Original Article

Efficacy and Safety of Biosimilar Infliximab (Remsima) in Comparison with Originator Infliximab (Remicade) in Inflammatory Bowel Diseases

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Abstract

Background: Relapsing-remitting inflammatory bowel disorders are chronic. Biologic therapy has expedited inflammatory bowel disease (IBD) treatment. Infliximab, a tumor necrosis factor (TNF)-alpha-targeting chimeric antibody, induces and maintains illness remission. Remsima and other biosimilars seek to cut medical expenses and increase medicine affordability. **Objective:** The aim of study is to compare the clinical efficacy, endoscopic changes, and safety of Remsima vs. Remicade in patients with IBD. **Materials and Methods:** From April 1, 2019, to April 1, 2020, Baghdad Medical City's Gastroenterology and Hepatology Hospital performed this investigation. Remsima and Remicade were given to 13 ulcerative colitis (UC) and 13 Crohn's disease patients, respectively. Disease activity was measured using Mayo Score in UC and Crohn disease activity index and simple endoscopic score for Crohn's disease (SES-CD) in CD initially and followed up 6 months after first dose of Remsima prospectively and retrospectively for Remicade by clinical data and endoscopic findings. **Results:** After 6 months of therapy, UC and CD Mayo scores decreased from 10.07 to 4.92 and 9.84 to 5.00 by Remsima and Remicade, respectively. Remsima and Remicade decreased CD mean from 436.07 to 212.84 and 428.30 to 199.53. Remsima and Remicade decreased CD SES scores from 15.15 to 6.92 and 12.69 to 5.00, respectively. 3 (23.1%) Remsima patients in both conditions had side symptoms, whereas 4 (30.8%) Remicade patients in UC and 5 (38.5%) in CD did. Groups gained weight significantly. Both medications were equally effective and safe ($P > 0.05$). **Conclusion:** Remsima and Remicade are a tolerable effective treatment with no significant adverse effects in IBD patients with moderate–severe disease.

Keywords: Efficacy, inflammatory bowel diseases, infliximab, infliximab, safety, (Remicade), (Remsima)

Introduction

Inflammatory bowel disease (IBD) is a chronic disorder that includes conditions such as ulcerative colitis (UC), Crohn's disease (CD), and indeterminate colitis.[1] These diseases have distinct clinical, radiological, endoscopic, and pathological features, and they can affect individuals of all age groups. The development of IBD is influenced by a combination of genetic and environmental risk factors.[2] Unclassified IBD (IBD-U) is a subtype of the disease that affects the colon and shares features of both UC and CD.[3] It accounts for about 5–15% of patients with IBD. The incidence and prevalence of UC and CD vary, with the peak age of onset occurring in the late teens to early thirties for both conditions.[4] The incidence of UC is nearly equal in males and females, while CD may have a slightly higher incidence in females.[5] There are ethnic differences in the incidence of IBD, with a greater prevalence observed in the Jewish population compared to non-Jews.[6] The pathogenesis of IBD involves complex interactions between genetic

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susceptibility and environmental factors, particularly related to the gut microbiome and mucosal barrier abnormalities.[7] Smoking has different effects on UC and CD, with an increased risk and complications associated with CD but a protective effect on UC. Additionally, a history of prior appendectomy is inversely associated with UC but not CD.[8] Clinical features of UC include abdominal pain, bloody diarrhea, mucus passage, and anemia, while CD is characterized by abdominal pain, frequent bowel movements, weight loss, and fever. Both UC and CD can have extraintestinal manifestations, and patients with long-standing colonic IBD are at increased risk of colorectal cancer.[9] The diagnosis of IBD requires a combination of medical history, physical examination, blood tests, stool examination, radiology, endoscopy, and histopathology. Scoring indices like the Crohn's disease activity index (CDAI) and Mayo score are used to assess disease activity and treatment response.[10] IBD management aims to achieve symptomatic remission and, more recently, deep remission and normalization of serological activity indices. Treatment strategies may involve step-up or top-down approaches, depending on disease severity, and response to therapy. Medical therapy includes aminosalicylates, corticosteroids, immunomodulators, antibiotics, enteral nutrition, and biologic agents targeting tumor necrosis factor (TNF)-alpha, integrins, or IL-12/23 p40 subunit.[11] Infliximab is an example of an anti-TNF-α biologic agent used to treat moderate to severe UC and CD. Biosimilars of infliximab, like CT-P13 (Remsima), have been developed and shown to be comparable in efficacy and safety to the original drug.[12] Primary and secondary loss of response may occur with infliximab, requiring dose escalation, alteration of therapy, or addition of an immunomodulator. The efficacy and loss of response with biosimilar CT-P13 are similar to the original infliximab.[13] The aim of study is to comparing the efficacy between Remsima and Remicade in the management of IBDs and comparing the safety between Remsima and Remicade.

Materials and Methods

The current study aimed to compare the efficacy and adverse effects of two biologic agents, Remsima and Remicade, in patients with IBD who attended the Gastroenterology and Hepatology Teaching Hospital—Medical City in Baghdad. The study period spanned from April 1, 2019, to April 1, 2020. Twenty-six patients with IBD were randomly selected, with 13 patients having UC and 13 patients having Crohn's colitis (CD). These patients were treated with either Remsima or Remicade. Another 26 patients (13 with UC and 13 with CD) were initially included in the study, but some were later excluded due to various reasons, such as loss to follow-up or death. Both Remsima and Remicade therapies were initiated in patients with active disease status. Patients were excluded from the study if they had certain conditions or risk factors, such as severe cardiac, hepatic, or renal diseases, fibrostenotic CD, malignancies, multiple sclerosis, positive HBs Ag and HCV Ab, recent IBD-related surgery, recent severe bacterial or viral infection, recent history of NSAID intake, patients switched from Remicade to Remsima, and primary loss of response to Remsima. Data collection involved a comprehensive assessment of patients' anthropometric and socio-demographic data, disease duration, symptoms, medical and surgical history, family history, and specific IBD treatment history. Laboratory investigations, radiological examinations, and colonoscopy were performed at baseline and after 6 months of treatment. Clinical assessments for patients with UC were based on symptoms, physical examination, and the Mayo score for clinical and endoscopic remission and response. For patients with CD, the CDAI and the simple endoscopic score for Crohn's disease (SES-CD) were used for clinical remission and response. Data analysis was performed using SPSS version 23, and statistical significance was set at $P \leq 0.05$.

Ethical approval

The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It was carried out with patients verbal and

Table 1: Patients distribution according to the study variables for UC and CD on both Remsima and Remicade groups

Study variables	*N*	%
Age (years)[a]		
< 20 years	8	15.40%
20–40 years	25	48.10%
40–60 years	16	30.80%
≥ 60 years	3	5.80%
Total	52	100.00%
Gender		
Male	28	53.80%
Female	24	46.20%
Total	52	100.00%
Smoking habit		
Smoker	6	11.50%
Nonsmoker	46	88.50%
Total	52	100.00%
Type of disease		
UC	26	50.00%
CD	26	50.00%
Total	52	100.00%
Duration of disease (years)[a]		
Below 5 years	17	32.70%
5–10 years	27	51.90%
≥ 10 years	8	15.40%
Total	52	100.00%

[a]The mean age of patients was 33.46 ± 13.80 years while the mean duration of diseases was 7.07 ± 5.23 years

analytical approval before sample was taken. The study protocol and the subject information and consent form were reviewed and approved by a local ethics committee according to the document number 11 (including the number and the date in March 3, 2019) to get this approval.

Results

Fifty-two patients were enrolled in the study; 26 patients (50%) of them was diagnosed as UC group while the other 26 patients (50%) was diagnosed as Crohn's diseases (CD group). Thirteen patients (50%) from each group were treated with Remsima and same number were treated with Remicade [Table 1].

In both groups multiple variables were studied and matched statistically. There was no statistically significant difference was found between Remsima and Remicade groups in both CD and UC as showed in Tables 2 and 3.

It was found that 30.8%, 38.5% of patients had remission, 46.2%, 38.5% had response, 38.4%, 38.3% had mild activity

Table 2: The association between types of treatment and study variables in UC

Study variables	Type of treatment		Total	X^2	*P* value
	Remsima	Remicade			
Age (years)`					
<20 years	1 (7.7)	1 (7.7)	2 (7.7)		1.000 f
20–40 years	7 (53.8)	7 (53.8)	14 (53.8)		
40–60 years	4 (30.8)	4 (30.8)	8 (30.8)		
≥ 60 years	1 (7.7)	1 (7.7)	2 (7.7)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Gender					
Male	6 (46.2)	7 (53.8)	13 (50.0)	0.154	1.000
Female	7 (53.8)	6 (46.2)	13 (50.0)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Smoking habit					
Smoker	1 (7.7)	2 (15.4)	3 (11.5)		1.000 f
Non smoker	12 (92.3)	11 (84.6)	23 (88.5)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Past medical history					
Positive	2 (15.4)	2 (15.4)	4 (15.4)		1.000 f
Negative	11 (84.6)	11 (84.6)	22 (84.6)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Extent of disease					
Pan colitis	6 (46.2)	5 (38.5)	11 (42.3)	0.158	0.691
Left side d colitis	7 (53.8)	8 (61.5)	15 (57.7)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Duration of disease (years)					
Below 5 years	4 (30.8)	2 (15.4)	6 (23.1)		0.852 f
5–10 years	7 (53.8)	9 (69.2)	16 (61.5)		
≥ 10 years	2 (15.4)	2 (15.4)	4 (15.4)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Type of treatment					
Azathioprine	9 (69.2)	10 (76.9)	19 (73.1)		1.000 f
Azathioprine and mesalazine	2 (15.4)	2 (15.4)	4 (15.4)		
Azathioprine and mesalazine	1 (7.7)	1 (7.7)	2 (7.7)		
No treatment	1 (7.7)	1 (7.7)	2 (7.7)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Delay of disease diagnosis					
No delay	3 (23.1)	1 (7.7)	4 (15.4)		0.51 f
Delay less than 1 year	3 (23.1)	3 (23.1)	6 (23.1)		
Delay 1–2 years	5 (38.5)	4 (30.8)	9 (34.6)		
Delay 2 years or more	2 (15.4)	5 (38.5)	7 (26.9)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		

p value ≤ 0.05 was significant. Fisher-exact test

Table 3: The association between types of treatment and study variables in CD

Study variables	Type of Treatment		Total	χ^2	*P* value
	Remsima	Remicade			
Age (years)`					
< 20 years	4 (30.8)	2 (15.4)	6 (23.1)		0.42 f
20–40 years	3 (23.0)	8 (61.5)	11 (42.3)		
40–60 years	5 (38.5)	3 (23.1)	8 (30.8)		
≥60 years	1 (7.7)	0 (0.0)	1 (3.8)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Gender					
Male	8 (61.5)	7 (53.8)	15 (57.7)	0.158	0.691
Female	5 (38.5)	6 (46.2)	11 (42.3)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Smoking habit					
Smoker	1 (7.7)	2 (15.4)	3 (11.5)		1.000 f
Non smoker	12 (92.3)	11 (84.6)	23 (88.5)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Past medical history					
Positive	2 (15.4)	1 (7.7)	3 (11.5)		1.000 f
Negative	11 (84.6)	12 (92.3)	23 (88.5)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Extent of disease					
Colonic	1 (7.7)	1 (7.7)	2 (7.7)		1.000 f
Ileal	6 (46.2)	5 (38.5)	11 (42.3)		
Ileocolon	6 (46.2)	7 (53.8)	13 (50.0)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Duration of disease (years)					
Below 5 years	6 (46.2)	5 (38.5)	11 (42.3)		1.000 f
5–10 years	5 (38.5)	6 (46.2)	11 (42.3)		
≥10 years	2 (15.4)	2 (15.4)	4 (15.4)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Type of treatment					
Azathioprine	11 (84.6)	12 (92.3)	23 (88.5)		1.000 f
Azathioprine and prednisolone	1 (7.7)	0 (0.0)	1 (3.8)		
Azathioprine and Mesalazine	1 (7.7)	1 (7.7)	2 (7.7)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		
Delay					
No delay	2 (15.4)	2 (15.4)	4 (15.4)		1.000 f
Delay less than 1 year	6 (46.2)	5 (38.5)	11 (42.3)		
Delay 1–2 years	3 (23.1)	4 (30.8)	7 (26.9)		
Delay 2 years or more	2 (15.4)	2 (15.4)	4 (15.4)		
Total	13 (100.0)	13 (100.0)	26 (100.0)		

p value ≤ 0.05 was significant. Fisher-exact test

in Remsima and Remicade group respectively. In both groups the remission and response were without statistically significant variation between both drugs (*P* value > 0.05). In UC, there was significant decrease in Mayo score in patients after 6 months posttreatment (mean decline from 10.07 to 4.92 and 9.84 to 5.00) by Remsima and Remicade Respectively (*P* value < 0.001 for both drugs). There was statistically no significant difference between both drugs as showed in Tables 4 and 5 (*P* value > 0.08) for both drugs.

Clinical remission and clinical response in CD was assessed by CDAI, it was found that 46.2%, 53.8% of patients had remission, 30.8%, 38.5% had response and 7.7%, 14.5% had mild activity in Remsima and Remicade group respectively. The difference in remission and response were statistically not significant between the two drugs (*P* value > 0.05). There was statistically significant decline in CDAI score after 6 months posttreatment in Remsima as well as in Remicade groups. Mean decline from 436.07 to 212.84 and 428.30 to 199.53, respectively (*P* value < 0.001 for both drugs). There was statistically not significant difference between the two drugs (*P* value > 0.05) as showed in Tables 6–8.

Table 4: The mean differences of Mayo score before and after treatment with Remsima and Remicade in UC

Mayo score	Study groups	*N*	Mean	*SD*	Paired *t* test	*P* value
Remsima	Before treatment	13	10.07	1.84	4.55	<0.001*
	After treatment	13	4.92	3.40		
Remicade	Before treatment	13	9.84	1.86	4.76	<0.001*
	After treatment	13	5.00	3.69		

*P value ≤ 0.05 was considered as significant

Table 5: The mean differences of Mayo score after use of Remsima and Remicade

Myo score	Study groups	*N*	Mean	*SD*	Paired *t* test	*P* value
Remsima	After treatment	13	4.92	4.92	−4.955	>0.08
Remicade	After treatment	13	5.00	3.69		

P value ≤ 0.05 was considered as significant

Table 6: The mean difference of CDAI and SES before and after use of Remsima

Study variables	Study groups	*N*	Mean	*SD*	Paired *t* test	*P* value
CDAI	Before treatment	13	436.07	79.52	4.58	0.001*
	After treatment	13	212.84	163.64		
SES	Before treatment	13	15.15	3.912	3.576	0.004*
	After treatment	13	6.92	6.84		

*P value ≤ 0.05 was considered as significant

Table 7: The mean difference of CDAI and SES before and after use of Remicade

Study variables	Study groups	*N*	Mean	*SD*	Paired *t* test	*P* value
CDAI	Before treatment	13	428.30	100.21	5.229	<0.001*
	After treatment	13	199.53	161.94		
SES	Before treatment	13	12.69	4.42	4.556	0.001*
	After treatment	13	5.00	3.16		

*P value ≤ 0.05 was considered as significant

Table 8: The mean differences of CDAI and SES after use of Remsima and Remicade

Drugs	study	No.	CDAI	*SD*	*P* value	SES	*SD*	*P* value
Remsima	After treatment	13	212.84	163.64	>0.08	6.92	6.84	>0.07
Remicade	After treatment	13	199.53	161.94		5.00	3.16	

*P value ≤ 0.05 was considered as significant

Discussion

The current study aimed to compare the efficacy and safety of two biologic agents, Remsima and Remicade, in patients with IBD including UC and CD. The results showed that both Remsima and Remicade were highly effective in inducing and maintaining remission in patients with active disease status at the start of the study. The mean age of the patients in both groups was consistent with previous studies, with most patients being diagnosed in the age range of 20–40 years, which is a typical age of onset for IBD.[14,15] In terms of smoking status, the majority of patients in both groups were nonsmokers, which aligns with previous research indicating that smoking may be a risk factor for developing CD.[16,17] Additionally, the gender distribution varied between UC and CD patients, with more males in the CD group. Gender differences in IBD prevalence have been observed in different geographic regions and age groups.[18,19] Weight gain was seen in both groups after treatment with Remsima or Remicade, which is consistent with previous studies showing that anti-TNF therapy can combat TNF-alpha-associated anorexia and restore a positive energy balance, leading to weight gain in some patients with CD.[20-24] Clinical assessment using the Mayo score for UC and the CDAI for CD showed that both Remsima and Remicade were effective in achieving remission and response in a significant proportion of patients. There was no statistically significant difference in efficacy between the two drugs in both UC and CD groups. These findings are in line with previous studies that have demonstrated comparable efficacy between biosimilar

infliximab (Remsima) and the originator drug.[25-29] In terms of safety, both Remsima and Remicade were well-tolerated, with a low rate of adverse reactions. The incidence of minor adverse reactions was slightly higher in the Remicade group compared to the Remsima group, but overall, the drugs were considered safe, and no patients had to discontinue the medication due to adverse effects. These findings are consistent with previous safety studies of biosimilar infliximab.[30-32] The results of this study add to the growing body of evidence supporting the clinical efficacy and safety of biosimilar infliximab (Remsima) in the treatment of IBD. The findings demonstrate that Remsima is as effective as Remicade in inducing and maintaining remission in both UC and CD patients.[30] Moreover, the safety profile of Remsima was favorable, with a low rate of adverse reactions. Biosimilar infliximab has the potential to improve patient access to biologic therapies and reduce healthcare costs. The comparable efficacy and safety of Remsima with the originator drug, as shown in this study, provide further support for its use in clinical practice.[31,32]

Conclusion

- Remsima is a tolerable effective treatment in severe form of IBD and in patients not responding to traditional treatment of UC and CD.
- Remsima was not inferior to Remicade in efficacy which assessed by the clinical, endoscopic response and remission between both drugs in UC and CD after 6 months of treatment.
- No significant adverse effects that merit drug discontinuation had been reported due to treatment with Remsima or Remicade for which no patient need to stop neither drugs.

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Conflicts of interest
There are no conflicts of interest.

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