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The Quality of Life and drug compliance of patients with Inflammatory Bowel Disease in the Gastroenterological Unit, South India.

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Abstract:
Background*: One of the most important goals of treatment in inflammatory bowel disease (IBD) is the overall improvement of patients Quality of Life (QOL), both Crohn's and ulcerative colitis needs lifelong drug treatment in order to maintain remission, This study has investigated the variables which can be attributed to Health related Quality of life (HRQOL) in patients with IBD. Medication non-adherence is common in inflammatory bowel diseases (IBD). The short-term consequences of non-adherence include increased disease relapse but the long-term impact upon patients in terms of daily functional impairment are less well characterized. Identifying negative outcomes, such as disability, may encourage adherence. The poor adherence of patients to the long-lasting medical therapy is one of the most important factors for treatment failure.*
Materials and Methods*: Using a Quantitative research approach, a descriptive cross sectional design was undertaken for 6 weeks of period, where 100 patients were selected for the study using convenience sampling technique. The purpose of the study was explained and after a written consent, the participants were asked to fill up the self-administered questionnaires.*
Results*: The overall score mean score of Quality of life of patients with IBD is 164.5 ± 35.38 which shows a better quality of life, Most of the participants had high adherence (64%) to drug therapy, and there is a significant correlation among domains especially in Emotional and Systemic systems with drug compliance. There was a statistically significant association identified between Quality of Life and demographic and clinical variables. There is no significant association between drug compliance and demographic and clinical variables (p<0.05).*
Conclusion: *Complications that arise from disease due to non-adherence is worst, sometimes it could turn to be life threatening scenario, which affects the Quality of life with IBD, and the current study shows the need for transforming the style of patient care by using modern gadgets and social media to improve the quality of information that reaches the patients.*
Key Word*: IBD, HRQOL, non-adherence, drug compliance, Complications, T.Mesocal, Multivitamin, Sulphasalazine.*

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I. Introduction

"Quality of life" has quickly become a catch-all term, but confusion over what it actually means could have serious negative consequences according to some recent research. Once a term largely used by health professionals; now everyone from economists and advertising executives care about offering good "quality of life." But what does it mean, and how can businesses, as well as physicians, help to improve it. A Matter of Life and Death as medical advances have helped to increase longevity, our focus has shifted from the quantity to the quality of life. While scientists may resort to rating scales to measure pain, or scoring systems to quantify disabilities, the authors believe that trying to measure "quality of life" this way may be going too far. Inflammatory bowel diseases (IBD), which encompasses ulcerative colitis (UC) and Crohn's disease (CD), are chronic diseases with a relapsing-remitting disease course requiring lifelong treatment. The goal of treatment for IBD is to reduce disease activity and to improve patient's perception of health and health related quality, Health related quality of Life (HRQOL) is a concept which reflects the physical, social, and emotional attitudes and behaviors of an individual as they relate to their prior and current health state. HRQOL assessment describes health status from the patients' perspective and serves as a Powerful tool to assess and explain disease

outcomes. Inflammatory bowel diseases (IBD) including Crohn's disease (CD) and ulcerative colitis. Inflammatory bowel diseases (IBD) including Crohn's disease (CD) and ulcerative colitis (UC) are chronic relapsing diseases with unknown etiology (UC) are chronic relapsing diseases with unknown etiology.

OBJECTIVES:

1. To assess the quality of life of patients with Inflammatory Bowel Disease.
2. To assess the drug compliance of patients with Inflammatory Bowel Disease.
3. To determine the relationship between quality of life and drug compliance of patients with Inflammatory Bowel Disease.
4. To Study the association of the quality of life and drug compliances with their demographic and clinical variables of patients with Inflammatory Bowel Disease.

II. Material And Methods

Design and Sample:

A Descriptive cross sectional study design was adopted for this study to assess the Quality of Life and drug compliance of patients with Inflammatory Bowel Disease in the IBD OPD of department of Gastroenterology of Christian Medical College, Vellore, The investigator used convenient sampling technique, A total of 100 patients (both male and females) of aged ≥ 18, years, who are diagnosed with IBD >3months and who could read, understand and write English, Tamil, Telugu, Hindi & Bengali, were included in the study.

Instruments:

The instrument consisted of three sections:

Section A: Demographic Variables and Clinical variables assessed in the study were Age, Gender, Marital Status, Educational Status, Employment Status, Previous Hospitalization, Smoking, Family History of IBD, Place of Residence, Origin, Income, Payment for medication., BMI ,Type of disease, Age of Symptoms started, Duration of disease, Current drugs and Comorbidities.

Section B: Self-reported questionnaire to measure the Quality of Life with Inflammatory Bowel Disease, IBDQ-32, (Permission obtained from the original author) which is the first published and most extensively validated, standardized tool to collect the data. This 32 item questionnaire has four domains with each item scored on a seven point Likert scale With a Cronbach's alpha = 0.92 for the global scale and a mean 0.82 for the subscales, internal consistencies proved adequate, P< 0.001, Construct validity was supported by a strong correlation of the IBDQ bowel function with the CDAI (r=−0.71; p<0.001).The total IBDQ score ranges between 32 and 224, with higher scores representing better Health related quality of life. A higher score shows better function in that area, domains such as bowel systems, emotional health, systemic systems, social function.

Section C: Self-reported questionnaire to measure the drug compliance of patients with Inflammatory Bowel Disease with 4-Item Morisky, Green and Levine Medication adherence scale, (MGLS- Permission obtained from the original author) which is a validated diagnostic adherence standardized tool with 4 item dichotomous response of "Yes" or "No" options, ranging from 0,1,2,3 the Low adherence to 4 the High adherence, the Internal consistency was assessed using Cronbach's Coefficient Alpha reliability is α 0.61, P<0.001.

Data Collection:

The investigator identified the patients who fulfill the inclusion criteria, after obtaining informed consent in their own language. The demographic variables were collected by interview. The clinical variables were collected from the patient record. Self-reported questionnaires on Quality of life and drug compliance were administered to patients individually after explaining the participants in their own language.

Data analysis:

Data analysis was done by using SPSS Version 21.0, data were summarized using mean (SD) and median (IQR) for continuous variables, Categorical data were expressed as number along with percentage. The mean(SD) of QOL and its domain were presented with 95% Confidence Interval (CI).The adherence percentage were presented with 95% CI Correlation between total IBD domain scores with drug adherence total score was analyzed using Pearson correlation and coefficient. The Pearson's correlation coefficient was found with p value of <0.05, The IBD total score and the Domain scores among low and high drug adherence were compared using Independent t- test. The IBD total score among demographic and clinical variables were compared using

the Independent t- test. The association of drug adherence with demographic and clinical data were compared using Pearson's Chi-Squared test.

III. Results

With regard to demographic variables,most of the (31%) subjects were between the age group of 31-45years.More than half the subjects (60%) were male participants. Among them, the majority (67%) of participants were married. (44%) had a college level of education. Nearly half (45%) of them were unemployed. Most of (71%) the subjects had previous hospitalization. Majority (84%) of them were non-smokers. Almost the majority (97%) of the population had no family history of IBD, The major participants (55%) were from south India. Most of them (63%) were from rural populations, Majority(95%) of them were self-paying participants for medication and treatment and most of the population(66%) were with monthly income Rs.<10,000.

In regards to Clinical variables, the majority of population (60%) were with normal BMI. Half the population (51%) had Ulcerative colitis. The age of symptoms started (26%) were between 26-35years.Almost majority of subjects (78%) had duration of disease >20 months. Most of them (48%) were on T. Mesacal (Mesalazine) Multivitamins and Sazo (Sulphasalazine).Majority of the population (81%) did not have any comorbidities. The study revealed that, overall Quality of life of enrolled patients with Inflammatory Bowel Disease is with the mean of 164.4 ± 35.38. Ranging from 32, worst to 224, best, A higher score indicates better Quality of Life. The majority of patients (73.4%) were satisfied with their life in general and had a better health related Quality of Life and about one quarter (26.57%) were unhappy and had a poor health related Quality of Life. The overall Quality of life of patients with Inflammatory Bowel Disease is good (73.43).According to the domains, a better quality in Bowel systems with a mean score of 5.52 ± 1.03 and poor quality in Systemic systems with a mean score of 4.74 ± 1.33 in participants with Inflammatory Bowel Disease. A higher score shows better function in that area (domains).This study revealed that majority of participants (64%) had high adherence to drug therapy,(95% Confidence Interval) the Quality of Life is better with high adherence to drug therapy with a mean score of 5.40 ± 1.04 and poor quality with low adherence with a mean of 4.73 ± 1.06. The major part of the population falls between the 25th and 50th Interquartile range, which signifies that the most of the subjects were below the median score. There is a significant correlation in Emotional with mean 4.96 ± 1.20 and Systemic domains with mean 4.74 ±1.33 with Drug compliance. There was a significant association between Quality of Life of participants with their employment status among the demographic variables and Type of disease (Crohn's and Ulcerative colitis) among the clinical variables. There is no significant association between the drug compliance and demographic variables and clinical variables.

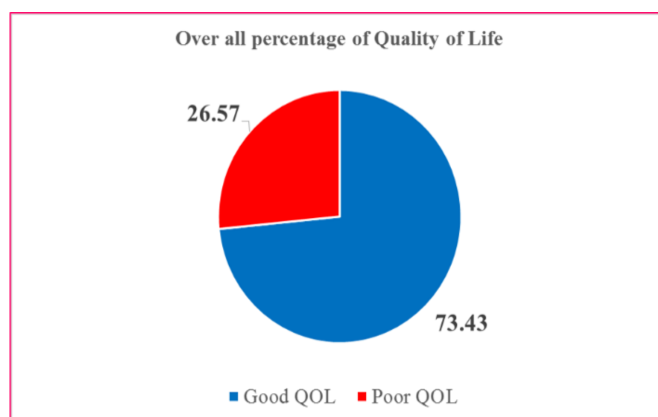

Figure 1 The above diagram shows the overall Quality of life of patients with Inflammatory Bowel Disease.(73.43).

Table 1 Overall distribution of participants according to their Quality of Life with Inflammatory Bowel Disease (IBD) (N=100).

Overall QOL with IBD	Mean Score	SD	Median	Minimum	Maximum
Total	164.5	± 35.38	169.00	76.00	222.00

The above table shows that the overall mean score of Quality of Life of subjects with IBD is 164.5 ± 35.38, with higher scores representing better quality of life.

Table 2 Distribution of the subjects according to the total IBD score with domains and drug compliance with Mean, Median, IQR and Confidence Interval.

Variables	Mean	(SD)	Median	IQR	95%Confidence Interval	
Total IBD	5.16	(±1.09)	5.25	(4.6 - 6.0)	4.94	5.38
Bowel Systems	5.52	(±1.03)	5.70	(4.9 - 6.3)	5.31	5.72
Emotional Health	4.96	(±1.20)	5.00	(4.05 -5.95)	4.72	5.19
Systemic Systems	4.74	(±1.33)	4.90	(3.8 -5.8)	4.47	5.00
Social Function	5.33	(±1.50)	5.65	(4.4 -6.6)	5.03	5.62
Drug compliance	3.32	(±1.01)	4.00	(3-4)	3.11	3.52

*** 95% Confidence Interval**.

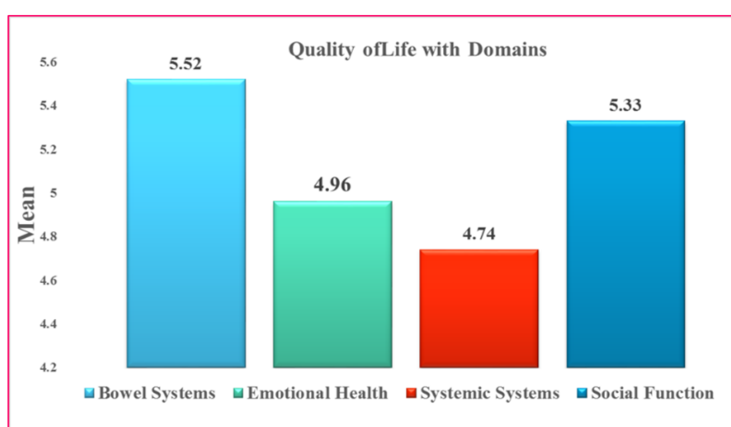

Figure 2 The above diagram shows better quality in Bowel systems with a mean score of 5.52 ± 1.03 and poor quality in Systemic systems with a mean score of 4.74 ± 1.33 in participants with Inflammatory Bowel Disease. A higher score shows better function in that area (domains).

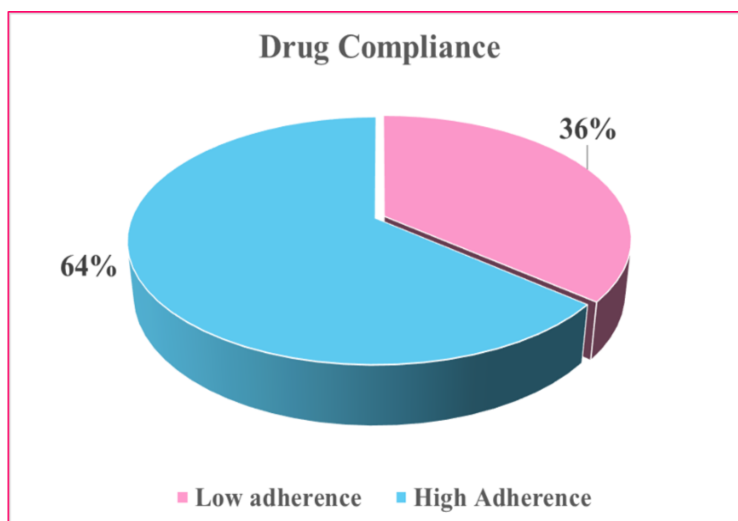

Figure 3 The above diagram shows that the majority of participants(64%) had high adherence to drug therapy,(95% Confidence Interval : 54.6, 73.4)

Table 3 Relationship between Quality of Life with domains and Drug compliance.

Variables	*Drug Compliance*			
	Mean	*SD*	*Correlation value (r)*	*p Value*
Total IBD Score	**5.16**	**± 1.09**	**0.180**	**0.072**
Domains **Bowel system**	**5.52**	**±1.03**	**0.103**	**0.304**
Emotional	**4.96**	**±1.20**	**0.195**	**0.050**
Systemic	**4.74**	**±1.33**	**0.232**	**0.020**
Social	**5.33**	**±1.50**	**0.107**	**0.285**

The above table Signifies that, there is a significant correlation in emotional and systemic domains of Quality of Life with total drug compliance ($p < 0.05$).

Table 4 Relationship between Quality of Life with domains and Low and High adherence to drug therapy.

Variables	*Low adherence (36%)*		*High adherence (64%)*			
	Mean	*SD*	*Mean*	*SD*	*t-value*	*p Value*
Total IBD Score	**4.74**	**±1.06**	**5.40**	**±1.04**	**3.040**	**0.003**
Domains **Bowel system**	**5.24**	**±1.16**	**5.68**	**±0.92**	**2.121**	**0.364**
Emotional	**4.50**	**±1.11**	**5.22**	**±1.18**	**2.997**	**0.003**
Systemic	**4.24**	**±1.39**	**5.02**	**±1.22**	**2.918**	**0.004**
Social	**4.94**	**±1.54**	**5.55**	**±1.45**	**1.945**	**0.054**

The above table Signifies that, the domain scores as well the total IBD score were more in high adherence group compared to low adherence group and remained significant for Emotional, Systemic domains and Total IBD scores, Statistical significance at ($p < 0.05$).

Table 5 Association of Quality of Life with selected Socio-demographic variables (N=100).

Variables	*N*	*Mean*	*SD*	*Statistical Value t / f*	*p Value*
Age	**100**	**39.8**	**±13.5**	**0.411[a]**	**0.68**
Gender					
Male	**60**	**5.15**	**± 1.06**	**0.157[a]**	**0.875**
Female	**4**	**5.19**	**± .15**		
Marital Status					
Married	**67**	**5.20**	**± 1.04**	**0.429[a]**	**0.668**
Single / Widowed	**33**	**5.10**	**± 1.20**		

Education					
School	**56**	**5.01**	**± 1.00**	**1.652[a]**	**0.101**
College	**44**	**5.37**	**± 1.18**		
Employment status					
Employed	**37**	**5.18**	**± 0.89**	**3.91 [b]**	**0.011**
Unemployed	**45**	**4.67**	**± 1.25**		
Student / Retired	**18**	**5.81**	**± 0.79**		
Previous Hospitalization					
Yes	**29**	**5.10**	**± 1.28**	**0.393[a]**	**0.694**
No	**71**	**5.19**	**± 1.02**		
Smoking					
Yes	**4**	**5.20**	**± 1.26**	**0.295[a]**	**0.768**
No	**84**	**5.18**	**± 1.09**		
Former Smoker	**12**	**5.08**	**± 1.15**		
Family History					
Yes	**3**	**4.63**	**± 0.84**		
No	**97**	**5.18**	**± 1.10**		
Place of Residence					
South India	**55**	**5.23**	**± 1.04**	**0.621[a]**	**0.535**
North India	**45**	**5.09**	**± 1.15**		
Origin					
Urban	**37**	**5.36**	**± 1.06**	**1.379[a]**	**0.171**
Rural	**63**	**5.05**	**± 1.10**		
Payment of Medication					
Self-Payment	**95**	**5.12**	**± 1.08**	**0.804[a]**	**0.423**
Others	**5**	**5.34**	**± 1.17**		
Monthly Income					
<10,000	**66**	**5.03**	**±1.12**	**1.28[b]**	**0.283**
11,000 – 20,000	**23**	**5.42**	**±1.03**		
>20,000	**11**	**5.37**	**±5.37**		

n = number of patients
SD- Standard deviation
P – p value
a-Independent t-test
b-Anova

The above table implies that, there is a significant association between Quality of Life of participants with their employment status among the demographic variables and no association between Quality of life with other socio-demographic variables.

Table 6 Association of Quality of Life with the selected clinical variables (N=100).

Variables	*n*	*Mean*	*SD*	*Correlation t / f*	*p Value*
Type of disease					
Crohn's disease	**49**	**5.42**	**±1.00**	**2.395**	**0.018**
Ulcerative Colitis	**51**	**4.91**	**±1.13**		
Duration of disease					
<15 months	**19**	**4.98**	**± 0.96**	**0.796**	**0.427**
>15 months	**81**	**5.21**	**±1.12**		
Current drugs					
Prednisolone /Azoran / MVT	**21**	**5.31**	**±0.89**	**0.66**	**0.577**
Mesocal / MVT/ Sazo	**48**	**5.06**	**±1.17**		
Penta and MVT	**7**	**4.82**	**±1.70**		
Sazo and MVT	**24**	**5.32**	**±0.87**		
Comorbidities					
No Co- morbidities	**81**	**5.11**	**±1.10**	**0.791**	**0.430**
Comorbidities - non communicable	**15**	**5.25**	**± 1.13**		
Others	**4**	**5.90**	**± 0.55**		

The above table signifies that, there is a significant association between Quality of Life of participants with their Type of disease, and no association between the Quality of Life with other clinical variables.

IV. Discussion

The present study revealed that, overall Quality of life of patients with Inflammatory Bowel Disease, the mean of enrolled patients is 164.4 ± 35.38. Ranging from 32 the worst to 224 the best, a higher score indicates better Quality of Life (Guyatt et al and Irvine et al, 1996) the majority of patients (73.4%) were satisfied with their life in general and had a better health related Quality of Life and about one quarter (26.57%) were unhappy and had a poor health related Quality of Life.

According to the domains, the present study revealed that, better quality of life in Bowel systems(mean 5.52 ± 1.03 SD)which is 78.8 % and poor quality of life in Systemic systems,(mean 4.74 ± 1.33 SD)with 67.7%.which is similar to a study done by Magalhaes et al, the systemic function was most affected domain, more than half the percentage of patients felt that fatigue adversely affected their Quality of Life, he also says that several studies have shown fatigue is the prevalent symptoms in IBD leading to impairment in patients daily Life with poor Health related Quality of Life.(Magalhães, Castro, Carvalho, Moreira, Cotter, et al., 2014).

The present study revealed that 64% of the subjects had high adherence to drug compliance and 36% were with Low adherence to drug compliance, with 95%CI. A similar study done by Ghadir et al, on Non adherence to medication in Inflammatory Bowel Disease, found that the overall rate of non-adherence was 33.3% out of them 27.6 % were intentional adherence and 5.7% were unintentional non adherence. He also says that the common reasons for intentional non adherence were discontinuing treatment after recovering from symptoms and unintentional non adherence were forgetfulness of patients visiting their gastroenterologist on time and purchasing drugs(Ghadir et al., 2016). Loftus et al, from his study to assess the medication adherence found 'Forgetfulness' was the most common comment of the non-adherence. He also significantly found that the highest proportion of non-adherence was observed among IBD patients being in remission. Patients in remission had the highest risk for becoming non-adherent to their prescribed treatment(Loftus, 2016). low

adherence with IBD participants were associated with forgetfulness and feeling dissatisfied during long period, feeling hassled about treatments, it was suggested designing smart reminder on patients cell phone may be effective, explanation of drugs which causes remission, regular evaluation of adherence to medication during follow up may be helpful.(Balaii, Olyanasab Narab, Khanabadi, Alsadat Anaraki, & Shahrokh, 2018).

The Quality of Life is better with high adherence to drug therapy was found to have a mean score of 5.40 with a standard deviation of ± 1.04 and poor Quality of Life with low adherence with a mean score of 4.73 and standard deviation of ± 1.06.. The recent study implies 64% of the subjects had high adherence to drug compliance and 36% were with Low adherence to drug compliance. This implies a significant correlation between overall Quality of Life and in emotional and systemic domains with the drug compliance with high adherence. Most of the studies found that, between 30 to 45% of people with Inflammatory Bowel Disease (IBD), do not take their medication as prescribed (Jackson, Clatworthy et al. 2010). The present study supports the hypothesis that there was a significant relationship between the Quality of Life and drug compliance of patients with Inflammatory Bowel Disease.

In the current study it was found that, there was statistically significant association between the Quality of Life with selected demographic and clinical variables. Those variables were Employment status and type of disease (Crohn’s or Ulcerative Colitis) of the subjects. A cohort study done by Charles Bernstein et al, examined the relationship between inflammatory Bowel disease and the socio- economic variables, it was found that, when comparing the general population, patients with IBD were more likely to be unemployed and the most common type of disease is Crohn’s which affects employment more than Ulcerative Colitis. The study concludes that based on the employment, Income and education, IBD patients are not with a higher Socio-economic background (C. Bernstein et al., 2017).

In the current study, about 51% of participants were with Ulcerative colitis and 49% were with Crohn's disease which is more or less similar without much difference among the disease type, and was found to have poor Quality of life.

Giakoumidakis et al, did a study on Quality of Life in patients with Inflammatory Bowel Disease, he found that, the results had a significant association with the type of disease, he found that, the patients with Ulcerative colitis were experiencing a better Quality of life than the patients with Crohn’s disease who experiencing a poor Quality of life, which was similar to the present study which had a significant association between the Quality of life with the type of disease(pValue <0.05)(Giakoumidakis, Kogoulis, Elefsiniotis, & Brokalaki-Pananoudaki, 2011).

There was no significant association between the drug compliance and demographic and clinical variables. But the study has proved that there is a significant relationship between the Quality of Life and socio-demographic and clinical variables and the Quality of Life with drug compliance of patients with Inflammatory Bowel Disease.

V. Conclusion

The present study highlights the overall Quality of Life of patients is good, in IBD domains the better Quality of life is found in Bowel systems and poor Quality found in Systemic domains. The study has proved the majority of participants were adherent to drug therapy and it was found that, the Quality of Life is better among participants with high adherence to drug therapy, and there is a significant correlation among domains especially in Emotional and Systemic systems with drug compliance. There was a statistically significant association identified between Quality of Life and demographic (employment status) and clinical variables (type of disease). There is no significant association between drug compliance and demographic and clinical variables in patients with Inflammatory Bowel Disease. As a conclusion, it can be said that the Quality of Life of patients will be better when there is a high adherence to drug therapy.

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