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# PROSPECTIVE OBSERVATIONAL STUDY ON SYMPTOMATIC INFLAMMATORY BOWEL DISEASE AND THERAPEUTIC MANAGEMENT

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## ABSTRACT

**Introduction:** Inflammatory Bowel Disease (IBD) is A Disorder involving long standing chronic inflammation of tissues in digestive tract. It commonly used to describe two forms of idiopathic diseases of the gastro intestinal tract, namely Ulcerative Colitis(UC) and Crohn's Disease(CD). UC involves in rectum and colon and lesions involved in primary mucosa and sub mucosa. CD involves from mouth to anus involving transmural inflammation that leads to fistula and strictures.[1] Patients report gastrointestinal symptoms of abdominal pain, diarrhea, and rectal bleeding as well as systemic symptoms of weight loss, fever, and fatigue.[2] The etiologies of both conditions are unknown. Although, factors such as age, race and diet, smoking, infection, enteric microflora, excessive use of drugs like non steroidal anti inflammatory medications, appendicectomy, stress, genetics, ethnic and familial factors may play a vital role.[3] **Methodology:** It is a six month prospective observational study that was carried out with teritiary hospital with the institutional ethical committee (IEC) approval. The subjects i.e Patients who meet the required study criteria are considered to take part. Patient's case reports, lab investigation reports, and medical records were used to gather the necessary information following the receipt of informed consent form from patients and their informants (primary care givers). The gathered information will be analyzed to understand the clinical symptoms, site of gastrointestinal tract affected and different prescribing patterns in the management of IBD (UC & CD). **Results:** Our research found that most common symptom in UC patients were blood in stools(80.7%) and abdominal pain(73.07%) followed by diarrhea (73.07%), loss of appetite (73.07%), weight loss(69.2%), fatigue(57.6%), urgency (26.9%) nausea/ vomiting(15.3%), mouth

ulcer(7.69%). Our research found that most common symptom in CD patients were abdominal pain(91.6%), weight loss(83.3%), diarrhea (75%), fatigue(58.3%), and followed by loss of appetite (54.16%), blood in stools(37.5%), nausea/ vomiting(37.5%), urgency (29.16%), arthritis(16.66%), mouth ulcer(8.33%). In my research, it was evident that most number of patients with UC were treated with dual therapy which included aminosalicylates and immunosuppressants and patients with CD were treated with triple therapy. Biologics were included in tripletherapy for patients who had severe form of the disease. Other drugs such as probiotics, cortecosteroids, Proton pump inhibitors, antibiotics, multivitamins, iron supplements and other analgesics were also prescribed to the patients. my study results have shown that the patients who had presented with mild condition of disease were mostly treated with aminosalicylates (monotherapy). In moderate conditions, patients were treated with corticosteroids and immunosuppressants (dualtherapy). Severe condition disease patients were treated with biologics (triple therapy) and (quadraple therapy). **Conclusion:** In my study, it was observed that Ulcerative Colitis and Crohn's disease is more prevalent in males than in females. The greatest incidence is reported in the same age group of 19-28 years old for both UC and CD. Blood in stool and abdominal pain were the most common symptoms of UC and CD patients with anemia being the most common complication for both. IBD is a long term illness that requires good therapy adherence. 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 required to assess the prescribing patterns for patients whose condition is worsening.

## INTRODUCTION

Inflammatory Bowel Disease (IBD) is A Disorder involving long standing chronic inflammation of tissues in digestive tract. It commonly used to describe two forms of idiopathic diseases of the gastro intestinal tract, namely Ulcerative Colitis(UC) and Crohn's Disease(CD). UC involves in rectum and colon and lesions involved in primary mucosa and sub mucosa. CD involves from mouth to anus involving transmural inflammation that leads to fistula and strictures.[1]

Idiopathic IBDs such as Crohn disease and ulcerative colitis occur in clinically immunocompetent individuals whose characteristic symptoms and signs arise from a robust, cytokine-driven (yet noninfectious) inflammation of the gut.[2] Crohn disease is associated

with excess IL-12/IL-23 and IFN-γ/IL-17 production that affects the small bowel and colon with discontinuous ulceration and full thickness bowel wall inflammation often including granulomas. Patients report gastrointestinal symptoms of abdominal pain, diarrhea, and rectal bleeding as well as systemic symptoms of weight loss, fever, and fatigue.[2] In comparison, ulcerative colitis is associated with excess IL-13 production, primarily affecting the colon, with a continuous inflammation of the mucosa nearly always involving the rectum and extending proximally.[2]

Possible extraintestinal manifestations include hepatobiliary complications, arthritis, uveitis, skin lesions, aphthous ulceration of the mouth.[2]

The etiologies of both conditions are unknown. Although, factors such as age, race and diet, smoking, infection, enteric microflora, excessive use of drugs like non steroidal anti inflammatory medications, appendicectomy, stress, genetics, ethnic and familial factors may play a vital role.[3]

The diagnosis of inflammatory bowel disease (IBD) with its 2 main subforms, Crohn's disease and ulcerative colitis, is based on clinical, endoscopic, radiologic, and histologic criteria.[4]

IBD is a relapsing and remitting disease requiring long term medication. The first line treatment for mild to moderate UC or CD consists of corticosteroids and amino salicylates as a main treatment, with immunosuppressants and biologic agents reserved for more moderate to severe cases. There are multiple therapeutic options for IBD like Aminosalicylates, immunosuppressants, anti interleukins, biologics(infliximab and vedolizumab) and anti TNF Alpha.[5]

Some of the gastrointestinal complications as a result of IBD include rectal fissures, fistulas, perirectal abscess and colon cancer. Crohn disease patients can also develop obstructing strictures of the bowel and inflammatory connections (fistulae) between segments of bowel or between the bowel and skin and other organs.[6]

## METHODOLOGY

### STUDY PROTOCOL

It is a six month prospective observational study that was carried out with teritiary hospital with the institutional ethical committee (IEC) approval.The subjects i.e Patients who meet the required study criteria are considered to take part. Patient's case reports, lab investigation reports, and medical records were used to gather the necessary information following the receipt of informed consent form from patients and their informants (primary care givers). The gathered information will be analyzed to understand the clinical symptoms, site of gastrointestinal tract affected and different prescribing patterns in the management of IBD (UC & CD).

**STUDY DESIGN**: Prospective Observational study.

**STUDY SITE**: The study was done at Yashoda Hospital- Secunderabad.

**STUDY PERIOD**: 6 months.

**STUDY POPULATION**: 50.

### STUDY CRITERIA

### INCLUSION CRITERIA

- IBD patients with confirmed diagnosis (biopsy + colonoscopy+ sigmoidoscopy) reports.
- Male and female patients > 18 years.
- Patients with mild to moderate and to severe cases of IBD.

### EXCLUSION CRITERIA

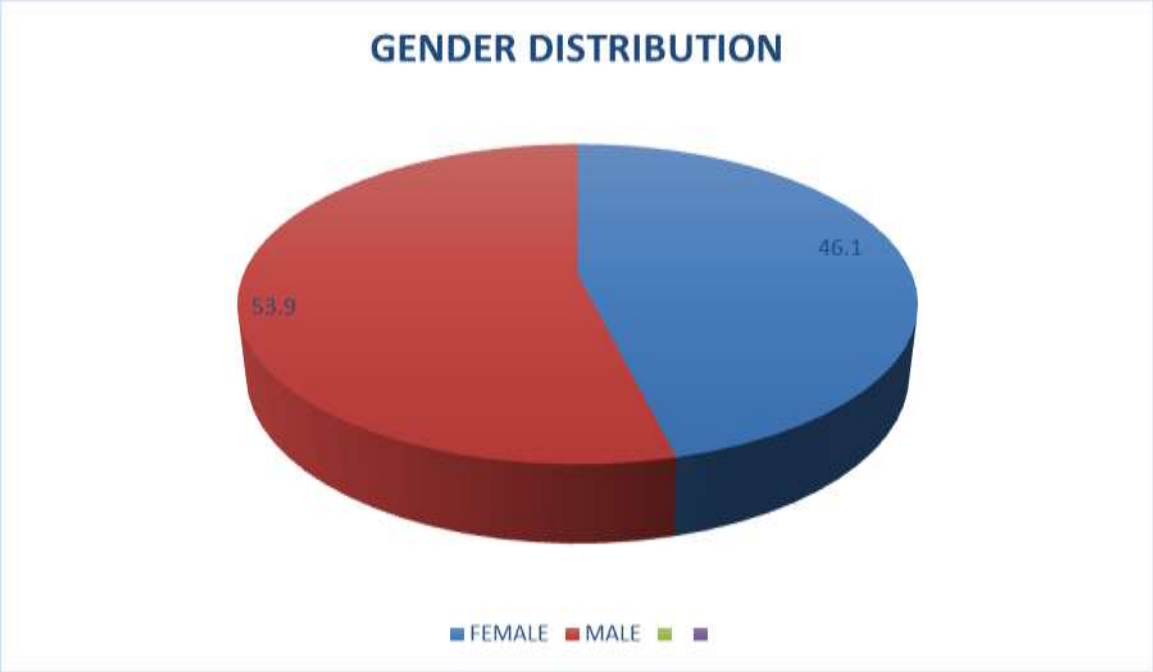
- Pregnant and lactating women.
- Pediatric patients.
- Patients with organ transplantation.

## RESULTS

### ULCERATIVE COLITIS

### GENDER DISTRIBUTION

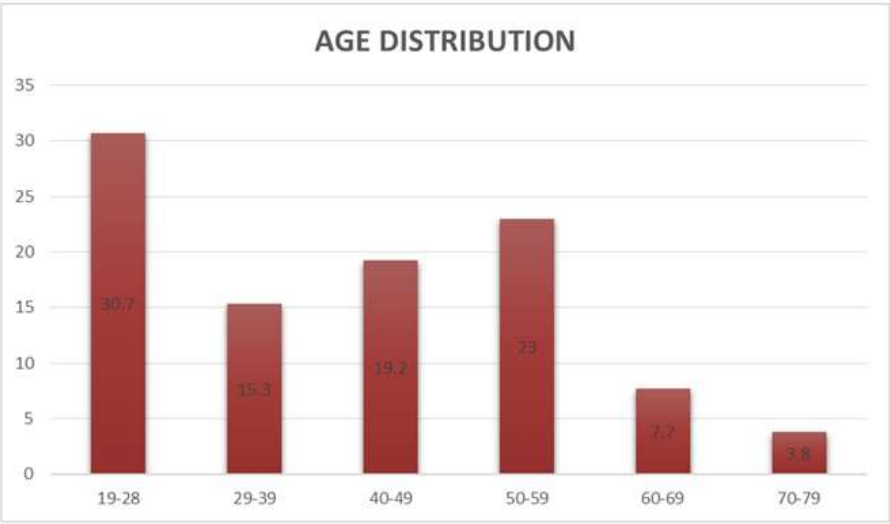
| GENDER | NO. OF PATIENTS | PERCENTAGE |
|---|---|---|
| FEMALE | **12** | **46.1%** |
| MALE | **14** | **53.9%** |




**This pie chart shows ulcerative colitis is more in males(53.9%) compared to females(46.1%)**

**AGE DISTRIBUTION**

| AGE | NO. OF PATIENTS | PERCENTAGE |
|---|---|---|
| 19-28 | 8 | 30.7% |
| 29-39 | 4 | 15.3% |
| 40-49 | 5 | 19.2% |
| 50-59 | 6 | 23% |
| 60-69 | 2 | 7.7% |
| 70-79 | 1 | 3.8% |




**This bar diagram shows the maximum number of patients with ulcerative colitis are in between age group of 19-28 years.**

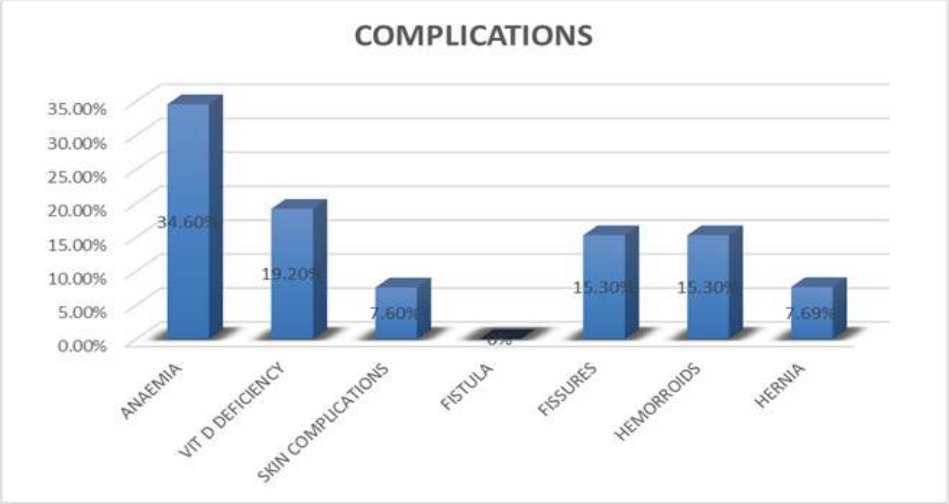
**DISTRIBUTION BASED ON SYMPTOMS:**

| SYMPTOMS | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| ABDOMINAL PAIN | 19 | 73.07% |
| MOUTH ULCERS | 2 | 7.69% |
| DIARRHEA | 19 | 73.07% |
| BLOOD IN STOOL | 21 | 80.7% |
| WEIGHT LOSS | 18 | 69.2% |
| URGENCY | 9 | 34.6% |
| ARTHRITIS/ARTHROPATHY | 7 | 26.9% |
| LOSS OF APPETITE | 19 | 73.07% |
| NAUSEA/VOMITING | 4 | 15.3% |
| FATIGUE | 15 | 57.69% |

**The above Table shows percentage (%) of symptoms in patients suffering from ulcerative colitis. Most of the patients complain of blood in stool (80.7%) and abdominal pain (73.07%), diarrhea (73.07%) among total subjects.**

**DISTRIBUTION BASED ON COMPLICATIONS IN INFLAMMATORY BOWEL DISEASE (ULCERATIVE COLLITIS)**

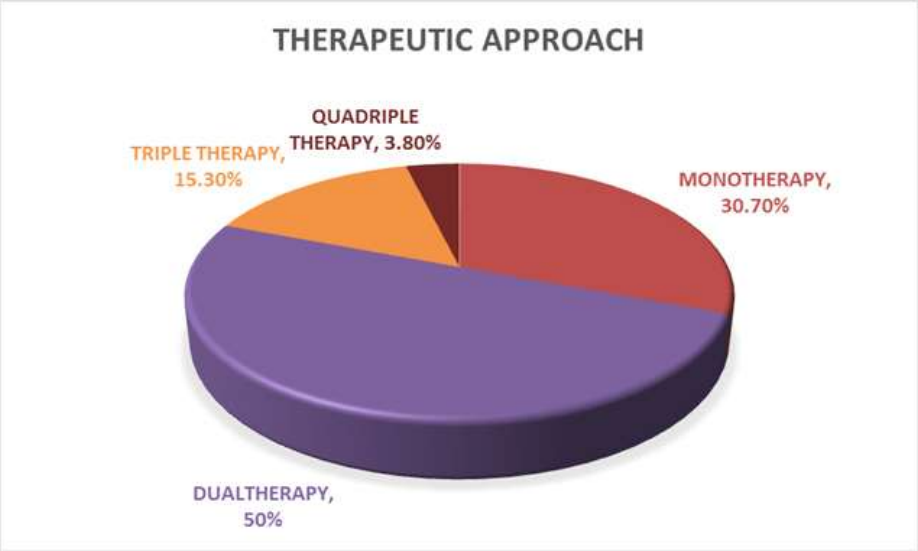
| COMPLICATIONS | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| ANAEMIA | **9** | **34.6%** |
| VIT D DEFICIENCY | **5** | **19.2%** |
| SKIN COMPLICATIONS | **1** | **7.6%** |
| FISTULA | **0** | **0%** |
| FISSURES | **4** | **15.3%** |
| HEMORROIDS | **3** | **15.3%** |
| HERNIA | **2** | **7.69%** |




**This bar graph shows that the maximum number of patients have anemia as a complication(46%) IN ULCERATIVE COLLITIS**

**DISTRIBUTION BASED ON THERAPEUTIC APPROACH.**

| | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| MONOTHERAPY | 8 | 30.7% |
| DUALTHERAPY | 13 | 50% |
| TRIPLE THERAPY | 4 | 15.3% |
| QUADRIPLE THERAPY | 1 | 3.8% |

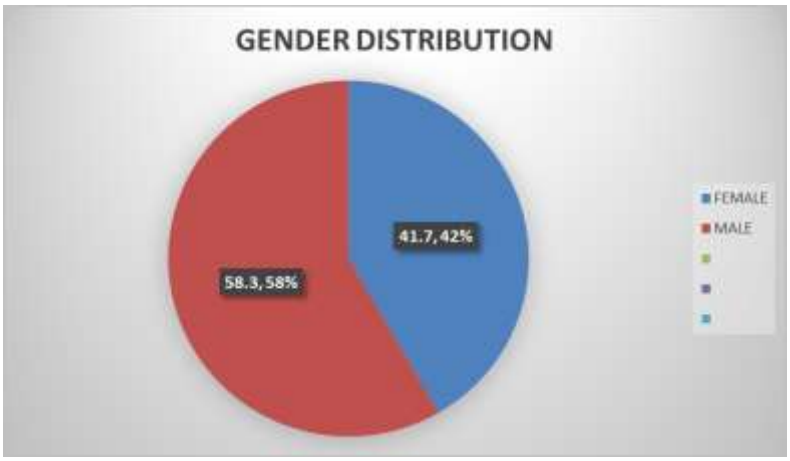



**This pie chart shows that dual therapy was most commonly used in treating ulcerative colitis patients.**

**CROHN'S DISEASE**

**GENDER DISTRIBUTION**

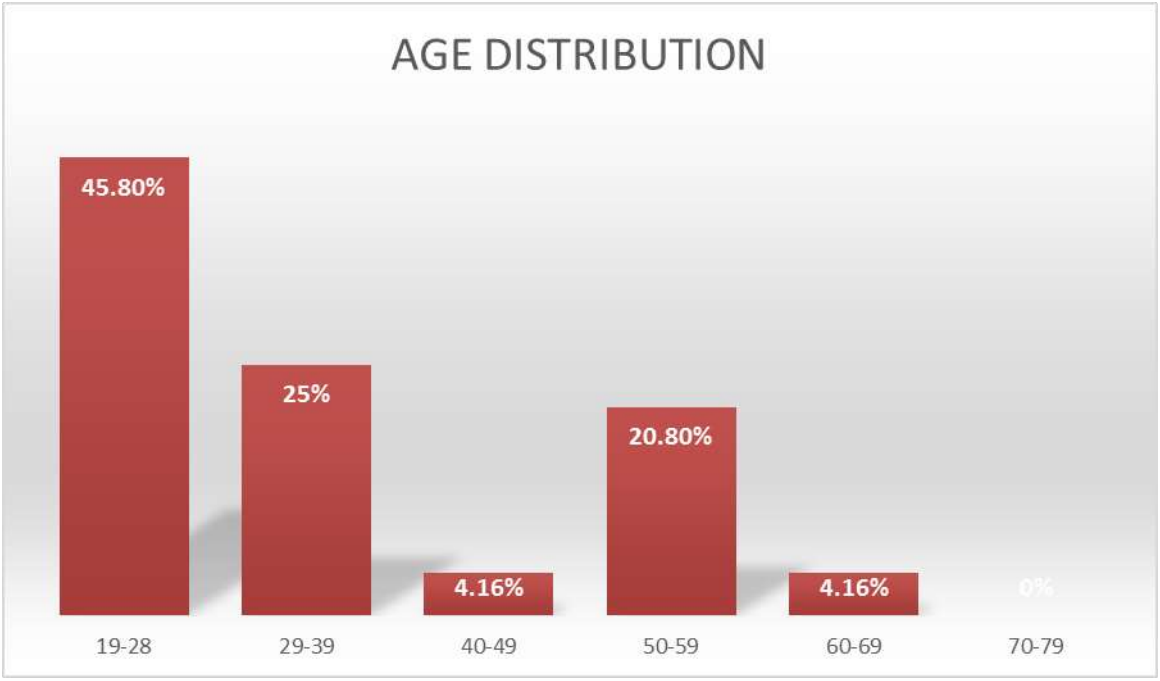
| GENDER | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| MALE | 14 | 58.3% |
| FEMALE | 10 | 41.7% |




This pie chart shows crohn's disease is more in males (58%) compared to females (42%)

**AGE DISTRIBUTION**

| AGE | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| 19-28 | 11 | 45.8% |
| 29-39 | 6 | 25% |
| 40-49 | 1 | 4.16% |
| 50-59 | 5 | 20.8% |
| 60-69 | 1 | 4.16% |
| 70-79 | 0 | 0% |




This bar diagram shows the maximum number of patients in chrons disease are affected in the between age group of 19-28 years.

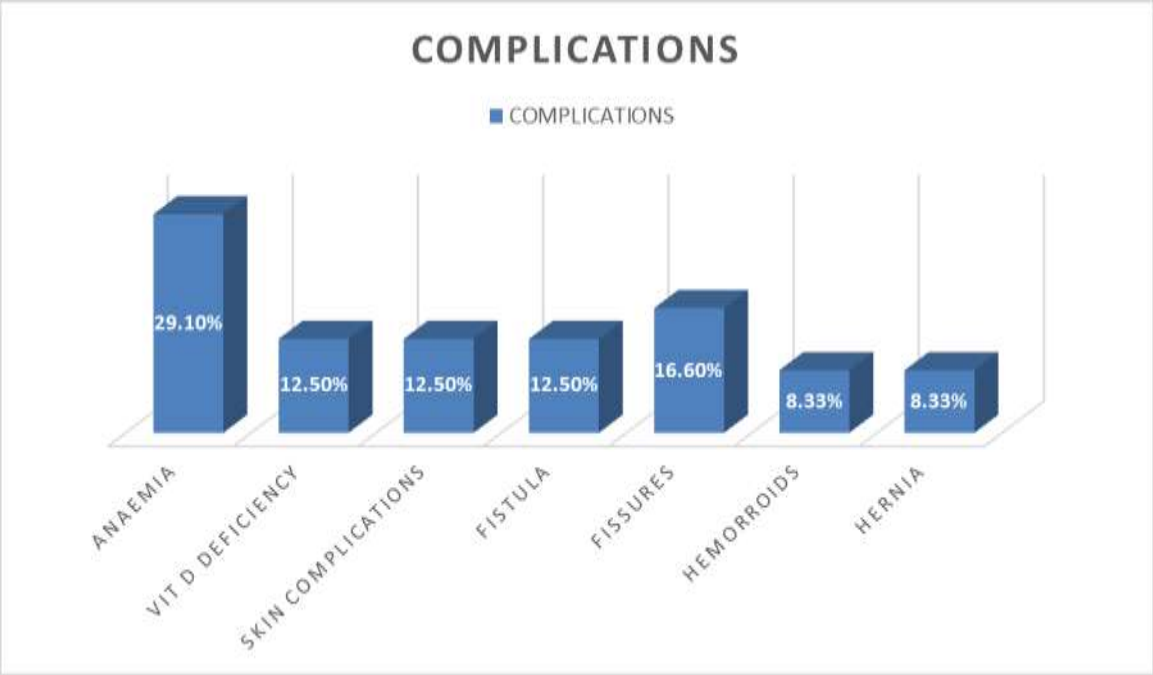
**DISTRIBUTION BASED ON SYMPTOMS:**

| SYMPTOMS | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| ABDOMINAL PAIN | 22 | 91.6% |
| MOUTH ULCERS | 2 | 8.33% |
| DIARRHEA | 18 | 75% |
| BLOOD IN STOOL | 9 | 37.5% |
| WEIGHT LOSS | 20 | 83.3% |
| URGENCY | 7 | 29.16% |
| ARTHRITIS/ARTHROPATHY | 4 | 16.66% |
| LOSS OF APPETITE | 13 | 54.16% |
| NAUSEA/VOMITING | 9 | 37.5% |
| FATIGUE | 14 | 58.33% |

**The above Table shows percentage (%) of symptoms in patients suffering from crohn's disease. Most of the patients complain of abdominal pain (91.6%) and weight loss (83.3%)**

**DISTRIBUTION BASED ON COMPLICATIONS.**

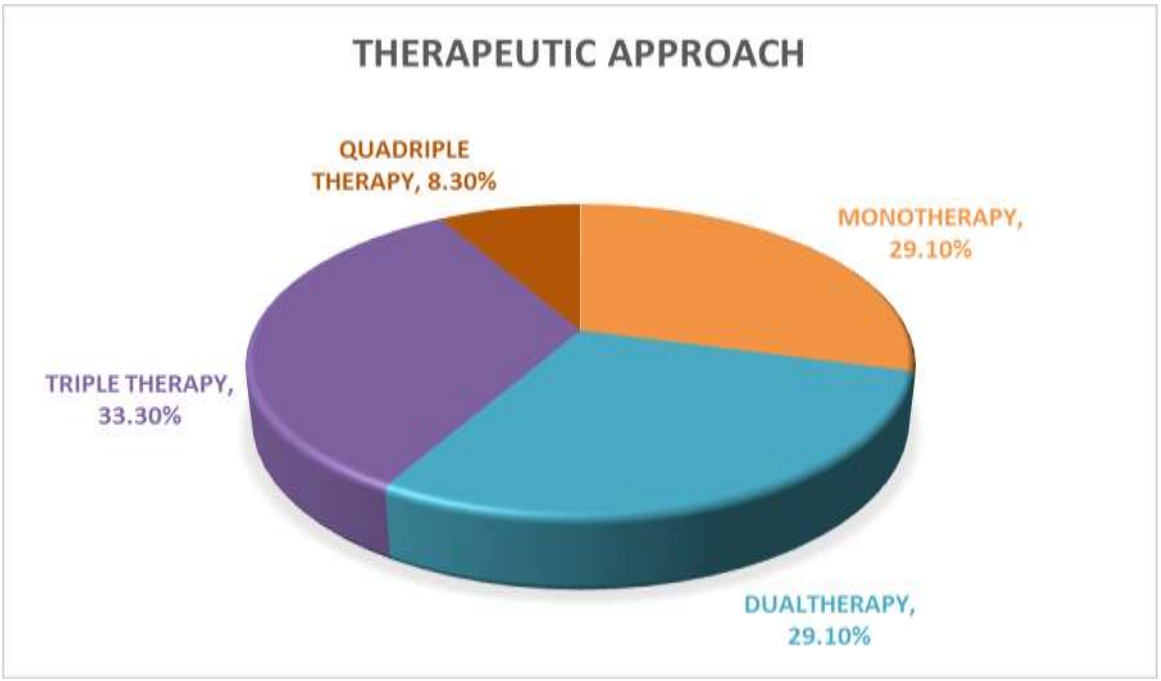
| COMPLICATIONS | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| ANAEMIA | **7** | **29.1%** |
| VIT D DEFICIENCY | **3** | **12.5%** |
| SKIN COMPLICATIONS | **3** | **12.5%** |
| FISTULA | **3** | **12.5%** |
| FISSURES | **4** | **16.6%** |
| HEMORROIDS | **2** | **8.33%** |
| HERNIA | **2** | **8.33%** |




**This bar graph shows that the maximum number of patients have anemia as a complication(29.10%)**

**DISTRIBUTION BASED ON THERAPEUTIC APPROACH:**

| | NO. OF SUBJECTS | PERCENTAGE |
|---|---|---|
| **MONOTHERAPY** | 7 | 29.1% |
| **DUALTHERAPY** | 7 | 29.1% |
| **TRIPLE THERAPY** | 8 | 33.3% |
| **QUADRIPLE THERAPY** | 2 | 8.3% |




**This pie chart shows that triple therapy was the most common treatment approach for Crohn's disease patients, followed by monotherapy and dualtherapy.**

## DISCUSSION

### ULCERATIVE COLITIS(UC)

The research study of sypmtoms and current therapies of ulcerative colitis patients in inflammatory bowel disease was examined at tertiary care hospital in south India. In my study, it was observed that the male subjects were more prone to developing UC than female subjects male (53.9%), female (46.1%). Based on the age group of 19-28 was reported to have greatest incidence of UC in our study (30.7%) followed by age group 50-59 being the second highest (23.07%).

Our research found that most common symptom in UC patients were blood in stools(80.7%) and abdominal pain(73.07%) followed by diarrhea (73.07%), loss of appetite (73.07%), weight loss(69.2%), fatigue(57.6%), urgency (26.9%) nausea/ vomiting(15.3%), mouth ulcer(7.69%).

Some of the patients have presented with complications such as anemia(34.6%) to varying degrees of hemoglobin levels. (15.3%) of patients have hemorrhoids, (19.2%) of patients had vit D deficiency, (15.3%) had fissures, (7.6%) had skin complications, (7.6%) had hernias and fistula not being reported as a complication in any UC patient.

**CHRON'S DISEASE(CD)**

The research study of sypmtoms and current therapies of chron's disease patients in inflammatory bowel disease was examined at tertiary care hospital in south India. In my study, it was observed that the male subjects were more prone to developing CD than female subjects male (58.3%), female (41.7%). Based on the age group of 19-28 was reported to have greatest incidence of CD in our study (45.8%) followed by age group 29-39 being the second highest (25%).

Our research found that most common symptom in CD patients were abdominal pain(91.6%), weight loss(83.3%), diarrhea (75%), fatigue(58.3%), and followed by loss of appetite (54.16%), blood in stools(37.5%), nausea/ vomiting(37.5%), urgency (29.16%), arthritis(16.66%), mouth ulcer(8.33%).

Some of the patients have presented with complications such as anemia(29.1%) to varying degrees of hemoglobin levels. (16.6%) had fissures, (12.5%) of patients had vit D deficiency, (12.5%) had skin complications, (12.2%) had fistulas, (8.33%) of patients have hemorrhoids, (8.33%) had hernias are being reported as a complication in any CD patient.

In my research, it was evident that most number of patients with UC were treated with dual therapy which included aminosalicylates and immunosuppressants and patients with CD were treated with triple therapy. Biologics were included in tripletherapy for patients who had severe form of the disease. Other drugs such as probiotics, cortecosteroids, Proton pump inhibitors, antibiotics, multivitamins, iron supplements and other analgesics were also prescribed to the patients.

my study results have shown that the patients who had presented with mild condition of disease were mostly treated with aminosalicylates (monotherapy). In moderate conditions, patients were treated with corticosteroids and immunosuppressants (dualtherapy). Severe condition disease patients were treated with biologics (triple therapy) and (quadraple therap)

**CONCLUSION**

In my study, it was observed that Ulcerative Colitis and Crohn's disease is more prevalent in males than in females. The greatest incidence is reported in the same age group of 19-28 years old for both UC and CD. Blood in stool and abdominal pain were the most common

symptoms of UC and CD patients with anemia being the most common complication for both.

IBD is a long term illness that requires good therapy adherence. 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 required to assess the prescribing patterns for patients whose condition is worsening.

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