

## PROSPECTIVE OBSERVATIONAL STUDY OF CLINICAL PRESENTATIONS AND PRESCRIPTION PATTERN IN IBD PATIENTS

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### Abstract

**Keywords:** *Ibd, ulcerative colitis, chrons disease, prescription, clinical presentations.*

Inflammatory bowel disease (IBD) is a chronic disorder in which inflammation of mainly the intestinal tract, along with other gastrointestinal and extra intestinal organs. despite the fact that etiology is yet unsure, ongoing information in pathogenesis has collected and novel indicative and helpful modalities have opened up for clinical use. which are not limited to bacterial contamination, a change in immune response and genetic mutations. Here in we summarize and analysed various treatment pattern prescribed for ibd patient in a south indian hospital care.

### Introduction

Inflammatory bowel disease (IBD) is a chronic disorder in which inflammation of mainly the intestinal tract, along with other gastrointestinal and extra intestinal organs. despite the fact that etiology is yet unsure, ongoing information in pathogenesis has collected and novel indicative and helpful modalities have opened up for clinical use. which are not limited to bacterial contamination, a change in immune response and genetic mutations. for example, a change in the NOD2 gene is related with an increment susceptibility to ibd through production of pro inflammatory cytokines. It is a term mainly used to describe 2 conditions : a) Ulcerative colitis b) Chron's disease.<sup>1</sup> Ulcerative colitis may only affects the colon (large intestine), where as chron's disease affects any part of digestive tract from mouth to anus. Not at all like UC, CD regularly connected with complication like abscesses, fistulas and strictures <sup>2</sup>. IBD was initially assumed to be primarily a concern in Western countries; however, ongoing investigations have indicated a significantly greater rise in the amount of IBD in Asian countries; it is more commonly used to diagnose in between 3rd and 4th yrs of time on earth, with really no distinction observed between males and females. Just around 5% of children are researched before the age of ten. Around 25% of impacted children have an IBD-positive family background. In any case, no discrepancy in sexual identity, breast feeding, formula intolerance, previous gastrointestinal illness, or emotional trauma have been noticed between typical infants and adolescents with IBD.<sup>3</sup>

### Characterizing UC & CD

#### *Ulcerative colitis*

U.C is a circumstance in which the inflammatory process and morphological changes stayed bound towards the colon. In 95 percent of patients, the rectum is engaged, with varying degrees of proximal expansion. The hallmark histologic findings are intense and ongoing aggravation of the epithelium by pmp cells.

#### *Chron's disease*

It has opposite to U.C, can take place in either gastrointestinal ( gi ) tract, starting from the oropharynx towards the perennial centric region. Infected portions are frequently isolated by intervening typical bowel moments, giving rise to the term "skip areas." Inflammatory response can be trans mural, almost always aching out through to the serosa, likely to result in tracts or fistula formation. Histopathology findings include small shallow ulcerations across a peyers patch (aphthoid ulcer) and central constant aggravation extending , which is sometimes preceded by due to abnormal granuloma initiation. In highest to the lowest of recurrence, the most well-known area of occurrence is the ileocecal zone, trailed either by distal ileum by itself, disperse small bowel, or seperate small intestinal disease.

## Epidemiology

IBD was perceived in European countries during modern revolution. the rate and prevalence fundamentally expanded in 20th century.<sup>4</sup>

### Incidence/prevalence in adolescent's

Approx 25% of patients with Inflammatory bowel disease have been analysed over the first twenty decades of life, the majority of whom are examined in their youth (ages 14 to 18), and the rate is increasing from the next ten decades of existence. Furthermore, studies from a variety of countries show that the prevalence of IBD is steadily rising in adolescence. Currently, the highest yearly rate of IBD in Europe is 24.3 per 100,000 people per year for UC and 12.7 per 100,000 people per year for CD. In North America, it was 19.2 per 1,000 person-years for UC and 20.2 per 1,000 person-years for CD, while in Asia and the Middle East, it was 6.3 per 1,000 individual for UC and 5 per 1,000 for CD<sup>6</sup>. A period pattern examination showed that 75% of concentrates on UC showed a rising frequency with factual significance ( $<0.05$ ).<sup>7</sup>

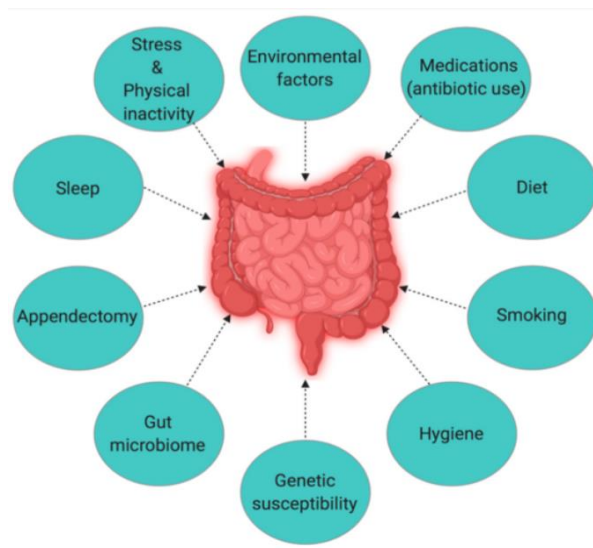
Per the latest reports, IBD is on the rise throughout Asia, but not as much as it is in Europe. In India, the majority of CD cases occurred around 23 years after UC. Since then, two epidemiological studies on UC have indeed been directed in north India<sup>10</sup>. India IBD Task Force Members were highly certified gastroenterologists from across India. UC ; CD seemed to be 751 ; 409 north 220 , east 159, central 255 south 466, west 59 of 1159 surveys investigated. As a result, the south has a higher prevalence than the rest of the country. The majority of this data came from hospitals<sup>11</sup>

## Etiology& risk factors of IBD

The cause of IBD is unconfirmed, although it is probably more common. Environmental and immunological factors on a genetically predisposed host can heavily influence disease pathogenesis.

The Hygiene Hypothesis is a dominant focus in the increased occurrence of the disease, but specifying which precise factors cause Disease remains difficult. Strachan postulated the Hygiene Hypothesis in 1989 to help us understand the increased frequency atopy (allergic reactions)<sup>12</sup>. Based on epidemiological studies as well as different experimental models, many scientists later claimed that autoimmune disorders might be influenced by such a broad environmental, infective responsibility rather than individual behavioural patterns.<sup>13-14</sup>

As per Rook's re - interpretation of something like the hygiene theory (Old Friends Theory, suggested in 2003)<sup>15</sup>, immunomodulatory abnormalities will indeed emerge the first one in people who already have had very little direct communication to harmful bacteria like mutualistic microbes and parasitic organisms , which are also known to foremost immune surveillance (Treg activity) with in human intestine. The dramatic growth in the mortality rate of IBD in both developing and developed countries be attributed to the improvement hygiene standards such like safe drinking water, non-contaminated food, and fewer children sizes<sup>16-17</sup>. Whereas the precise reason of IBD is uncertain, many scholars refer to 10 different potential causes, with heritability, ecologic, and nutrition (that also influence this same patient's intestinal flora) being just the three major factors.<sup>17</sup>



### Environmental factors

Even before UC and CD were first depicted, there has been a strong push to find irresistible specialists. despite the fact that few microorganisms can cause indistinguishable side effects and pathologic changes similar to those seen in UC and CD Bacterial infections have several highlights, including a self-limited course, the effectiveness of antibiotic treatment, and the ability to return to normal histopathology after therapies. The most frequent cause of self-limited colitis are campylobacter, shigella, salmonella, and pathogenic coli. Viruses and parasites (amoebae, schistosomiasis) (herpes, cytomegalo ,rota ,influenza ,norwalk agent viruses). Measle virus has long been advocated as a causative factor. However, the link is still being debated.<sup>18</sup>

### Immunological factors

One of the most active areas of research in IBD is immunology. Rising numbers of lymphocytes in the lamina propria, indicators indicating humoral and cellular inflammatory activation, correlation with other immune-related conditions, and appropriate therapy with steroids and drugs have all been linked to patients' immune responses becoming disturbed. As a result, changes in intestinal mucosal immune function have been proposed as a possible explanation for IBD's clinical and histological presentations.

### Genetic factors

There seems to be compelling evidence that genetic predisposition plays a vital role in the development of disease. This notion is supported by a number of investigations.

For instance, families of Patients presenting are more likely to develop the condition. In first degree relatives, the occurrence of a positive family history of IBD is increasing in contrast to the general population. Family aggregation is more widespread in CD than in UC, meaning that CD has a higher genetic propensity. On the other hand, the data on familial aggregation need not match a simple Mendelian model of inheritance<sup>20</sup>.

Second, the incidence and prevalence of IBD varied significantly by geographic region and ethnic group. Western countries, particularly North and West Europe and North America, have a higher incidence and prevalence of both UC and CD than the rest of the globe. Caucasians have a higher frequency of IBD than black and Asian populations. Finally, recent full genome screening studies involving and use of microsatellite markers to rebuild the entire genome for IBD-related loci in families with many IBD patients have highlighted the importance of genetic determinants in the development of IBD<sup>21</sup>. These are continuous research efforts that have identified a chromosome 16 CD sensitivity locus. The locus is recognized to it as IBD1. Later came Ohmen and colleagues.

**Immunogenetic factors**

HLA-GENES: The Human Leukocyte Antigen (HLA) complex, which is the primary Histocompatibility Complex (MHC) in humans, is found on the short arm of chromosome 6, which spans 3500 kilobases (approximately 4 centimorgans) of DNA21-22. More than 100 MHC genes have been found in the HLA complex. HLA-A, HLA-B, and HLA-C molecules are encoded for by HLA class I genes, while HLA-DP, HLA-DQ, and HLA-DR molecules are encoded for by HLA class II genes. Class I molecules present peptides derived from proteins expressed endogenously in the cytosol to CD8+ T cells. Class II molecules communicate peptides produced from exogenous or lipopolysaccharides to CD4 + T cells. A cell surface molecule is encoded by each HLA gene, and the majority of HLA genes are polymorphic. And HLA molecules are investigated extensively in immune-related illnesses, including IBD, since they play a significant role in antigen detection and immunological response<sup>23</sup>.

The findings of CD studies are inconsistent. Several studies have identified a link between HLA-B44 and HLA-B18 allele frequency and HLA class I alleles, whereas others have found no link<sup>24</sup>.

**Cytokine genes**

TNF and LT genes TNF and TNF beta (TNF or lymphotoxin alpha, LT) are strong cytokines that seem to have a broad range of biological roles comprising tumour necrosis, cytotoxicity, and immunoregulation. Just on short arm of chromosome 6<sup>25</sup>, the TNF and LT genes are present together during the MHC's class III or core region. This area is significant in immune system control since it encodes at least 30 distinct proteins that govern macrophage and T cell activity, B cell proliferation, and cytokine production.

IL-1 and IL-1ra genes: Brett et colleagues discovered an elevated prevalence of IL-1ra allele 2 in UC patients, with the majority of the link thought to have started in the pouchitis group, implying that allele 2 in UC patients affects illness prognosis<sup>29</sup>. Three other studies, on the other hand, revealed no link between allele 2 and UC<sup>30</sup>.

**Diet & smoking**

Diet has a big impact on the microbiota's composition and metabolism in the human gut. There is growing worry that the Western diet, which is high in fats and carbohydrates, is causing a shift in the variety and metabolic activity of the human gut microbiota, which is leading to the rise in the prevalence of IBD. An increase in *Bifidobacterium wadsworthia* abundance as a result of an animal-based diet can boost the growth of organisms that can cause IBD. *B. wadsworthia* also produces hydrogen sulphide, which can harm intestinal tissues<sup>31</sup>.

**Clinical features**

UC and CD are related to both intestinal and extraintestinal symptoms. Extra - intestinal manifestations are commonly associated with intestinal disease activity and it may appear pre or post intestinal symptoms. While the clinical presentations of UC and CD are similar, differentiating features are highlighted below.

**Extra-intestinal features**

**Fevers:** Fevers are present in 40% of IBD patients when they are initially recognised. Fevers can be high-spiking in rare cases, although they are often low-grade and recurring, and go undetected.

**Weight loss:** IBD may cause weight loss in both adults and children. The most frequent systemic symptom of IBD in children is weight loss or inability to maintain normal growth velocity, which is more common in CD than in UC.

**Hepato-biliary disease:** The chronic cholestatic liver illness primary sclerosing cholangitis (PSC) is characterised by fibrosis and bile duct obliteration. It is frequently found in conjunction with UC. PSC can be asymptomatic and was only discovered when the levels of alkaline phosphatase and -glutamyltransferase in the blood were considerably higher during normal blood tests. Patients may have pruritus and PSC before developing IBD-related bowel symptoms. The majority of PSC patients exhibit peripheral antineutrophilic cytoplasmic antibodies, which may be an indication of hereditary vulnerability to the illness.

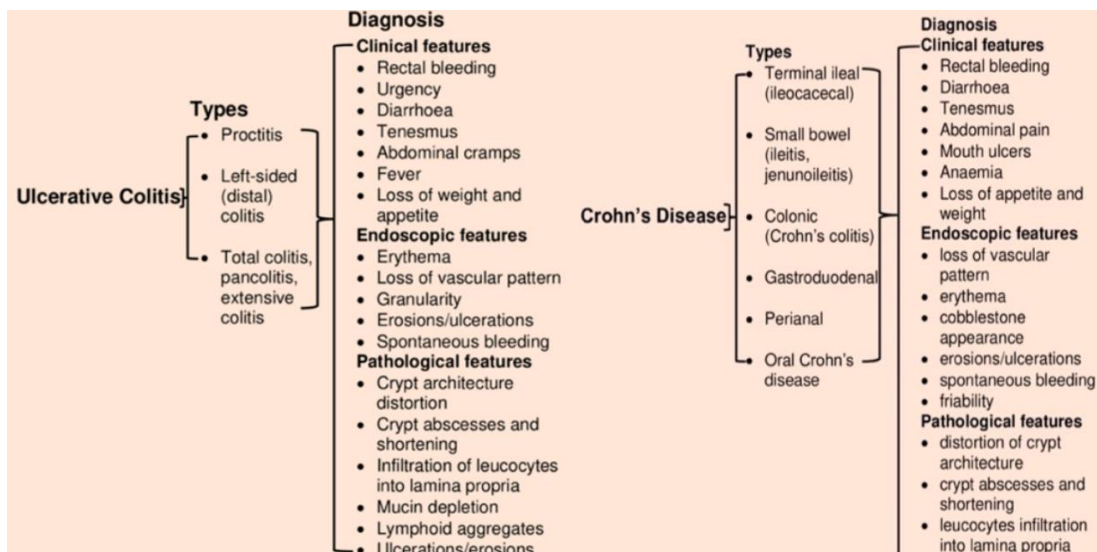
**Renal disease:** acid calculi are the most prevalent manifestations of nephrolithiasis. Hypercalciuria caused by prolonged bed rest or corticosteroid medication appears to be a risk factor. Secondary amyloidosis is extremely uncommon, however it has been observed in CD patients. Obstructive problems in CD might result from ureteral compression caused by inflammatory masses or enterovesicular fistulae can obstruct complications.

**Bone abnormalities:** Osteopenia (low bone mass) can arise during the start of IBD as well as as a side effect of long-term corticosteroid therapy. Because childhood and adolescence account for significantly and over 90% of peak bone mass, osteopenia is a severe possible consequence of paediatric IBD. Failure to achieve maximal bone mass raises the likelihood of future fractures. IbmD was found in 33 percent of the children with CD in the author's study project of 99 children with IBD, with having substantially decreased . In comparison, around 10% of UC patients showed poor lumbar spine bone mineral density.

### Diagnosis

It is impossible to stress the importance of enteric infections before confirming an I.B.D diagnosis or during an I.B.D flare. Pathogens that may be causing I.B.D include , E.coli , Clostri difficile, Giardia lamblia, Histoplasma, Myco tuberculosis, and Ent.amoeba histolytica. Pt with I.b.d may have multiple infection at the same time, yet their symptoms may not improve with antibiotics and repeat within days to weeks. Once gastrointestinal infections have been ruled out, further examination might begin. The tests used to for diag I.B.D are detailed below.

TEST	FINDING'S
1) CBP	Leucocytosis, decreased platelets, thrombocytosis
2) Acute-phase Reactants	ESR and Sr oroso-mucoid , and CRP values
3) Clinical Chemistry	Sr iron level, hypo-albuminemia, increased liver function tests
4) Sero.logical assays	P-ANCA, A.SCA
5) Stool culture	Exclude micro org , ova and parasites, occult blood, and fecal leukocytes if present.
6) Endoscopy	Esophago-gastroduodenoscopy with biopsy, colono.scopy with bio-psy.
7) Radiological tests	Upper GI tract along with barium studies



## Pharmacological treatment

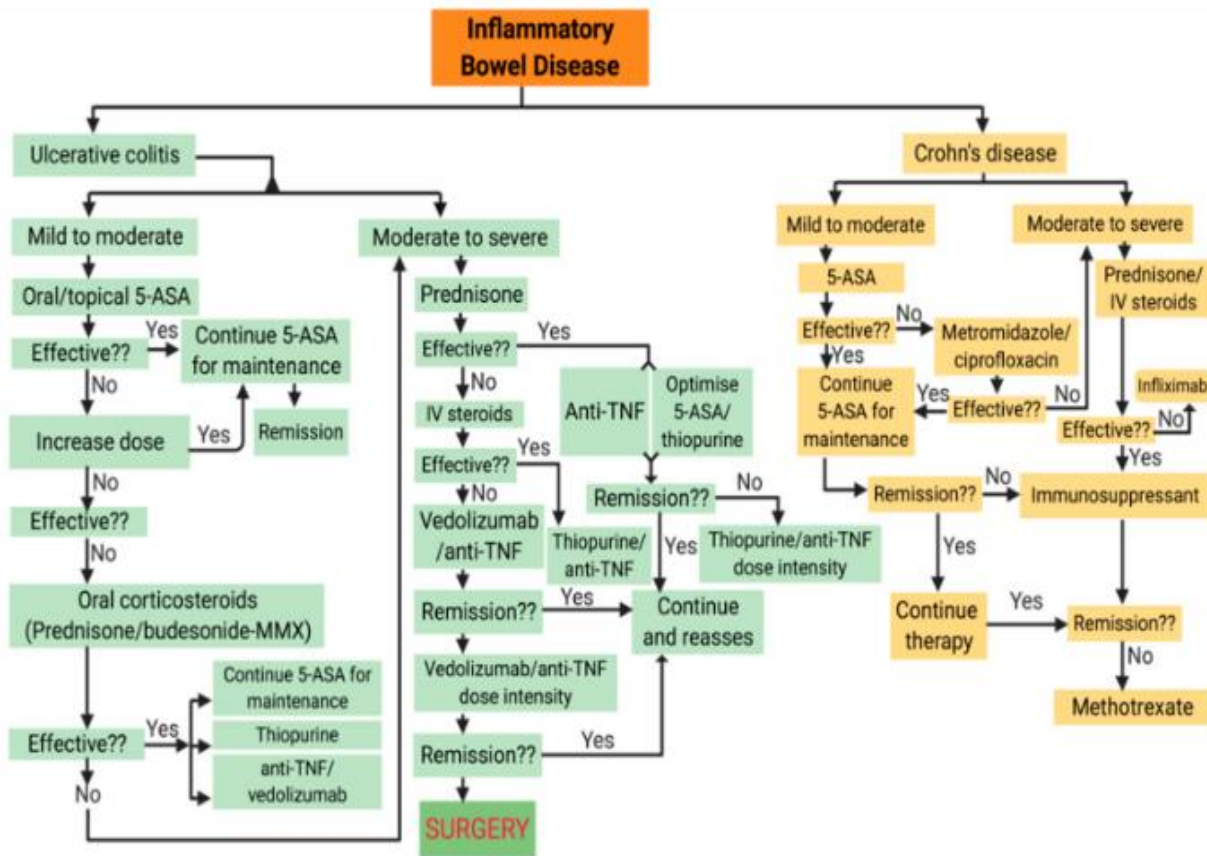
### Clinical management of U.C

**Mild disease:** sulfasalazine (PO) is used alone or in conjunction with several topical medications to treat moderate conditions. Patients who are unable to take sulfasalazine because of SE may benefit from newer 5-ASA medications (olsalazine, balsalazide, mesalamine). Patients with minimal distal colonic disease may benefit from topical therapies such as 5-ASA & steroid enemas, mesalamine suppositories, and steroid foam.

**Moderate / severe disease:** Patients who have severe stomach cramps, bloody diarrhoea, abdominal discomfort, anaemia, or hypoalbuminemia should be admitted to the hospital for intensive monitoring, intravenous therapy (steroids), fluids, and food. Antispasmodic drugs should not be taken due to the increased risk of toxic megacolon. Chemistry and blood counts are carefully maintained. The intravenous steroid medicine is kept going until the stomach pains and hematochezia subside. As disease activity responds to medical treatment, dietary limitations such as avoiding high-fiber, and spicy rich foods are relaxed. To sustain remission, concomitant therapy with sulfa drug /5-ASA formulations is initiated once the first symptoms have passed.

**Immunosuppressive therapy:** Because corticosteroids are hazardous to about 50% of patients, azathioprine and 6-mercaptopurine are used for its sparing properties. Because of their delayed start of action, these medications are not utilised to treat acute colitis. When surgery appeared to be the only option, cyclosporine and tacrolimus were administered to treat acute steroid-refractory UC. Clinical improvement occurs within 7 to 10 days for patients who achieve remission<sup>66</sup>. When these treatments are discontinued, the vast majority of patients relapse. Beginning azathioprine or 6-mcp at least four weeks before discontinuing cyclosporine therapy helps to sustain remission<sup>67</sup>.

**Prognosis:** Colectomy is required in around 25- 40% of people with severe UC. People who are diagnosed of proctosigmoiditis first before age of 21 were more likely to have the disease develop further than the splenic flexure and have a colectomy for those who had the disease stay confined. People with severe colitis are need to get a surveillance colonoscopy every 8 years to screen for dysplasia. Following the init of the surveillance colonoscopy, repeat colonoscopies should be performed every one to two years. After 15 years, most likelihood of developing cancer at colon in Swedish patients diagnosed quite before the age of 15 was 1%, 6.5 percent following 20 years, but 15% after 26 years.<sup>69</sup>



### Clinical- management of ulcerative chron's disease

**Corticosteroid's:** Corticosteroids (1 mg/kg/day) significantly decrease activity and produce remission in the majority of people. Long-term use of corticosteroids, on the other hand, is not advised because of negative SE (growth impacts, inhibition of vascular growth in children, and osteo-penia). Corticosteroids have not been shown to be very effective in sustaining remission. Budesonide is a beneficial steroid with first-pass metabolism (hepatic), although it still produces negative effects in around one in ten people.

**Sulfasalazine & mesalamine:** Both of them are medications that are used to treat illness and to maintain corti.costeroid-induced remissions. Sulfasalazine is More effec in treating ileo-colonic and colonic disorders. Around 30% of individuals are unable to take sulfa.salazine because of adverse effects, most notably headaches, which can sometimes be avoided by starting with a lower dose and gradually increasing the amount as tolertd. Other SE include hemo.lytic anaemia and pruritic,dermatitis( SKIN ITCHING). Pentasa, a novel mesalamine formulation, has been utilised for small bowel CD to help with steroid discontinuation and decrease recurrence rates.<sup>70</sup>

**Antibiotics:** Metronidazole and ciprofloxacin are medications used to treat illness in adolescents with the disease and severe infection consequences. Sensory neuro-pathy, which can occur with long-term Metronid.azole usage, normally disappears or improves once the person discontinues taking the medication.

**Immunosuppressive therapy:** Pts who are on steroid dependence, may experience severe exacerbations , a hx of previous resections, gastro-duodenal disorders, and perianal disease, particularly with resistant fistulae, should be given 6-Mercaptopurine or azathioprine.A recent study of 95 childrens with CD was found to be azathioprine/6-mercaptopurine was well tolerated in 82 percent of cases and resulted in a significant decrease in steroids in 87

percent of cases<sup>71</sup>. In 18% of cases, azathioprine or 6-mercaptopurine had to be stopped due to hypersensitivity responses (pancreatitis or high fever) or infection problems. Other adverse effects, such as progressively rising aminotransferase levels, leukopenia, and gastrointestinal discomfort, respond to dosage decrease or disappear on their own. Methotrexate has been used to keep adult CD patients in remission for a long time. Cyclosporine has been used to treat severe CD patients.

**Biological therapies:** In CD, inflammatory cyto-kines, notably (TNF-), have been found to be upregulated in both normal and inflamed mucosa. Targan et al. found that a single infusion of 5 mg of a chimeric MonAb against TNF- (infliximab) per kg elicited a clinical response in 80% of CD patients and clinical remission in 48%, compared to 18 and 3% in the placebo group<sup>72</sup>. Infliximab infusions have since been used successfully to attain sustained functional recovery as well as to treat fistulae in CD patients. Thalidomide, which was originally used to treat sedation and nausea, been found to decrease TNF- alpha production by monocytes and other cells. Two recent thalidomide trials discovered people with persistently active, steroid-dependent CD. Thalidomide was proved to be efficient, the most common side effects were drowsiness, peripheral neuropathy, swelling, dermatitis.

**Prognosis:** CD is with a 55 to 79 percent recurrence probability within the first 18 to 26 months after diagnosis. Surgery is performed due a variety of reasons, including resistance to medicines, suspected perforation or abscess, intestinal blockage, and haemorrhage. The prospect of reversing growth failure in children, especially if the sickness is limited to a small area, is a rare occurrence. Recurrence, on the other hand, is common following surgery, with 34 to 86 percent of patients relapsing within three years.<sup>73</sup>

### **Surgical treatment**

Surgery would result in significant small bowel loss and impairment, including permanent ostomies, and is thus usually reserved as a last resort therapeutic option, particularly in a complex situation where long-term treatment would do more harm than surgical alternatives<sup>100</sup>. Unlike CD surgery, UC surgery is a curative therapy since the disease is limited to the colon and rectum, whereas CD surgery can only treat the disease's consequences.

The benefits and drawbacks of each surgical procedure impact the choice to have surgery. Restorative proctocolectomy<sup>101</sup> with ileal pouch-anal anastomosis (IPAA), for example, is considered standard surgical therapy for UC patients because it retains a natural route of faeces by joining the ileal pouch to the anal canal and avoids ostomy permanently.

While many IBD patients' opinions regarding operation as a very last option remain unaltered, fewer chronically patients think that, because to the wide and ineffectual pharmacological regimens, it is preferable to have it done 'once and for all' via medical procedures. As a result, it is referred to as a "alternative treatment approach" and a "new treatment from last resort." IBD is difficult to diagnose, and it is commonly confused with irritable bowel syndrome (IBS), making surgical therapies more challenging if the incorrect diagnosis is made. It is difficult for underdeveloped nations with limited resources to overcome a lack of surgical skill and technology<sup>102</sup>. This factor regularly impacts the decisions of health care professionals and IBD patients.

### **Non pharmacological treatment**

Diet, physical activity and exercise, and psychotherapy are types of non Pharmacological treatments for IBD<sup>103</sup>.

**DIET:** Even though patients with IBD have inflammation in their intestines, and some people who have had surgery have problems like blockage in their intestines, patients with IBD should avoid all raw vegetables, potato skins, nuts seeds, coconuts, and other foods. Fresh liquids are preferred over refined carbohydrates and a low-fiber diet.

**PHYSICAL ACTIVITY/EXERCISE:** Patients were significantly less physically active after receiving an IBD diagnosis, which was especially noticeable in UC patients. Exercise has been shown to increase immunological response in IBD patients, as well as quality of life, fatigue levels, and BM density. In people suffering from IBD, exercise is both safe and likely beneficial.

**PSYCHOTHERAPY:** Patients with IBD are treated with psychotherapy and psychotropic medicines. Psychotherapy is used to help the patient understand the disease process. Psychotherapies for IBD patients include cognitive



behavioural therapy and acceptance-commitment therapy. In IBD patients, cognitive behavioural therapy has more consistent positive benefits

## Aim's and objectives

### Aims

To assess the clinical presentations,diagnostic findings,and treatment pattern in IBD patients.

### Objectives

- To evaluate drug prescription pattern in IBD patients( both UC&CD)
- To obtain information on clinical presentations,demographic details with which the patient is presenting.
- To assess the efficacy of various treatment options in terms of patient symptom improvement and its relationship to laboratory parameters such as haemoglobin level during a follow-up visit.
- To study characteristics of IBD locations in various patient population

## Need for study

ULCERATIVE COLITIS (UC) & CHRON'S DISEASE(CD) are characterized by inflammation of colon,rectum or anyother part of gastro intestinal tract respectively. The clinical manifestations of IBD is signified by exerbations and remissions, and it has a major effect on the patient's quality of life.

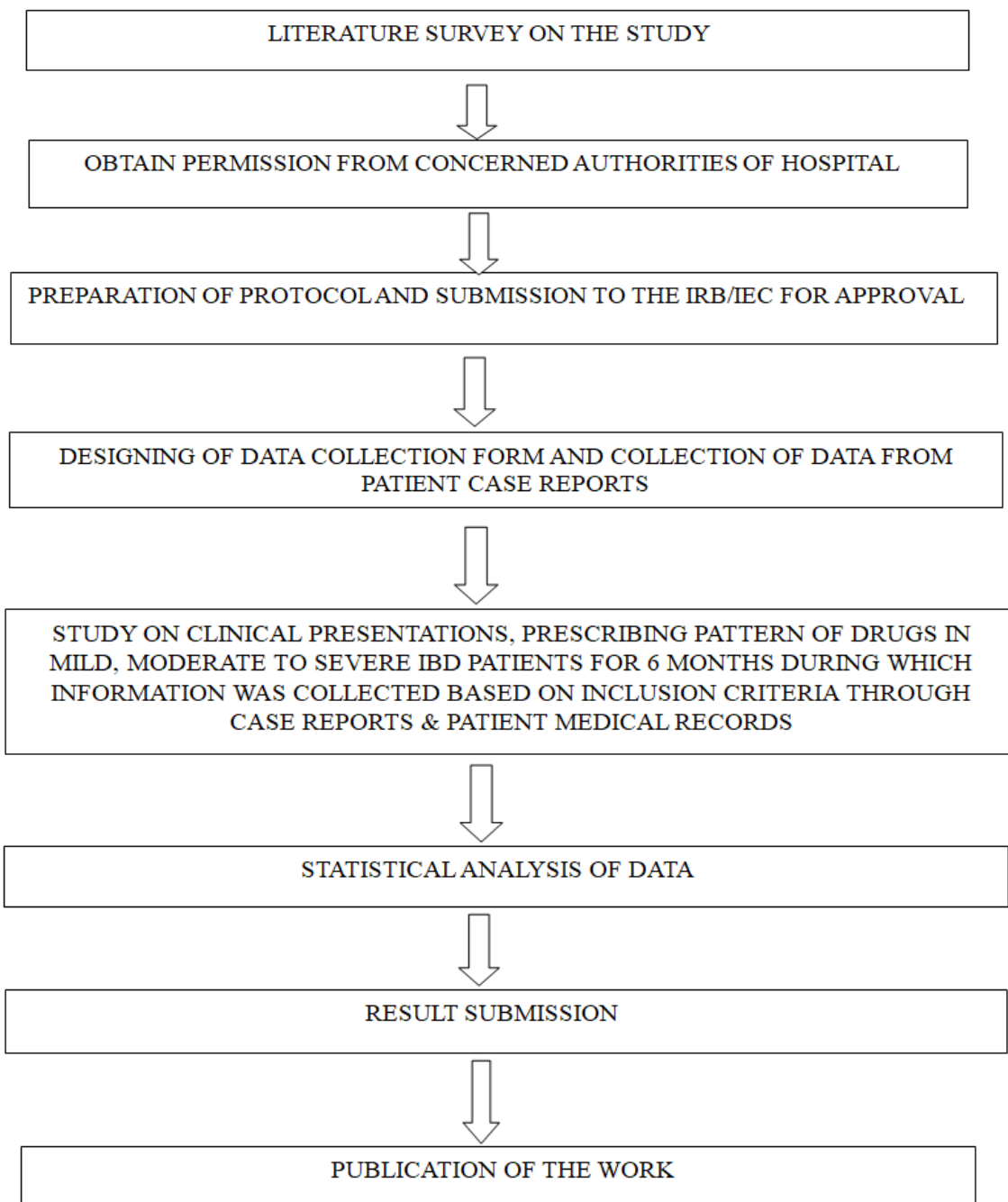
UC: It has a distinguishable area impact in the colon and rectum and an unknown underlying causes; it was first described in 1875. Bloody stools, abdominal pain, diarrhoea, weight loss, and other extraintestinal symptoms are the most common clinical manifestations. The prevalence and incidence of UC in India are 42.8-44.3/lakh, with the peak age of onset between 15 and 25. Males and females have roughly equal occurrence rates. UC is thought to be exactly unusual in India.

CD: It was believed to be almost non-existent until 1986, but it's been reported more frequently from different parts of India during last 15 years. The peak early onset is between the ages of 15 and 30, with a male to female ratio of 1.1 -1.8:1. The prevalence rate is much higher in people from upper social classes and in cities.

The risk of UC,CD Increase with some factors and underlying condition's

Since there are few studies on the management of UC and CD at the present time, the ongoing research aims to evaluate the prescription pattern strategies used mostly for UC&CD and their outcome measures in tertiary care hospital settings.

**Plan of work**



**Methodology**

**Study protocol**

It is a six-month prospective observational study that was carried out after the institutional ethical committee approved it (IEC). Patients who meet the study criteria are invited to take part. Patients' case reports, lab investigation reports, and medical records were used to gather the necessary information. Following the receipt of

informed consent from patients and their informants ( primary take care giver). The gathered information will indeed be analyzed to understand clinical manifestations, disease location, and different prescribing patterns in the management of IBD (UC&CD).

**Study design:** Prospective observational study

**Study site:** The study was conducted in GANDHIHOSPITAL-SECUNDERABAD.

**Study-period:** The study lasted six months.

**Study population:** The present study include 59-UC&18-CD total of 77 patients.

### Study criteria

#### *Inclusion criteria*

- IBD patients with confirmed diagnosis(stool culture+biopsy+colonoscopy) reports.
- MALE & FEMALE patients >18yrs
- Patients with mild,active to severe cases with mayo score 1-3(as per GAI), In case of CD (150-600) of CDAI score.

#### *Exclusion criteria*

- Pregnant and lactating women
- Pediatric patients
- Organ transplantation
- Patients with severe degree of renal diseases and those with underlying dialysis are excluded

## Results

- *Software used: SPSS version 20*
- *Sample Size: Ulcerative colitis = 59; Crohn's disease = 18*
- *Confidence interval is 95%, hence P value <0.05 is considered significant*
- *Test Performed: Chi square test*

### **Crohn's disease**

Mean± SD is 48.17± 8.27

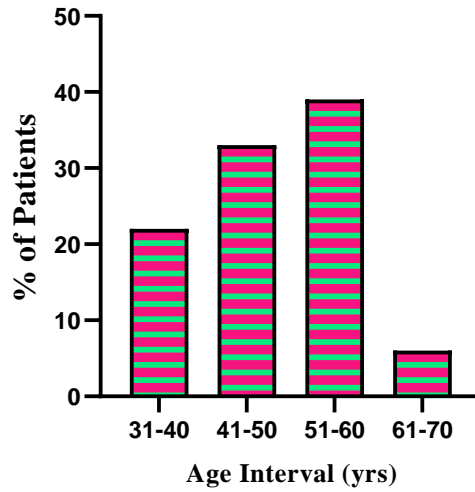


Figure 1: Age Distribution

This bar diagram shows the maximum number of patients are between 51-60 years

Male  
Female

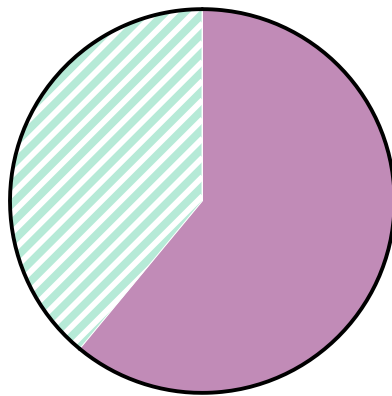


Figure 2: Gender Distribution

-The pie chart shows distribution of chron's disease is more in males(61%) compared to females(39%

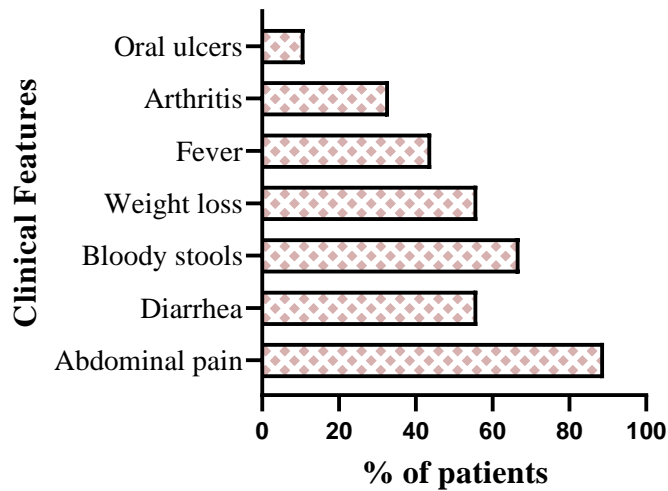


Figure 3: Clinical Features

This graph shows % clinical features in patients suffering from CHRON'S DISEASE. Most of them are complaining of Abdominal pain(89%) and extra intestinal presentation oral (11%) was complained leastly

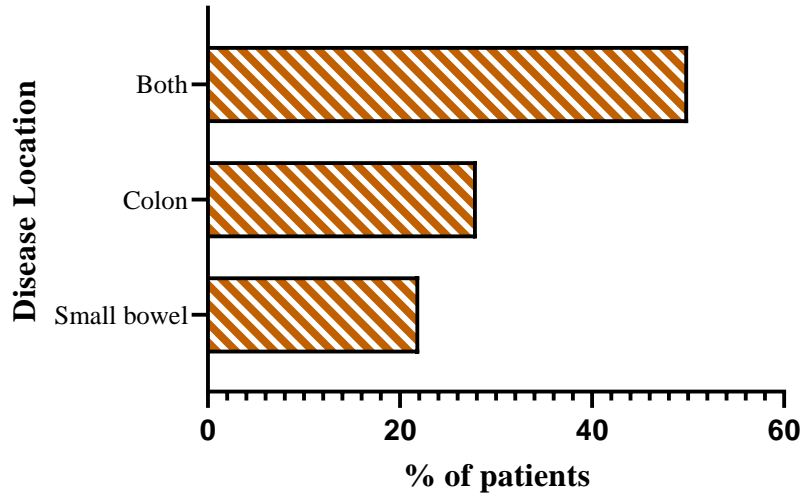


Figure 5: Disease Location

-This graph shows in most of the patients suffering with chrons disease the disease location affected is both colon and rectum(50%), pt's with disease location restricted to colon(28%) and restricted small bowel (22%)

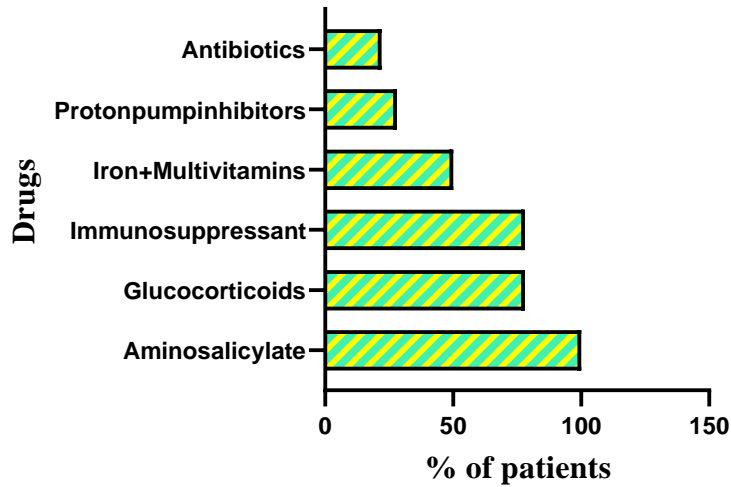


Figure 7: Drug Categories Prescribed

This graph shows prescribing trends of different class of drugs in chron’s disease, in which aminosalicylates are almost 100% prescribed in every patient who is actively diagnosed with cd. Next comes glucocorticoids & immunosuppressants share 78% each respectively. Along with them ppi, multivitamin’s, antibiotic’s share 28%,50%,22% are prescribed

**Ulcerative colitis**

Mean± SD is 48.17± 8.32

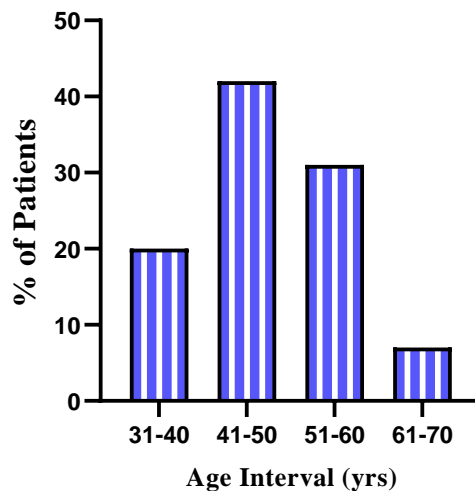


Figure 1: Age Distribution

This bar diagram shows the maximum number of patients suffering with UC are between 41-50 years

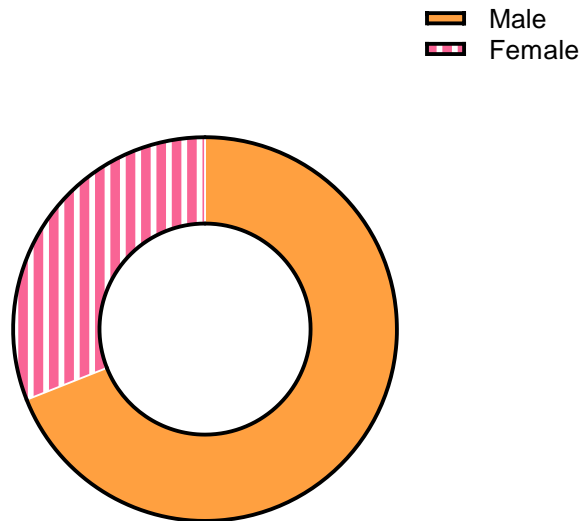


Figure 2: Gender Distribution

The pie chart shows distribution of UC is more in males(69%) compared to females(31%)

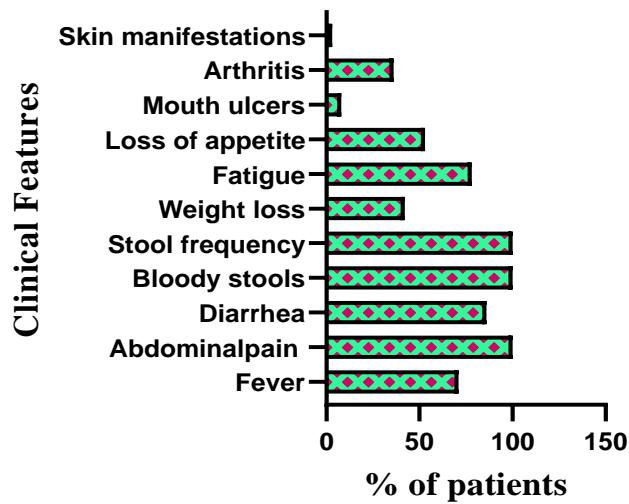


Figure 3: Clinical Features

This graph shows % clinical features in patients suffering from UC. Most of them are complaining of Abdominal pain, Increased stool frequency, Bloody stools(nearly 100%) and extra intestinal presentations mouth ulcers (8%) was complained leastly

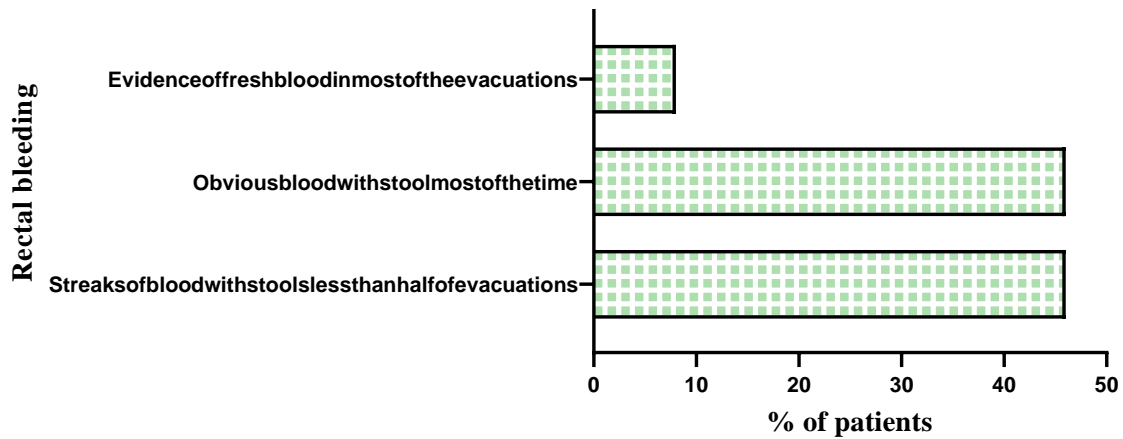


Figure 5: Rectal Bleeding

The above graph shows rectal bleeding % severity during passing of stools

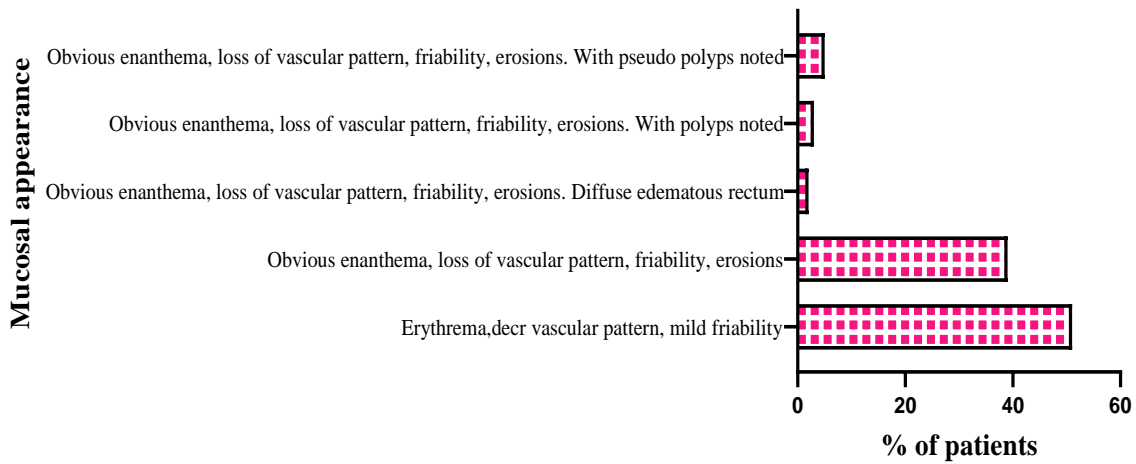


Figure 6: Mucosal Appearance

-This graph shows appearance of intestinal mucosa in patients suffering with UC, most of them have erythema decr vascular pattern, mild friability(51%).



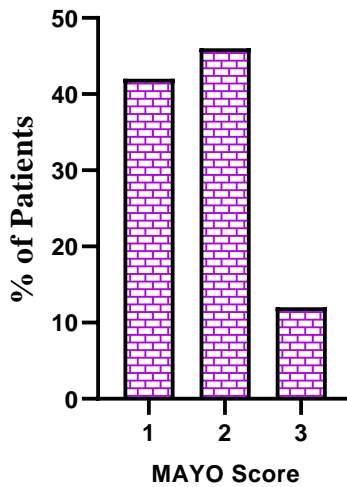


Figure 8: MAYO Endoscopic Score

- The Mayo score is one of the most widely used patients with active indices in UC. Rectal bleeding, stool frequency, physician assessment, and endoscopy appearance are the four broad categories. Each component is scored on a scale of 0 to 3, for a total score of 0 to 12. A score of 3 to 5 represents mildly active disease, 6 to 10 represents moderately active disease, and 11 to 12 represents severely active disease.

- The percentages of patients with mild, moderate, and severe UC are seen in this graph (42 percent ,46 percent ,12 percent ).

Table 11: Laboratory Parameters

Parameter	Minimum	Maximum	Mean± SD
Serum albumin	1.80	8.90	4.55±1.46
WBC	1.50	14.50	10.26±2.28
ESR	13.10	73	38.79±11.80
CRP	0.50	12.40	6.48±3.57

-The above table provides characteristic laboratory parameters of the patient and their mean values accordingly.

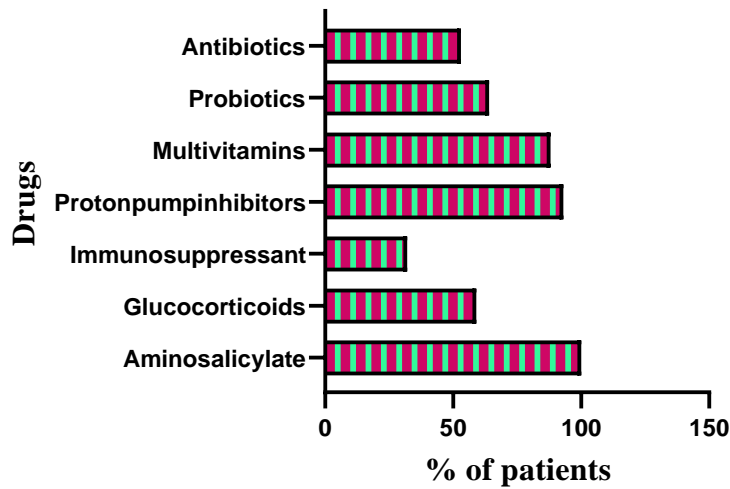


Figure 11: Drug Categories Prescribed

This graph shows prescribing trends of different class of drugs in UC, in which aminosalicylates are almost 100% prescribed in every patient who is actively diagnosed with UC. Next comes glucocorticoids & immunosuppressants share 59%, 32% each respectively. Along with them ppi, multivitamin's, antibiotic's & Probiotics share 93%,88%, 53%, 64% are prescribed respectively.

## Discussion

### Chron's disease

The researchers investigated the drug prescribing pattern and treatment efficacy in terms of improving patients' symptoms in 18 Crohn's disease patients at a tertiary care teaching hospital in Secundrabad. According to our findings, this same age group 51-56 years had the highest incidence of CD. This corroborated previous findings. The current study found a male predominance, which is consistent with other Indian studies. Western research, on the other hand, has found a small but noticeable female dominance in CD.

The far more common symptom in CD patients was abdominal pain (89%). Earlier studies from India confirmed similar results. Abdominal pain is a common symptom of CD because pain receptors in the serosa are involved due to transmural involvement.

76.5 percent of the patients had anaemia to varying degrees, with haemoglobin levels below 12 g percent; the mean Hb level (11.73 2.19 g percent) was higher than that reported by Kumar et al (8.9 2 g percent). When compared to Zacharias et al., the significance difference was not found during first visit and followup visit of the patient ( $p=0.8825$ )

The Prescription rates for various drug classes, in our study participants varied slightly from that reported by Philip et al in Crohn's disease, which shows prescription rates of 100, 78, and 78% for aminosalicylates, steroids, and immunosuppressants, respectively, and ppi,multivitamins, antibiotics are 50, 28, 22 respectively.

None of the biologic agents were administered to any of the patients in our study population. It could be attributed to conventional drugs' ability to effectively treat a large number of people, especially if used in combined effect. Numerous different explanations can include increased treatment costs as well as negative side effects related through the use of immunotherapies. The dosages of aminosalicylates, glucocorticoids, and immunosuppressive agents used in our research project had been in full compliance with ACG recommendations. Despite the lower cost,

sulfasalazine really does have a low prescription rate due to patient safety profile due to side effects produced by the sulfapyridine moiety of sulfasalazine.

It was found to be both small bowel and colon affected patients(50%) percentage is more compared to individual part affected (22%,28%) respectively.

### Ulcerative colitis

This research examined at the drug prescribing habits of UC patients at a tertiary care teaching hospital in South India. The age group of 41-50 years was reported to have the greatest incidence of UC in our study. This was significant compared to other studies conducted in India. However, our study did not find the second peak of the disease in the elderly between the ages of 60 and 70, as described in previous studies. Our study found a male predominance (69%), which is consistent with other Indian studies. However, no gender difference in the occurrence of uc has been found in western studies. The most common presenting symptoms among the patients in our study were bloody stools (100%) and diarrhoea (86%), Abdominal pain constant(64%). Previous research from India also revealed almost similar findings.

70% percent of the patients had anaemia of varying severity, with haemoglobin levels below 12 g percent. This study looked at the drug prescribing habits of UC patients at a higher level than Tandon et al findings..s (47.6 percent ). ESR Values mean is much higher (38.79±11.80), and 52.1 percent of patients had hypoalbuminemia mean value ranges from (4.55±1.46). mean crp value is also much greater ( 6.48±3.57).

In our analysis, aminosaliclates were used more frequently (nearly100% percent) than immunosuppressants(32%). Herrinton et al in IBD reported a similar trend in drug prescription. Aminosaliclates are the mainstay of therapy in mild and moderate UC for both the initiation and maintenance of relapse; this could explain the increased use of these drugs in UC. However, new research suggests that immunosuppressants may play a role in UC. In our study, (59%) of the steroids received a prescription. No biologic agents were given to any of the patients in our study. The much more likely explanation is that conventional drugs can effectively treat a large number of patients, particularly when used in combination. Other possible motivations include the high treatment costs and the negative consequences associated with the use of biologic agents. The various aminosaliclate, glucocorticoid, and immunosuppressant doses used during our survey were completely compliant acc to guidelines.

Mesalamine (1.2 to 4 g/day) was perhaps the most commonly prescribed aminosaliclate. Sulfasalazine was prescribed to a limited group of patients and is used in daily dosage ranging between 1.5 and 3 g Considering low cost, sulfasalazine seems to have a lower prescription rate because most patients might not even tolerate it due to The sulfapyridine moiety in sulfasalazine causes side effects.

The much more commonly prescribed steroid was dexamethasone (41% percent ). It was taken orally in doses ranging from 4-20mg/day, with the most common dose being 10 mg/day. The various prednisolone dosage being used our research were equivalent to the (AGA) recommendations, that recommended 40-60 mg oral prednisolone per day until clinically meaningful improvement occurs, after which tapering the daily intake 5-10 mg weekly until the daily dose reaches 20 mg. At this point, tapering is usually done at a rate of 2.5 mg per week. The immunosuppressant azathioprine was the most commonly prescribed (32 percent ). This was taken orally in dose levels varying from 25 to 150 mg. 6-MP and other immunosuppressants were not given to any of the patients. A combination of aminosaliclates and steroids was the most commonly prescribed treatment regimen, followed by aminosaliclate monotherapy. This is primarily determined by the severity of the condition and its symptoms. Probiotic pills and proton pump antagonists can help relieve symptoms and improve care quality.

To treat mild to moderate anaemia, iron and vitamin supplements were used, and nearly 8 patients have under went blood transfusions to treat severe anaemia.

### Conclusion

Ultimately, in our study, aminosalicylates have been the most commonly prescribed drugs for both ulcerative colitis & chrons disease. An combination of aminosalicylate, steroid, and immunosuppressant were frequently employed. The vast majority of patients were relieved with their clinical manifestations. There was a clear association between reduction in symptoms and laboratory parameters such as an increase in haemoglobin levels.

Our study's limitations included a small sample size, an insufficient information on disease severity, and a three-month follow-up duration from the first visit. This is a long-term illness that requires ongoing treatment. Poor drug adherence has been a major roadblock to successful IBD therapy. Non-adherence has been linked to a higher likelihood of relapse, a greater risk of colorectal cancer, a lower quality of life, and significantly higher health-care expenses. As a result, promoting drug adherence is an essential strategy for improving IBD clinical outcomes. More research is needed to assess the situation of prescribing patterns for patients whose condition is worse and lead to surgery.

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