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Research Article.....!!!

**ASSESSMENT OF MEDICATION ADHERENCE AND QUALITY OF LIFE IN
INFLAMMATORY BOWEL DISEASE (IBD) PATIENTS**

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ABSTRACT

KEYWORDS:

Inflammatory bowel disease,
Quality of life, Ulcerative
colitis, Crohn's diseases.

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Aim and objectives: The aim of the present study is to assess medication adherence and quality of life in IBD patients. The present study was to compare and examine the frequencies of demographic variables, whether patient education improves medication adherence and to prepare patient information leaflet for IBD medications and to examine the relationship between medication adherence and quality of life (QOL) in patients with inflammatory bowel disease (IBD). **Methods:** This is prospective observational study conducted at the Department of gastroenterology, KMCH Hospital at Coimbatore conducted for the duration of 6 months, we included New or existing diagnosis of IBD proven via endoscopy, pathology and radiology findings. We assessed by the Morisky medication adherence scale, quality of life was assessed by the SIBDQ. **Result:** A total of 65 patients were assessed, 27(41.5%) were males and 38(58.5%) were female Out of 27 male patients 18(27.69%) have UC and 9(13.84%) have CD. Whereas among the 38 female patients 16(24.61%) have UC and 22(33.84%) have CD. Medication adherence score was evaluated at first and second follow up with a mean score of 2.84. **Conclusion:** In conclusion patient education had most impact on medication adherence. Medication adherence improved after counselling of patients .Hence by this study it could be concluded that pharmacist intervention can play a major role in the improvement of medication adherence and QOL of patients.

INTRODUCTION:

Inflammatory bowel disease (IBD), which is of two types Crohn's disease (CD) and ulcerative colitis (UC). It is a chronic, intermittent, and unpredictable inflammation of the gastrointestinal tract. Its symptoms are recurrent diarrhoea, abdominal pain, fatigue, arthritis, growth delay, delayed puberty, and perianal disease.⁽¹⁾ IBD mostly begins in young people. It generally goes on with alternate courses of remission and flare which can lead to complications such as surgery and hospitalization.⁽²⁾ The GI tract is responsible for digestion of food, absorption of nutrients, and elimination of waste. Inflammation impairs the ability of GI organs to function properly, leading to symptoms such as persistent diarrhea, abdominal pain, rectal bleeding, weight loss and fatigue. Medication non adherence is a growing concern to healthcare systems, physicians and other stakeholders because of mounting evidence that it is prevalent and associated with adverse outcomes and higher costs of care. Patients with chronic diseases often receiving multiple medications, are at higher risk for non-adherence to medication and medication adherence can be essential for improving health outcomes.

Non-adherence in IBD is associated with an increase in disease activity, relapse, loss of response (LOR) to anti- TNF agents, higher morbidity and mortality (e.g., with colorectal cancer), increased health expenditure, poor quality of life (QOL) and higher disability. Patient-tailored interventions to improve adherence are required, and may have a greater impact on population health than improvements in specific medical treatments.

One of the most commonly used self-reported measure of medication non-adherence is the four-item Morisky Green Levine Medication Adherence Scale (MGLS). Although MGLS is widely used for measuring the extent of medication non-adherence, Voils and colleagues argue that MGLS contains the items that identify respondents' reasons for non-adherence. Therefore, conceptually MGLS cannot be appropriately classified as a measure of extent of medication non-adherence (i.e., an effect indicator model) and more appropriately falls into the category of measures of causes of medication non-adherence (i.e., a causal indicator model). These two models have divergent implications for measure validation.

Methodology**Study design:**

A prospective observational study on medication adherence assessment, and quality of life of IBD patients. Assessment of medication adherence and quality of life was done in their pre visit and PILS were provided in order to make them better understanding. On their post visit, adherence and

quality of life were re-assessed and the difference were analyzed the study was conducted for the duration of 6 months.

Inclusion Criteria:

- New or existing diagnosis of IBD proven via endoscopy, pathology and radiology findings
- Maintained or started on a medication for IBD at the time of enrolment.
- Patient's ≥ 18 years of age.
- Ability to communicate and phone availability

Exclusion criteria:

- The patients having lack of cooperation and diagnosed mental illness.
- History of myocardial infarction, stroke, heart failure, and/or renal failure on dialysis.
- Patients receiving chemo as a part of their treatment
- The patient above 75 yrs.
- Who were unable to read.

DATA COLLECTION

A specially designed and validated data collection form will be utilized to collect patient's demographic details, past and present medical conditions, psychological factors, clinical features, intestinal manifestation and all other details required for the study.

STUDY PROCEDURE

The following activities will be carried out during the study period:

1. Designing of data entry form, patient consent form, etc.
 2. Obtaining ethical clearance from IRB/IEC.
 3. Selection of study subjects and obtaining consent to participate in the study.
 4. Collection of data.
 5. Analyze and validation of collected data.
 6. Perform calculations on collected data.
 7. Writing results and discussion.
 8. Drawing out the conclusion.
- **Standardized data collection form.**

Data collection sheet collects demographic data (age, gender, nationality, marital status, education level, smoking habits, etc.) and clinical data {disease duration, age at first diagnosis of the disease (age of onset), and disease activity (remission or relapse), method of treatment (medical or surgical), etc.}. Any surgical intervention performed to treat IBD was considered surgical treatment. However, patients under medical treatment did not receive any surgical intervention

concerning IBD at all. Disease activity was classified as relapse or remission based on the charts' documentation. Physicians in the study hospital considered clinical remission as having no bowel symptoms associated with active disease, i.e., no diarrhoea or blood in stools and receiving no acute treatment.⁽⁴⁹⁾

STUDY TOOLS

- Data collection form
- MGL (Morisky- Green- Levine) to assess medication adherence
- SIBDQ (to assess the quality of life)

STUDY PROTOCOL:

The study has to carry out after getting the approval from the Ethical Committee of the hospital. The patients diagnosed by IBD has to be included in the study. The essential data is collected using data collection form. Patients are interviewed with MGL and SIBDQ questionnaire. All the patients should provide counselling and patient information leaflets regarding the disease. These patients are interviewed again with these MGL and SIBDQ questionnaire.

MEDICATION ADHERENCE ASSESSMENT

The Morisky Medication Adherence Scale is the most commonly used questionnaire worldwide. Its original version, developed by Morisky, Green and Levine (MGL) in 1986, This is a uni - dimensional questionnaire containing four items.⁽⁵⁷⁾

QUALITY OF LIFE ASSESSMENT

The SIBDQ uses 10 questions derived from the original 32 item full Inflammatory Bowel Disease Questionnaire to subjectively assess the HRQoL in patients with IBD. The SIBDQ examines four domains: bowel symptoms, systemic symptoms, emotional function, and social function. Each question is scored from 0 to 7 with a total score ranging from 10 (worst health) to 70 (best health).

DISCUSSION

Inflammatory Bowel Disease is characterized as a chronic disorder that are related to unknown etiology. Adherence to therapies in IBD is crucial because non- adherence has a negative impact not only on the prognosis of IBD, predisposing to recurrence, poor quality of life, and higher morbidity and mortality (e.g. with colorectal cancer),but also on global health costs. This prospective observational study was aimed to assess the medication adherence and their quality of life

I. DEMOGRAPHIC FEATURES

A total of 65 patients were enrolled in the study. There are 27 males and 38 female patients. The mean age of this study participants was 42.5692 ± 14.0745 ,

- a) Age: Out of 65 patients, 34 (52.3%) were UC patients and 31 (47.7%) were CD patients. There were 16 patients falls within the age group 21-30 (24.6%). The type of UC and CD distribution in this age group is 9 and 7 respectively and 20 patients falls within the age group 31-40. This study correlates with the study done by **Saurabh Kedia et al (2017)** which mentioned that the peak incidence is found within the mean age of 35.9 years. The type of UC and CD distribution in this age group is equal in number. There were 29 patients in the age group 41-70 and was % respectively. Our study correlates with the study conducted by **Reghuet al (2017)** as the majority of their patients came under age group 31-40 years.
- b) Gender: Gender wise distribution in this study was 27 male and 38 female patients. Out of 27 male patients 18 (27.69%) were having UC and 9 (13.84%) were having CD. The type of UC and CD distribution in the female category was 16 (24.61%) and 22 (33.84%) respectively. Same result was obtained in a study conducted by **Shah SC et al (2018)** which reveals that the females had a higher risk of CD and males have significantly higher incidence of UC than women.
- c) Educational status: out of 65 patients, educational status of 27 (41.5%) patients were at school level and remaining 38 (58.5 %) patients were graduates. This study contradicts with the study done by **Bernstein CN et al (2001)** which reveals that only fewer patients with IBD achieved post secondary education.
- d) Duration of IBD : Out of 65 patients 38 were diagnosed with IBD with a duration less than <1 year.
- e) Disease severity: The disease severity was classified into 3 categories, mild, moderate and severe. Disease severity was classified into three categories .Patients who were diagnosed as mild condition is 16 (24.6%) in which 6 (9.23%) were UC and 10 (15.3%) were CD. In moderate condition 17 (26.15%) patients were UC and 8 (12.3%) were CD .On the other hand 11 (16.9%) were UC and 13 (20%) were CD in severe condition. This study correlates with results obtained from the study done by **Siegal CA et al (2018)** which reveals that CD severity is more as compared to UC severity.
- f) Relapse the condition: There is more chance of re occurring the disease again in some patients. Some of the studies shows so. In this study only 16 (24.6 %) patients were relapsed one.
- g) Smoking: out of 65 patients, 36.9% of patients have smoking habits , 6 patients in CD and 18 in UC. This study shows that smoking leads to poor quality of life of patients. This

correlates with the study conducted by **Sandra MQ et al(2016)** which revealed that SIBDQ scores for never smokers remained highest.

SIBDQ

Comparison of SIBDQ components

The SIBDQ, consisting of totally 10 questions which examines four domains: bowel symptoms, systemic, emotional and social functions. The comparison of quality of life was done before and after intervention of the patients. Each component shown the difference in the mean value. The components got significant difference in systemic domain, social domain, and in bowel domain.($p < 0.05$). In our study, females were found to be more mean score than males in every the domain.

Medication adherence with Demographic Characters

The relationship between adherence score and demographics were evaluated among them except duration all the other characteristics shows statistically significant with medication adherence score at 0.05 significant levels. Relapsed patients shows significant decrease in medication adherence. This study correlates with the study conducted by **PetrCervený et al (2007)** which revealed high rate of non adherence with demographic features.

Medication adherence pre – visit and post – visit

Medication adherence score was evaluated at first and second follow up. The first and second visit adherence data shows a mean increase in medication adherence at 0.05 statistical significant levels. This study correlates with the study conducted by **Reghu et al (2017)** which shows increase in the medication adherence level after pharmacist intervention.

Association of medication adherence and quality of life

The mean score of QOL is increased from the baseline visit but significantly both MGL and SIBDQ has no relation. Significances between scores of adherence and QOL before patient education is found to be less and after intervention it is increased. This results correlates with the study conducted by **Horvath G, et al (2012)** which states that there was no association between the sum of HRQOL, which is not affected by drug therapy.

CONCLUSION:

Patient education and medication counselling are essential components in the management of chronic diseases like IBD. Medication adherence can be achieved by educating the patient about the disease, drugs and their uses. In conclusion patient education had most impact on medication adherence. Medication adherence improved after counselling of patients .Hence by this study it

could be concluded that pharmacist intervention can play a major role in the improvement of medication adherence and QOL of patients.

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