



SHORT TERM CLINICAL AND BIOCHEMICAL RESPONSE TO TREATMENT IN CROHNS DISEASE PATIENTS

General Medicine

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ABSTRACT

Introduction: Crohns disease is a chronic inflammatory disorder that may involve any part of the alimentary tract from mouth to anus, but with a propensity for the distal small intestine and proximal large bowel. **Aims and objectives:** To assess the short term clinical and biochemical response to treatment in crohns disease patients. The objectives of the study was to assess the change in the Crohns disease activity index score and the change in mean ESR, CRP, haemoglobin and serum albumin levels with three months of treatment. **Materials and Methods:** The current study was an observational study conducted at a hospital. This research was carried out at Guwahati Medical College and Hospital from June 2021 to May 2022. This study included 45 participants. **Result:** The study found out that biologicals along with 5 aminosalicylates and Azathioprine, was associated with a significant improvement in clinical response in upto 75% of the patients. At the end of three months of treatment, 68.8% patients were in remission stage with improvement in their mean haemoglobin, ESR, CRP and serum albumin levels. **Conclusion:** The combination of biologicals along with 5 aminosalicylates and Azathioprine was associated with a significant improvement in the clinical and biochemical parameters in crohns disease patients. However, a larger study recruiting more patients with a longer duration of follow up is necessary for a better understanding of the disease.

KEYWORDS

Crohns Disease, Biologicals, Clinical Response, Biochemical Response

INTRODUCTION

Inflammatory Bowel Disease (IBD) comprises of conditions characterized by chronic or relapsing immune activation and inflammation within the gastrointestinal tract. Crohn's disease and Ulcerative colitis are the two major forms of idiopathic IBD.

Crohn's disease can involve any part of the gastrointestinal tract from the oropharynx to the perianal area. Inflammation can be transmural, often extending through to the serosa, resulting in sinus tracts or fistula formation. Diseased segments frequently are separated by intervening normal bowel, leading to the term "skip areas."

Histologic findings include small superficial ulcerations over a Peyer's patch (aphthoid ulcer) and focal chronic inflammation extending to the submucosa, sometimes accompanied by noncaseating granuloma formation. The most common location is the ileocecal region, followed by the terminal ileum, diffuse small bowel, or isolated colonic disease in decreasing order of frequency.

Crohns disease is associated with both intestinal and extraintestinal manifestations. Extraintestinal manifestations are usually related to intestinal disease activity and may precede or develop concurrently with intestinal symptoms. Various indices are used to evaluate the disease activity including clinical (objective), endoscopic-histological (subjective) and laboratory parameters like haemoglobin, CRP, ESR and serum albumin levels.

The goals of therapy of crohns disease are to induce remission, to maintain remission, to maintain adequate nutrition, to minimize disease and treatment related complications and to improve the patient's quality of life. Current management strategy focuses on using appropriate medical therapy and optimizing timing of surgery. The various agents used includes oral or topical preparations of 5 aminosalicylate compounds, oral or injectable corticosteroids, immunomodulators, biologicals and other experimental therapies.

AIM

To assess the short term clinical and biochemical response to treatment in crohns disease patients

OBJECTIVES

To assess the change in the Crohns disease activity index score and the change in mean ESR, CRP, haemoglobin and serum albumin levels with three months of treatment.

METHODS:

Sources of Data

- 1) **Study Design:** Hospital based observational study
- 2) **Study Setting:** Guwahati Medical College and Hospital
- 3) **Study Duration:** June 2021 to May 2022
- 4) **Study Population:** Patients admitted in Medicine department of GMCH
- 5) **Patient Selection:**

Inclusion Criteria:

- 1) Patients with history and clinical features suggestive of Crohns disease
- 2) Colonoscopic and histological features suggestive of Crohns disease.
- 3) Laboratory findings and radiological features suggestive of Crohns disease.

Exclusion Criteria:

- 1) Ischaemic colitis
- 2) Infective colitis
- 3) Radiation colitis
- 4) Irritable bowel syndrome
- 6) **Sampling Technique:** Purposive sampling
- 7) **Ethical clearance:** Ethical clearance was obtained from the institutional ethics committee of Guwahati Medical College and Hospital
- 8) **Consent:** Written and informed consent was taken from all patients

RESULTS:

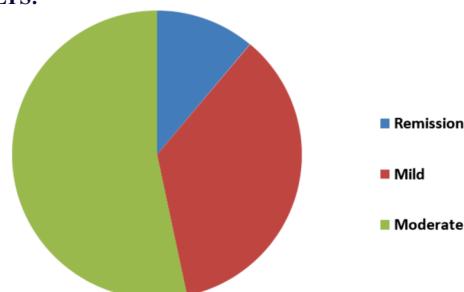


Fig 1: Pie chart showing the severity of Crohns disease patients at presentation

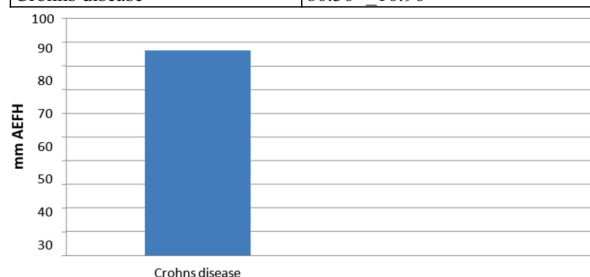
Table 1: Severity Of Crohns Disease Patients At Presentation (crohns Disease Activity Index)

Disease severity	Number/Percentage
Remission(CDAI score <150)	5(11.11%)
Mild(CDAI score 150-219)	16(35.5%)
Moderate(CDAI score 220- 450)	24(53.3%)
Severe(CDAI score >450)	0(0%)

Comment: Majority of Crohns disease patients were having moderate disease activity at presentation 53.3%(24)

Table 2: Mean ESR In Crohns Disease Patients At Presentation

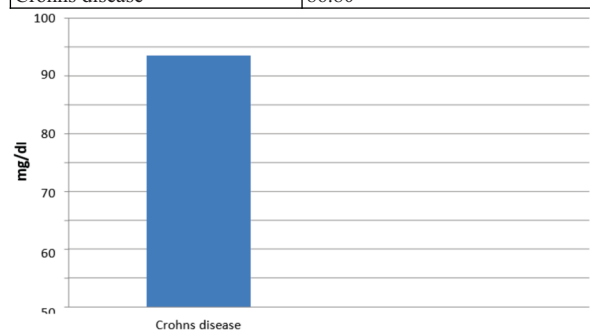
Crohns disease	Mean ESR(mm AEFH)
	86.36+ 16.96

**Fig 2:** Bar diagram showing mean ESR in Crohns disease patients at presentation

Comment: The mean ESR in Crohns disease patients at presentation was 86.36+ 16.96 mm AEFH

Table 3: Mean CRP In Crohns Disease Patients At Presentation

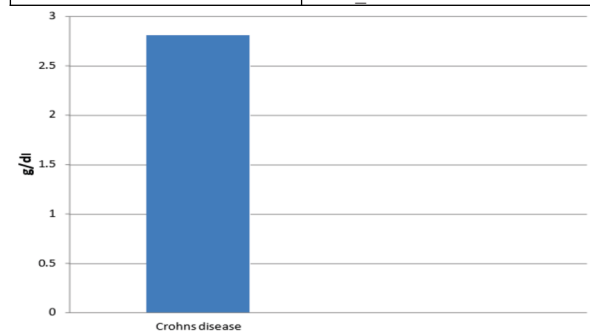
Crohns disease	Mean CRP(mg/dl)
	86.80

**Fig 3 :** Bar diagram showing mean CRP in Crohns disease patients at presentation

Comment: The mean CRP in Crohns disease patients at presentation was 86.80 mg/dl

Table 4: Mean Albumin Level In Crohns Disease Patients At Presentation

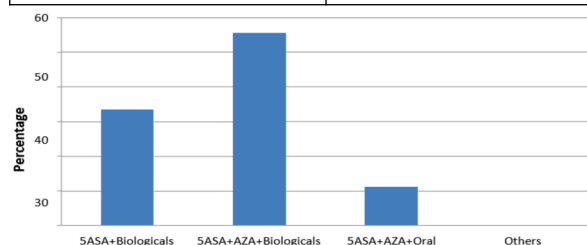
Crohns disease	Mean albumin(g/dl)
	2.81+ 0.86

**Fig 4 :** Bar diagram showing the mean albumin level in Crohns disease patients at presentation

Comment: The mean albumin level in Crohns disease patients at presentation was 2.81+ 0.86 g/dl

Table 5: Initial Twelve Weeks Treatment In Crohns Disease Patients

Treatment	Number/Percentage
5ASA+Biologicals	15(33.3%)
5ASA+AZA+Biologicals	25(55.5%)
5ASA+AZA+Oral corticosteroids	5(11.11%)
Others	0

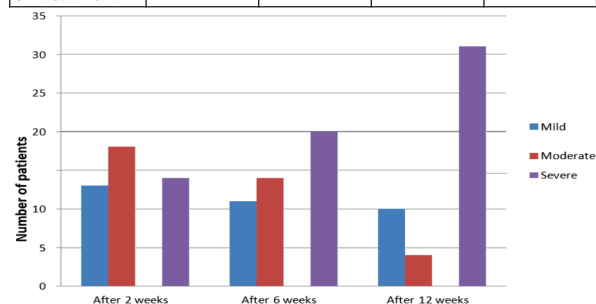
**Table 5:** Bar Diagram Showing Initial Twelve Weeks Treatment In Crohns Disease Patients

Comment:

- 55.55% (25) of Crohns disease patients were treated with 5ASA+AZA+Biologicals.
- 33.3% (15) patients were treated with 5ASA+Biologicals
- 11.11% (5) patients were treated with 5ASA+AZA+Oral corticosteroids

Table 6: Change In CDAI Score In Crohns Disease Patients With Twelve Weeks Of Treatment

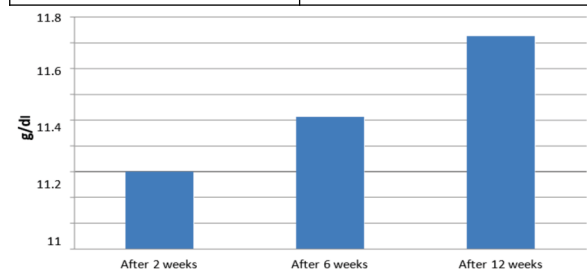
Time interval	Mild (n/%)	Moderate (n/%)	Severe (n/%)	Remission (n/%)
After 2 weeks of treatment	13(28.8%)	18(40%)	0	14(31.1%)
After 6 weeks of treatment	11(24%)	14(26.6%)	0	20(42.6%)
After 12 weeks of treatment	10(26.6%)	4(8.8%)	0	31(68.8%)

**Fig 6:** Bar diagram showing the change in severity of Crohns disease patients with twelve weeks treatment

Comment: After twelve weeks of treatment, 10(26.6%), 4(8.8%) and 31(68.8%) patients were in mild, moderate and remission stage respectively. No patients had severe disease activity.

Table 7: Changes In Haemoglobin In Crohns Disease Patients With Twelve Weeks Treatment

Time interval(in weeks)	Haemoglobin(g/dl)
After 2 weeks of treatment	10.23
After 6 weeks of treatment	10.89
After 12 weeks of treatment	11.08

**Fig 7:** Bar diagram showing the change in mean haemoglobin in Crohns disease patients with twelve weeks treatment

Comment: The mean haemoglobin in crohns disease patients after 2 weeks, 6weeks and 12 weeks of treatment were **10.23,10.89 and 11.08 g/dl** respectively.

Table 8: Changes In ESR In Crohns Disease Patients With Twelve Weeks Treatment

Time interval(in weeks)	Mean ESR(mm AEFH)
After 2 weeks of treatment	46.5
After 6 weeks of treatment	28.08
After 12 weeks of treatment	21.53

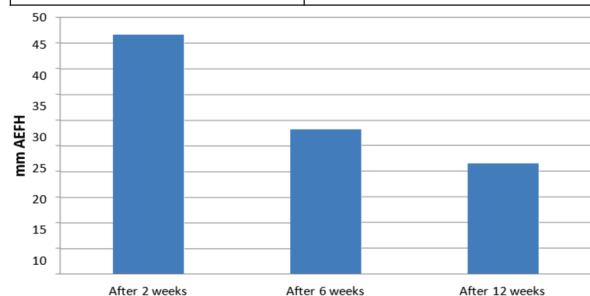


Fig 8: Bar diagram showing the change in mean ESR in crohns disease patients with twelve weeks treatment

Comment: The mean ESR in Crohns disease patients after 2 weeks, 6 weeks and 12 weeks of treatment were **46.5, 28.08 and 21.53 mm AEFH** respectively

Table 9: Changes In CRP In Crohns Disease Patients With Twelve Weeks Of Treatment

Time intervals(in weeks)	Mean CRP(mg/dl)
After 2 weeks of treatment	65.39
After 6 weeks of treatment	41.14
After 12 weeks of treatment	21.03

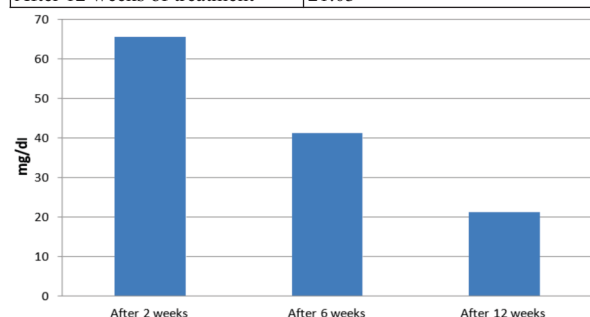


Fig 9: Bar diagram showing the change in mean CRP in crohns disease patients with twelve weeks treatment

Comment: The mean CRP in Crohns disease patients after 2 weeks, 6 weeks and 12 weeks of treatment were **65.39, 41.14 and 21.03 mg/dl** respectively.

Table 10: Changes In Albumin Levels In Crohns Disease Patients With Twelve Weeks Treatment

Time interval(in weeks)	Mean albumin(g/dl)
After 2 weeks of treatment	3.01
After 6 weeks of treatment	3.25
After 14 weeks of treatment	3.41

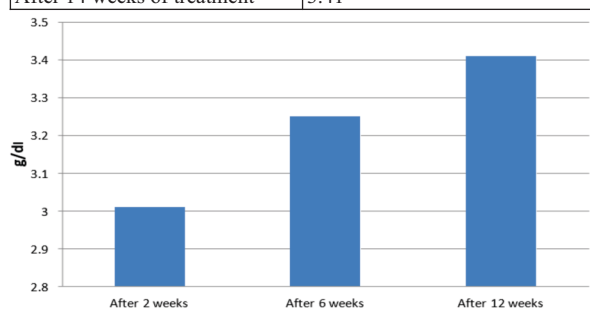


Fig 10: Bar diagram showing the change in mean albumin levels with twelve weeks treatment

Comment: The mean albumin level in crohns disease patients after 2 weeks, 6 weeks and 12 weeks of treatment were **3.01, 3.25 and 3.41 g/dl** respectively.

DISCUSSION

In the present study majority of crohns disease patients were having moderate disease activity at presentation. Mild disease was present in 35.55% of total patients whereas 11.1% were in remission stage. Gunisetty S et al (2012) reported mild, moderate and severe disease in 30%, 60.51% and 2.5% of their patients respectively. Ha CY et al (2010) observed 22.5%, 64.8% and 2.6% of their patients had mild, moderate and severe disease respectively at presentation.

During the initial twelve weeks of study, majority of the patients (55.5%) were treated with combination of 5 Aminosalicylates, Azathioprine and biologicals. (33%) of the patients were treated with combination of 5 Aminosalicylates and biologicals whereas (11%) of patients were treated with 5 Aminosalicylates, Azathioprine and biologicals. The patients in remission stage were excluded from biologicals, although they were followed up in our study.

After second week of treatment, 28.8%, 40% and 31.1% of the patients were in mild, moderate and remission stage respectively. After six weeks of treatment 24%, 26.6% and 42.6% of the patients were in mild, moderate and remission stage respectively. After twelve weeks of treatment, 26.6%, 8.8% and 68.8% were in mild, moderate and remission stage respectively. No patients had severe disease activity.

During the study after the addition of biologicals along with 5 aminosalicylates and Azathioprine, there was significant improvement in clinical response in upto 75% of the patients. Similar response was observed by Targan et al (2001) where clinical response rate was found to be 61% and 81% at six weeks and twelve weeks respectively after addition of two doses of infliximab.

The addition of Azathioprine to 5 aminosalicylates leads to significant improvement in clinical response by 55% at twelve weeks of treatment. Ardizzone et al (2003) found a clinical remission rate from 33% to 63% at 3 months of treatment. Willoughby et al (2006) demonstrated a median age of 10.7 weeks is required to achieve clinical response with azathioprine.

At the end of twelve weeks of treatment, there was 35.73 and 42.3 reduction in mean CRP and ESR levels whereas there was an increase in the mean serum albumin levels by 0.32. In the study, in 73% of the patients their was normalisation of CRP at 12 weeks of treatment. In the study by (Reinisch et al), normalization of CRP at week 14 (< 5 mg/L) predicted a higher rate of response and remission during the first year. Similar results were achieved by (Kiss LS et al 2005) where lower CRP levels at week 12 (< 5 mg/L) were associated with a higher likelihood of clinical remission at one year of treatment

In the study, in 90% of the patients there was normalisation of ESR by twelve weeks of treatment whereas the mean albumin level increased by 0.32 at 12 weeks of treatment. In similar studies, (Hishashi et al 2020) reported an improvement in mean albumin level by 0.4 after three months of treatment

CONCLUSION

Majority of the patients of crohns disease had moderate disease activity at presentation All the patients were managed with medical therapy and most of them were treated with a combination of 5 aminosalicylates, azathioprine and biologicals. At the end of three months of treatment 68.8 % of the patients were in the remission stage with improvement in their mean haemoglobin, ESR, CRP and serum albumin levels.

A larger study recruiting more patients with a longer duration of follow up is necessary for a better understanding of the disease and to arrive at definite conclusions especially in North east India.

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4. disease in 30%, 60.51% and 2.5% their patients respectively. Ha CY et al (2010) observed 22.5%, 64.8% and 2.6% of their patients had mild, moderate and severe disease respectively at presentation.