disease-related factors (type of IBD, associated extraintestinal events, history of surgery, complications)
- Treatment and its mode of administration

Bivariate analysis of quantitative variables: Tables 3 and 4 present the results of the bivariate analysis between therapeutic compliance and various quantitative factors.

There was a significant correlation between compliance and the following quantitative variables:

- Number of hospitalizations in the last year ($p = 0.028$)
- Number of consultations in the last year ($p = 0.008$)
- Number of doses per day ($p = 0.001$)
- Cost of treatment ($p < 0.001$)

There was no correlation between therapeutic compliance and:

- Number of children
- Disease-related factors (years since diagnosis, number of flare-ups, number of consultations, number of colonoscopies)

Table 1: Factors related to therapeutic compliance

Factors linked to therapeutic compliance		Number	Percentage
Morisky 8-item adherence scale	Good compliance (MMAS-8 = 8)	56	46,70%
	Average compliance (6 ≥ MMAS-8 ≥ 7)	34	28,30%
	Poor compliance (MMAS-8 < 6)	30	25,00%
Causes of abundant treatment	No abundance	85	70,83%
	Lack of means	14	11,60%
	Feels better without treatment	9	7,50%
	Treatment broken	3	2,50%
	Taking the treatment is a real nuisance	3	2,50%
	Pregnancy	2	1,70%
	Death of attending physician	1	0,83%
	Patient lost to follow-up (Covid	1	0,83%
	Allergic reaction	1	0,83%
	Depression/mourning	1	0,83%

Table 2: Therapeutic compliance rates according to various socio-economic, demographic, patient-related, family-related, and treatment-related parameters

Factors likely to influence therapeutic compliance		Compliance	Non-Compliance	Pearson khi-square (two-tailer)
				P value
Gender	M	31,1%	60,0%	**0,005**
	F	68,9%	40,0%	
Status marital	Married, single, divorced or widowed			0,155
Social security coverage	With or without			0,325
Education level	Educated or not			0,501
Monthly income	low	90,0%	90,0%	**<0.001**
	medium	8,9%	6,7%	
	High	1,1%	3,3%	
Occupation	With or without	84,4%	70,0%	0,163
place of residence	Rural	28,9%	30,0%	0,908
	Urbain	71,1%	70,0%	
Type of IBD	Crohn	75,60%	60,00%	0,102
	UC	24,40%	40,00%	
Type treatment				0,134
Method of administration				0,142
Perception of importance of treatment	yes	97,80%	70,00%	**<0,001**
	no	2,20%	30,00%	
Accessibility to treating physician	Reachable	90,00%	63,30%	**0,001**
	Not reachable	10,00%	36,70%	
Mode of communication	Travel to hospital	94,40%	80,00%	**0,036**
	Travel to hospital + Telephone	3,30%	16,70%	
	Telephone	2,20%	3,30%	
Family involvement in treatment	Family included	97,8%	66,7%	**<0,001**
	Familly not included	2,2%	33,3%	
Psychological experience after diagnosis	Stable psychological state	58,90%	66,70%	0,636
	Anxiety	28,90%	26,70%	
	Depression	12,20%	6,70%	

Table 3: Therapeutic compliance according to quantitative factors.

Factors likely to influence therapeutic adherence		Observant	Non observant	P value	Odds ratio	Odds ratio 95% confidence interval for Odds ratio	
						Inf	Sup
Age	[17,24]	8,90%	13,30%	0,224	0,736	0,448	1,207
	[24,31]	11,10%	20,00%				
	[31,38]	25,60%	26,70%				
	[38,45]	14,40%	20,00%				
	[45,52]	18,90%	10,00%				
	[52,59]	13,30%	3,30%				
	[59,66]	4,40%	3,30%				
	[66,69]	3,30%	3,30%				
N° on children	No children	25,60%	46,70%	0,698	1,281	0,367	4,468
	Between 1 and 3 children	56,70%	36,70%				
	Between 4 and 7 children	16,70%	16,70%				
	More than 7 children	1,10%	0,00%				
N° of years since diagnosis	[1,5]	35,60%	26,70%	0,511	1,202	0,694	2,084
	[5,9]	35,60%	53,30%				
	[9,13]	15,60%	6,70%				
	[13,17]	4,40%	6,70%				
	[17,21]	5,60%	0,00%				
	[21,25]	2,20%	0,00%				
	[25,32]	1,10%	6,70%				
Number of flare-ups in the last year	One flare	33,30%	53,30%	0,622	0,686	0,154	3,062
	None	41,10%	23,30%				
	Flare	25,60%	23,30%				

Table 4: Summary table of therapeutic compliance rates according to quantitative factors

Factors likely to influence therapeutic compliance		Observant	Non observant	P value	Odds ratio	Odds ratio 95% confidence interval for odds ratio	
						Inf	Sup
Number of hospitalizations	No hospitalization	80,00%	90,00%	**0,028**	0,036	0,002	0,697
	Hospitalized once a year	17,80%	3,30%				
	≥ 2 hospitalizations per year	2,20%	6,70%				
Number of colonoscopies	No colonoscopy	53,30%	66,70%	0,429	2,454	0,266	22,663
	One colonoscopy	37,80%	26,70%				
	≤ 2 colonoscopies	8,90%	6,70%				
Number of consultations in the last year	≤ 2 consultations	2,20%	20,00%	**0,008**	0,072	0,01	0,508
	≥ 3 consultations	97,80%	80,00%				
Number of intakes per day	one intakes	12,20%	10,00%	**0,001**	11,285	2,819	45,175
	Two intakes	31,10%	16,70%				
	three intakes	56,70%	43,30%				
	Stopping treatment	0,00%	30,00%				
Cost of treatment	[38,263]	3,30%	3,30%	**<0,001**	6,348	2,495	16,153
	[263,488]	88,90%	63,30%				
	[488,713]	4,40%	0,00%				
	[713,938]	1,10%	0,00%				
	[1388,1610]	2,20%	3,30%				

Discussion

Therapeutic compliance encompasses compliance with medication, adherence to general medical follow-up, and adherence to hygienic-dietary rules. In our study, we primarily focused on medication adherence. There are numerous methods to measure compliance, with questionnaires being one indirect method that requires a certain level of objectivity from the patient regarding their medication intake. Questions should be as neutral as possible and tailored to different pathologies and the patients' sociodemographic levels. The scale used in this study to evaluate therapeutic compliance is the Morisky Medication Adherence Scale (MMAS), developed by Morisky. It is a self-questionnaire consisting of four items for the oldest version from 1986 and eight items for the most recent version from 2008. It assesses the extent and reasons for non-adherence. MMAS-8 is an eight-item scale with two response modalities (yes or no) for the first seven items. One point is assigned to each question to which the patient answered "no" for questions 1-4 and 6-7, and one point is assigned to question 5 for a "yes" answer. The score ranges from zero to eight, with adherence considered adequate for individuals scoring eight, moderate for those scoring six or seven, and low for those scoring less than six. Determinants of therapeutic non-adherence are multiple, heterogeneous, personal to each individual, dynamic over time, dependent on the doctor-patient relationship, the disease, the treatment, and environmental factors. They are categorized as follows:

- Patient-related factors
- Socioeconomic factors
- System-related factors
- Disease-related factors

Treatment-related factors Regarding patient-related factors, these include age, gender, marital status, education level, the patient's psychological experience, and their relationship with their family. In our study, there was a statistically significant correlation between therapeutic compliance and gender and the family-patient relationship. Our results align with literature data concerning gender, as some studies have shown better therapeutic compliance among women. However, the correlation between the family-patient relationship and compliance has not always been proven in Western series, unlike our study. Indeed, Moroccan society has maintained this unique and rewarding aspect of support and solidarity, in line with our noble cultural, social, and religious values. For socioeconomic factors (social coverage, socioeconomic level, and place of residence), they were not determining factors for compliance in our patients, which is consistent with other studies. Regarding system-related factors, communication with the physician is crucial for improving therapeutic compliance. It allows for more effective transmission of important clinical information, discussions about barriers to compliance, and encourages adherence. However, the number of hospitalizations and consultations did not unanimously affect compliance. Lasa et al. did not find a correlation with therapeutic compliance, unlike our study, which demonstrated that these two variables determined compliance. As for treatment-related factors, there was a statistically significant correlation between the number of doses, perception of treatment importance, treatment cost, and therapeutic compliance, confirming the results of previously published studies. Given the magnitude of therapeutic non-compliance, its multifactorial and multidimensional complexity, and its detrimental consequences on patients with chronic diseases and the healthcare system, various multivariate actions have been developed to improve therapeutic compliance:

Patient therapeutic education, which is central to medicine and the social sciences.
Simplifying the therapeutic regimen (explaining prescriptions, the importance of treatment, favoring single-dose and fixed-dose combinations).
Better training healthcare professionals in communicating about their treatments.
Mobilizing patient associations and families.
Using behavioral approaches to facilitate the adoption and integration of medication intake into daily life.

Conclusion

Therapeutic compliance in chronic diseases is a global public health problem. To improve patient compliance, it is essential to decipher the meaning of non-compliance, which is by definition unique to each patient. Regardless, compliance reflects the existential experience of the patient regarding a specific condition. Faced with

a problem of non-compliance, there are no clear answers or one-size-fits-all solutions. It is important to conduct an analysis that identifies the specific factors at play, which will lead to better management.

Conflicts of Interest

The authors declare no conflicts of interest.

Authors' Contributions

All authors contributed to the conduct of this study. All authors have read and approved the final manuscript.

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None

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