

# Clinical Pharmacist's Interventions on Medication Adherence and Knowledge of Inflammatory Bowel Disease Patients

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## ABSTRACT

**Objective:** To evaluate whether clinical pharmacist's interventions have any impact on medication adherence of patients having inflammatory bowel disease and to assess the awareness of patients about their disease and the significance of medications they use. **Materials and Methods:** A prospective, interventional follow up study was conducted in the outpatients visiting Gastroenterology and Hepatology department of Amrita Institute of Medical Sciences, Kochi. To assess the level of medication adherence and patient's awareness, MMAS-8 and CCKNOW has been utilized. Once this baseline information's were collected, counselling was given to patients and they were supplemented with pill cards and patient information leaflets as educational material. During the follow up visit, all the above parameters were reassessed and compared with the baseline visit. **Result:** About 110 IBD patients have participated in this study. In baseline visit, 6.36% patients had low adherence, 62.73% patients had medium adherence, 30.91% patients had high adherence. During follow up visit, after intervention by clinical pharmacist, 3.64% patients had low adherence, 18.18% patients had medium adherence and 78.18 % patients had high adherence. From this study, it was notified that the average score of CCKNOW was only 8.15 in the beginning. Later on, it was escalated to 11.65 during the revisit periods. **Conclusion:** Knowledge of patients about

their disease and medications were insufficient during baseline visit. Adherence to medication was found to be poor among IBD patients. Counselling provided by clinical pharmacist about the importance of medication adherence and provision of information leaflets and pill cards lead to an improvement in medication adherence and knowledge of IBD patients.

**Key words:** IBD - Inflammatory Bowel Disease, MMAS-8 - Modified Morisky Adherence Scale-8, CCKNOW - Crohn's and Colitis Knowledge assessment questionnaire, OPD – Outpatient Department.

**Key message:** Evaluation of knowledge, patient medication adherence in IBD patients.

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## INTRODUCTION

IBD has been considered as a condition highly probable for non-adherence. To overcome this proper medication adherence is needed. The relationship of a doctor-patient and other disease aspects has a vital role in medication adherence and makes it a complicated one. Among this, treatment period, detrimental impacts of medications and low or even no symptoms during the remission phase must be taken into consideration.<sup>1-3</sup> Medication claims to be a keystone of advanced treatment tactics for inflammatory bowel disease (IBD).<sup>4-7</sup> The proper usage of medication will trigger the remission and improve the quality of life of the patients .According to WHO medication adherence is defined as the extent to which a person's behaviour in taking medications corresponds with agreed recommendations from a health care provider.<sup>8</sup> In simple words medication adherence is defined as taking medication as prescribed for the proposed duration.<sup>9</sup> In spite of that, the high medication expense and complications in handling the dreadful side effects will affect the best outcomes of the treatment regimen and disease management. In this circumstance, treatment adherence has a vital role in the wellbeing of patients and providing the best outcomes of the treatment.<sup>10-11</sup> Adherence with medication regimens is necessary for attaining maximal therapeutic benefits.<sup>12</sup> It is important in successful management of chronic diseases.<sup>13</sup> IBD patients, mainly those having UC, need medications throughout their life with periodic dosing and occasionally, enemas and infusions may also be required. Treatment without adherence is highly regarded as the significant factor for relapse

occurrence.<sup>14</sup> Awareness is needed for chronic diseases like IBD to attain adequate control and require patient education in order to achieve adequate control and reduce harmful health issues. Disease based information has also a crucial role in helping patients to accept their health condition with an ease and to understand proper behavioral alterations that are needed in order to take part in the treatment effectively and also in enhancing the relationship of the doctor and patient.<sup>15-18</sup>

## METHODOLOGY

The study protocol was approved by the Institutional Ethics Committee.

### Study design

This was a prospective, interventional, follow up study carried out for a period of 1 year in 110 IBD patients.

In order to select participants for the study, following criteria were used.

- Patients who are clinically diagnosed with IBD and consuming at least a single drug as part of the treatment.
- Patients willing to provide written agreement for the participation.
- Patients' ≥ 18 years of age.
- Patients who know to read and speak English or the local language Malayalam.

Those who are not willing to complete follow-up questionnaires, with malignancies like colorectal and other GI cancers, pregnant and lactating

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women, psychiatric issues, or hearing impairment were excluded from the study.

#### Data collection tools

- Standardised data collection form.
- Modified Morisky Adherence Scale-8 (MMAS-8)
- Crohn's and Colitis knowledge assessment questionnaire (CCKNOW)

#### Study procedure

During the baseline visit, informed consent was obtained directly from selected patient who satisfied inclusion and exclusion criteria. A standardized data collection form was prepared and pertinent datas were recorded. Baseline knowledge regarding the disease and medications were assessed using CCKNOW questionnaire. Patient's medication adherence was assessed using MMAS – 8 questionnaire. All the patients included in the study received a standard care of treatment and counselling from the consultant gastroenterologist. Apart from the care of gastroenterologist, clinical pharmacist counselled all the patients and made them aware about the disease and the benefits of drugs, common ADR's and extraintestinal complication, significance of patient's adherence to treatment, alterations on diet etc. Throughout the patient counselling period, specially designed pill cards and patient information leaflets in English and Malayalam (local language) were provided to the patients. Patients were then asked to clarify their doubts, if any. In the follow up visit after 3 months, patient's knowledge and medication adherence were reassessed using the same questionnaires.

#### Statistical analysis

In this analysis, IBM SPSS version 20.0 software was used. For demonstrating the categorical variables, frequency and percentage were utilized. Similarly, the mean and standard deviation depicts the continuous variables. For finding the mean difference of scores between baseline and revisit, paired t test was used. For finding the mean score comparison between two groups in each visit, two sample t test was used and between 3 groups, one-way ANOVA was used.

## RESULTS

A total of 110 patients completed the study. Male patients were predominant ( $n= 70, 63.64\%$ ) than females ( $n=40, 36.36\%$ ). The mean age of the study participants was  $37.33 \pm 15.12$  years. Majority of patient's falls within the age group 18-37 years. 82 patients had Crohn's disease (74.55%) which constitutes majority and 28 patients had ulcerative colitis (25.45%). Regarding the education status of the patients, majority of them completed graduation/post-graduation (48.18%), 41.82% completed secondary education and 10% completed primary education. There were no illiterates in the study. With regard to employment status, 49.09% patients were employed, 34.55% were unemployed and 16.36% were students. Therapy received were oral 5-amino-salicylic acid (ASA) (73.64%), azathioprine (52.72%), oral steroids (32.72%), 5 -ASA enema (4.55%), infliximab (3.63%), probiotics (3.63%), oral antibiotics (3.63%), 5-ASA suppository (2.73%), tacrolimus (1.81%), methotrexate (0.9%). MMAS-8 was used to determine medication adherence. In the baseline visit, 6.36% patients had low adherence, 62.73% patients had medium adherence, 30.91% patients had high adherence. Medication adherence scores of patients in baseline visit and revisit are shown in Figure 1. During follow up visit, 3.64% patients had low adherence, 18.18% patients had medium adherence and 78.18 % patients had high adherence. The mean medication adherence score of patients during baseline visit and follow up visit were  $6.03 \pm 1.16$  and  $3.96 \pm 1.60$  respectively. Here the mean medication

adherence score during revisit showed statistically significant improvement from baseline visit ( $p < 0.001$ )

Busy/occupied (28.18%) was one of the main reasons for poor adherence followed by forgetfulness (20.91%), lifelong treatment (11.82%), side effects of drugs (11.82%), cost of medicine (10.90%), disease remission (8.18%), inconvenience (4.55%), and multiple daily dosing (3.64%). For male patients, the mean CCKNOW score was  $7.61 \pm 2.30$  and for female patients the score was  $9.08 \pm 2.97$ ; females had higher mean CCKNOW score than males which was statistically significant ( $p=0.009$ ). Younger age of diagnosis was associated with higher mean CCKNOW scores i.e the age group 18-37 had higher mean CCKNOW score ( $9.33 \pm 2.85$ ) compared to age group 38-57 ( $7.06 \pm 1.32$ ) and 58-77 ( $5.71 \pm 0.72$ ), ( $p<0.001$ ). Higher levels of education were associated with higher mean CCKNOW scores ( $9.43 \pm 2.66$ ), ( $p < 0.001$ ). Students had higher mean CCKNOW score ( $9.50 \pm 3.01$ ) than employed patients ( $8.17 \pm 2.66$ ) and unemployed patients ( $7.47 \pm 2.23$ ), ( $p = 0.026$ ).

Patients with crohn's disease (CD) had higher mean CCKNOW score ( $8.63 \pm 2.75$ ) compared to patients with ulcerative colitis (UC) ( $6.71 \pm 1.65$ ), ( $p<0.001$ ). However duration of IBD, IBD related surgeries, extra intestinal manifestations were not associated with CCKNOW score.

The mean CCKNOW score during the baseline visit and revisit period were  $8.15 \pm 2.65$  and  $11.65 \pm 3.55$  respectively. The mean CCKNOW scores showed statistically significant improvement during revisit from baseline visit ( $p<0.001$ ). Demographics and disease characteristics and their association with CCKNOW score during baseline visit are shown in tables 1 & 2. According to the questions, during the baseline visit the percentage of IBD patients' knowledge varies from 6.36% to 80.90% and only less than 50% of correct answers for 18 out of 24 questions. percentage of correct answers for each question –baseline visit and revisit is shown in Figure 2. The knowledge level was reassessed in the revisiting time and it ranged from 16.36% to 91.81% and this time only 14 questions out of the 24 questions has got less than 50% of correct answers. Among the questions, question on the aim of immunosuppressants showed higher percentage of correct answers in baseline visit (80.90%) and revisit (91.81%).The question on removal of terminal ileum showed the least percentage of correct answers in baseline visit 6.36% and revisit 16.36%.

## DISCUSSION

#### Salient features of our study are as follows:

In our study, gender distribution of patients showed a high preponderance of male patients (63.64%) than female patients (36.36%). This matches with the studies conducted in Asian population.<sup>19-22</sup> Majority of the patients in this study comes in the age group 20-40 years with a mean age of  $37.33 \pm 15.12$ .In our study crohn's disease was more common (74.55%) than ulcerative colitis (25.45%). Studies have shown that there

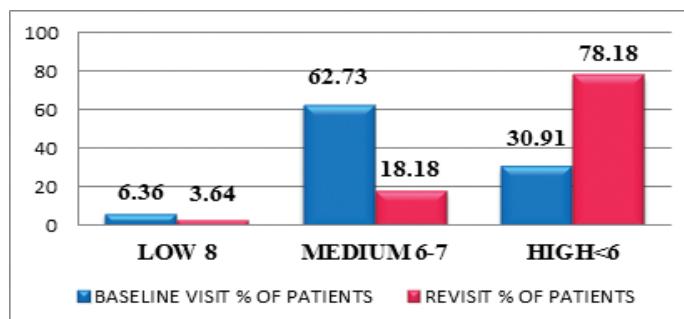


Figure 1: Medication adherence scores of patients in baseline visit and revisit"

**Table 1: Demographic characteristics of the study population and their association with patient knowledge (CCKNOW score) during baseline visit**

Variable	No. of patients (n=110)	%	Mean score	Range	SD	p Value
<b>GENDER</b>						
Male	70	63.64	11.13	6-21	3.15	0.060
Female	40	36.36	12.55	6-20	4.06	
<b>AGE</b>						
18-37	61	55.45	13.38	7-21	3.48	
38-57	35	31.82	10.11	7-14	2.12	<0.001*
58-77	14	12.73	7.93	6-9	1.63	
<b>EDUCATION STATUS</b>						
Primary (grade 1-5)	11	10	8.00	6-11	1.73	
Secondary (grade 6-12)	46	41.81	10.20	7-18	2.63	<0.001*
Higher (University/PG)	53	48.18	13.66	6-21	3.33	
<b>EMPLOYMENT STATUS</b>						
Employed	18	49.09	11.87	7-19	3.42	
Unemployed	54	34.55	10.34	6-18	3.16	
Student	38	16.36	13.72	7-21	3.79	0.003*

\* SD- standard deviation

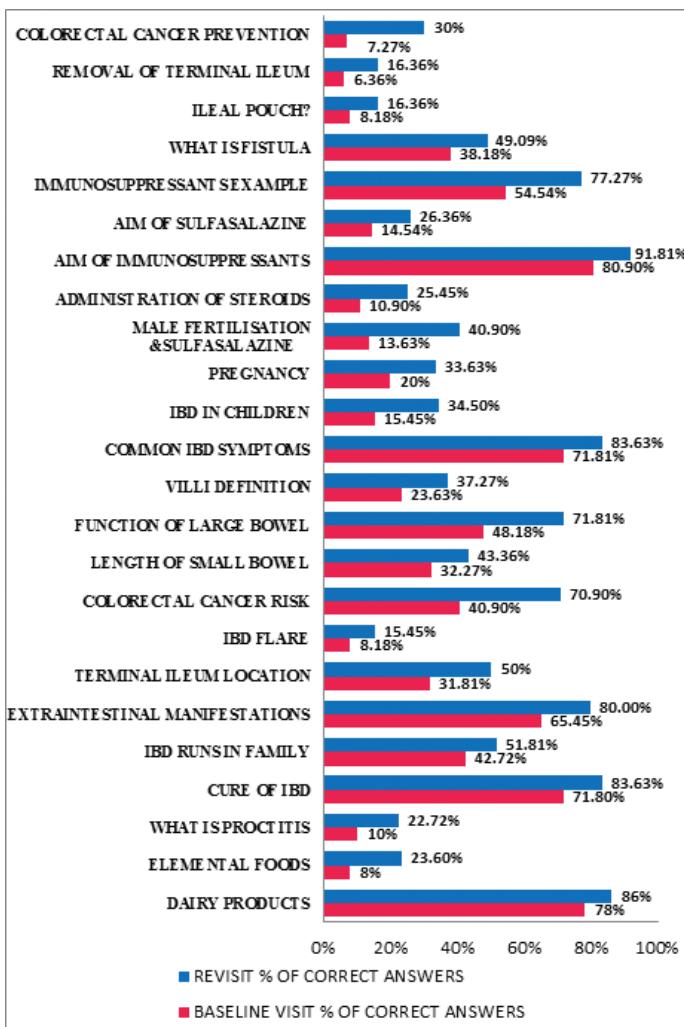
**Table 2: Disease characteristics and their association with patient knowledge (CCKNOW score) during baseline visit**

Disease characteristics	No. of patients (n=110)	Percentage (%)	Mean score	Range	SD	p Value
<b>Type of IBD</b>						
UC	28	25.45	6.71	5-13	1.65	<0.001*
CD	82	74.55	8.63	5-17	2.75	
<b>Duration of IBD (years)</b>						
<5	62	56.36	8.48	4-17	2.95	0.114
≥5	48	43.64	7.71	5-13	2.15	
<b>IBD related surgeries</b>						
Yes	12	10.91	7.25	5-10	1.54	0.216
No	98	89.09	8.26	4-17	2.74	
<b>Extra Intestinal-manifestations</b>						
Present	65	59.09	8.42	5-17	2.81	0.200
Nil	45	40.91	7.76	4-15	2.36	

CD-Crohn's disease, IBD-Inflammatory bowel disease, UC-Ulcerative colitis, SD – standard deviation,

are vast geographic changes in the frequency and CD to UC ratio among Asian countries<sup>23</sup> and even among different areas within a country.<sup>24-25</sup> Mean duration of disease in our study participants was 5 years (range 0-24 years). Regarding the education status of the patients, majority of them completed graduation/post-graduation (48.18%). There were no illiterates in the study, which is likely to be so, as Kerala is distinguished from the rest of the India by a high literacy rate (literacy rate 93.9% in 2011). The mean medication adherence score during revisit showed statistically significant improvement from baseline visit ( $p < 0.001$ ). After the counselling session, the adherence of patients towards medication

has significantly improved. So additional care by clinical pharmacist resulted in improved medication adherence. Study conducted by Greenley R et al<sup>26</sup> proved that specific IBD education about its effects and management can possibly enhance patient adherence and improve the patients' outcome. Majority of our patients had involuntary non-adherence. Busy/occupied (28.18%) and forgetfulness (20.91%) accounts for the causes of involuntary non-adherence. This is because majority of our patients were employed or students. In western countries, research has been carried on IBD related knowledge and education demands related to IBD disease. Unfortunately, a country like India where there is a rapid



**Figure 2:** Percentage of correct answers for each question- baseline visit and revisit (CCKNOW)

increase in the occurrence of IBD has only few reports on this disease affected patients. In our study female patients had high CCKNOW score than males it may be due to their high interest in getting the knowledge of disease related things especially in their childbearing age by taking into consideration about the harmful effects of the disease during their pregnancy and childbirth periods.<sup>27</sup> Patients diagnosed at younger age, having higher education qualifications (college/post graduate) had high CCKNOW score. This is a similar result from the study conducted by Jason K Hou et al.<sup>28</sup> Patients in the young age groups had higher CCKNOW score as they require more information, regarding effective management of disease, than the other ones since they are active participants in social activities. Rather than high school graduates, university graduates showed more interest in disease management. This is due to their inspiration and requirement to actively cope up with the disease and because of their higher qualifications they understand the seriousness of their disease and take part in the decision-makings for their treatment.<sup>29</sup> Duration of disease, IBD related surgeries, extra intestinal manifestations were not significantly associated with CCKNOW scores. During revisit, scores were reassessed and for all these variables scores have showed statistically significant improvement. From this study, we found out that there was deficit in the knowledge of patients. More severe deficit was regarding the knowledge about complications of IBD. 6.36% of patients knew that removal of terminal ileum can cause impaired absorption of vit b12. Only 7.27% of patients knew that prolonged IBD

can increase the risk of colorectal cancer, our results were lower than the results by Eaden et al (23%).<sup>16</sup> Lack of knowledge about IBD complications can lead to untoward consequences, patient needs to be informed about the significance of cancer screening. Regarding the treatment related questions, majority of the patients (80.90%) knew about the aim of immunosuppressants. General knowledge of IBD and medications was better than the knowledge about complications, majority of the patients knew about common IBD symptoms (71.81%) and extra intestinal manifestations (65.45%). Among the diet related questions 78% of patients correctly answered the question on dairy products but very few patients correctly answered the question on elemental feed (8%). As a whole baseline knowledge of the patients about disease and medications were low. During revisit, questionnaire was reassessed and percentage of correct answers increased for each questions. This shows that there is a positive impact of clinical pharmacist's interventions in IBD patients, after giving necessary counselling to the patients and providing them with information leaflets and pill cards, there knowledge level had improved.

## CONCLUSION

Knowledge of patients about their disease and medications were insufficient during baseline visit. After educating the patient and providing them with educational materials, there was significant improvement in patient knowledge during revisit. Adherence to medication was found to be poor among IBD patients. Counselling provided by clinical pharmacist about the importance of medication adherence and provision of information leaflets and pill cards lead to an improvement in medication adherence. On assessing correlation, we found that improvement in patient knowledge resulted in improved medication adherence. This study clearly signifies that intervention of the clinical pharmacist can bring about major changes in the knowledge of patient about the disease and medications, adherence related attitude of the patients eventually result in better quality of life of the patients.

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## CONFLICT OF INTEREST

Nil.

## ABBREVIATION USED

MMAS 8: Modified morisky medication adherence scale 8; CCKNOW: Crohn's and colitis knowledge assessment questionnaire; IBD: Inflammatory bowel disease; OPD: Outpatient department.

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