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Research Article

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USTEKINUMAB EFFECTIVENESS AND SUSTAINABILITY IN ULCERATIVE COLITIS AND CROHN'S DISEASE

USTEKINUMAB'IN ÜLSERATİF KOLİT VE CROHN HASTALIĞI'NDA ETKİNLİĞİ VE SÜRDÜRÜLEBİLİRLİĞİ



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Abstract

Objective: This study aimed to investigate the effectiveness, sustainability, and side effects of ustekinumab in patients with ulcerative colitis (UC) and Crohn's disease (CD).

Material and Methods: The data of 48 inflammatory bowel disease patients who were unresponsive to previous treatment and were followed up at a tertiary centre were retrospectively investigated. Demographic features, characteristics of bowel diseases, treatment experiences, laboratory and endoscopic features, and disease scores [Crohn's Disease Activity Index (CDAI) and Simple Clinical Colitis Activity Index (SCCAI)] were analysed.

Results: Of the total 48 patients, 35 (73%) were CD and 26 (54.2%) were women. The mean age of the patients was 42.1±13.3 years, and the mean age of disease was 136.8±92 months. There was previous use of biological agents in 100% of both UC and CD. The most common reason for switching to ustekinumab in patients was a lack of response to previous biologics (90%). The mean duration of use of ustekinumab was 17.1±8 months. At the end of the follow-up, 71% of the CD patients had CDAI<150 and were in complete clinical remission, and 53.8% of the UC patients had SCCAI<5 and were in complete clinical remission. Control endoscopy was performed for 13 UCs, and 6 (46.2%) had endoscopic remission. Control endoscopy was performed for 5 CDs, and 3 (60%) had endoscopic remission.

Öz

Amaç: Bu çalışmanın amacı, ülseratif kolit (ÜK) ve Crohn hastalığı (CH) olan hastalarda ustekinumabın etkinliğini, sürdürülebilirliğini ve yan etkilerini araştırmaktır.

Gereç ve Yöntemler: Önceki tedavilere yanıt vermeyen ve tersiyer bir merkezde takip edilen 48 inflamatuvar barsak hastasının verileri retrospektif olarak incelendi. Hastaların demografik özellikleri, barsak hastalıklarının özellikleri, tedavi deneyimleri, laboratuvar ve endoskopik özellikleri ve hastalık skorları Crohn Hastalığı Aktivite İndeksi (CHAI) ve Basit Klinik Kolit Aktivite indeksi (BKKAİ) incelendi.

Bulgular: Toplam 48 hastanın 35'i (%73) CH, 26'sı (%54,2) kadındı. Hastaların yaş ortalaması 42,1±13,3 yıl, hastalık yaşı ortalaması 136,8±92 aydı. Hem ÜK hem de CH'nın %100'ünde daha önce biyolojik ajan kullanımı vardı. Hastalarda ustekinumaba geçişin en yaygın nedeni önceki biyolojik ilaçlara yanıtızlıktı (%90). Ustekinumabın ortalama kullanım süresi 17,1±8 aydı. Takip sonunda CH'larının %71'inde CDAI<150 idi ve tam klinik remisyondaydı. ÜK hastalarının %53,8'inde SCCAI<5 idi ve tam klinik remisyondaydı. 13 ÜK hastasına kontrol kolonoskopi yapıldı ve 6'sında (%46,2) endoskopik remisyon görüldü. 5 CH'na kontrol kolonoskopi yapıldı ve 3 (%60) hastada endoskopik remisyon görüldü.



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Conclusion: Ustekinumab is an effective treatment method in achieving clinical remission in CD and UC resistant to previous treatments in the follow-up.

Keywords Crohn's disease · ulcerative colitis · ustekinumab

Sonuç: Ustekinumab, daha önceki tedavilere dirençli CH ve ÜK'de takipte klinik remisyon sağlanmasında etkili bir tedavi yöntemidir.

Anahtar Kelimeler Crohn hastalığı · ülseratif kolit · ustekinumab

INTRODUCTION

Inflammatory bowel diseases (IBD), which consist of Crohn's disease (CD) and ulcerative colitis (UC), are chronic inflammatory diseases of the gastrointestinal tract that progress with remissions and relapses.

IBD treatment consists of remission induction and maintenance. Options for treating IBD are increasing. 5-aminosalicylic acid, immunomodulatory drugs (methotrexate, azathioprine, and 6-mercaptopurine), biological agents (anti-tumour necrosis factor (Anti-TNF), anti-integrin, and anti-interleukin 12/23), and Janus kinase (JAK) inhibitors (small molecules) are used in the treatment (1). In cases of unresponsiveness to conventional treatments, biological agents have an important place in the treatment. Anti-TNFs, vedolizumab, ustekinumab, and small molecules should be selected according to the characteristics of the patient and the disease. However, in many countries, non-AntiTNF biologics are still preferred in the second or third step.

In this study, we aimed to investigate the effectiveness, sustainability, and side effects of ustekinumab in patients with CD and UC.

MATERIALS AND METHODS

A total of 48 CD and UC patients, who were unresponsive to previous treatments and therefore switched to ustekinumab (anti-interleukin 12/23) for their medical treatment, were investigated at the gastroenterology clinic of the Istanbul Faculty of Medicine between 2021 and 2024. The study was planned retrospectively. Patient information was obtained by examining the hospital data system. During their follow-up, all patients were given the first dose of ustekinumab intravenously according to their weight, and then 90 mg subcutaneous ustekinumab was administered every 8 weeks. The first dose of ustekinumab was given as 260 mg to patients weighing ≤ 55 kilogrammes (kg), 390 mg to patients weighing >55 - ≤ 85 kg, and 520 mg to patients weighing >85 kg. No dose increase was made to the patients during their follow-up.

The investigated variables of the patients were demographic data, characteristics of bowel diseases, treatment experiences, laboratory and endoscopic features, and disease scores.

It was classified according to the CD Montreal classification (2). According to this classification, CD was defined as A1 if

the age at diagnosis was ≤ 16 , A2 if it was between 17 and 40, and A3 if it was >40 . According to the disease location, those with ileal involvement were defined as L1, those with colonic involvement were defined as L2, those with ileocolonic involvement were defined as L3, and those with isolated upper gastrointestinal system involvement were defined as L4. According to the disease behaviour pattern, those with non-structuring and non-penetrating diseases were also listed as B1, those with structuring as B2, those with penetrating as B3, and those with the perianal disease were also specified.

Ulcerative colitis patients were classified as proctitis (E1), left colon involvement (E2), and pancolitis (E3).

CD clinical remission was examined with the Crohn's disease activity index (CDAI) score (3), and UC clinical remission was examined with the Simple Clinical Colitis Activity Index (SCCAI) score (4). CDAI ≤ 150 was defined as clinical remission for CD, and SCCAI ≤ 5 for UC.

Endoscopy control was performed for those who completed the 6th month after ustekinumab. Endoscopic remission in patients with CD was determined according to the simple endoscopic score for Crohn's disease (SES-CD) score (5). SES-CD=0-3 was considered endoscopic remission. SES-CD score of 4-10 is considered mild; 11-19 is considered moderate; and ≥ 20 is considered severely active. Endoscopic remission in UC patients was determined according to the MAYO subscore (6). MAYO subscore 0-1 endoscopic remission was accepted.

The requirement for written informed consent was waived due to the study's retrospective nature.

Ethics statement

This study was approved by the Istanbul Faculty of Medicine, Clinical Research Ethics Committee (Date: 15.12.2023, No: 25). All the applied procedures complied with the ethical standards of the Human Testing Committee of our institution and the Declaration of Helsinki.

Statistical analysis

In the descriptive statistics of the data, the mean, standard deviation, median (IQR 25-75), and frequency values were used. Categorical data are shown as numbers (n) and percentages (%). The independent samples t-test was used to analyse quantitative independent data. The paired sample t-test was used to analyse the dependent quantitative data. The chi-square test was used in the analysis of the independent



qualitative data. Statistical significance level of p value was <0.05 . Data analysis was performed using SPSS (IBM SPSS Corp., Armonk, NY, USA, version 22.0).

RESULTS

There were 48 CD and UC patients in our study. Of these, 35 (73%) had CD and 13 (27%) had UC. 26 (54.2%) of the patients were female and 22 (45.8%) were male. The mean age of the total group was 42.2 ± 13.3 (20-69) years, and the mean disease age was 136.8 ± 92 (17-516) months. When the groups were evaluated within themselves, the mean age of the CD patients was 42.4 ± 12 years, the mean age of the UC patients was 41.3 ± 16.8 years, and the CD and UK patients did not differ from each other in terms of age ($p=0.789$). The mean disease duration of CD was 125 ± 65.5 months, the mean disease duration of UC patients was 168.5 ± 139.5 months, and there was no difference between the disease ages of CD and UK patients ($p=0.298$). The features of patients are given in Table 1.

The mean duration of use of ustekinumab in the total group was 17.1 ± 8 (5-50) months. When the groups were examined separately, the mean duration of ustekinumab use in CD patients was 18.1 ± 8.2 months, the mean duration of ustekinumab use in UC patients was 14.3 ± 7.1 months, and there was no significant difference in terms of duration of ustekinumab use between the groups ($p=0.143$).

At the end of the follow-up, 71% ($n=25$) of the CD patients had $CDAI < 150$ and were in complete clinical remission, and 29% had $CDAI$ between 150 and 219 and were in partial clinical

remission. At the end of follow-up, 53.8% ($n=7$) of UC patients had $SCCAI < 5$ and were in complete clinical remission. The change in the clinical remission scores of the CD and UC patients over time with treatment is shown in Figures 1 and 2.

Control endoscopy was performed in 13 of the CD patients, and 6 of them (46.2%) were in endoscopically remission ($SES-CD < 4$) [median 6 months, IQR (25-75) (6-7.3)]. Control endoscopy was performed for 5 of the UC patients, and 3 (60%) were in endoscopically remission (MAYO subscore 0-1) [median 6 months, IQR (25-75) (6-6)].

When the patients were evaluated biochemically, haemoglobin and albumin values of the CD patients increased significantly during the treatment with ustekinumab ($p=0.001$ and $p=0.011$, respectively), while the platelet and sedimentation values significantly decreased ($p=0.026$ and $p=0.011$, respectively). Likewise, $CDAI$, which evaluates clinical remission in CD, decreased significantly with treatment ($p < 0.001$) (Table 2, Figure 1). In UC patients, haemoglobin values increased significantly with treatment, and sedimentation levels decreased significantly ($p=0.012$ and $p=0.027$, respectively). However, there was no significant change in $SCCAI$, which is considered the clinical remission score in UC patients ($p=0.058$) (Table 3, Figure 2).

No ustekinumab-related side effects were observed in any patient during their treatment.

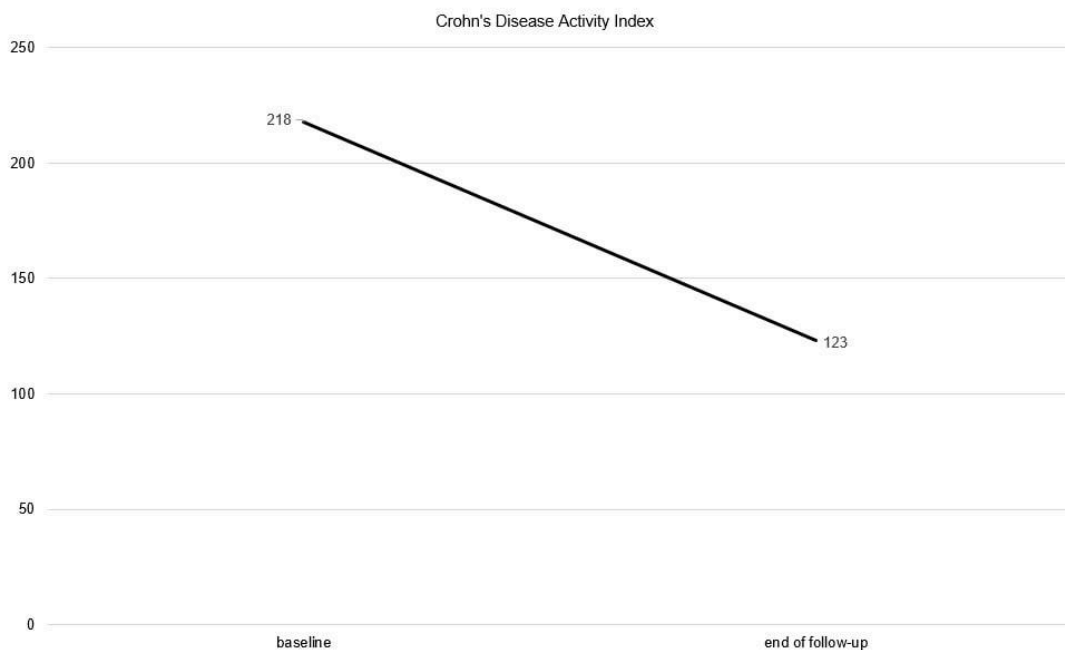


Figure 1. Crohn's disease activity index score in patients with Crohn's disease

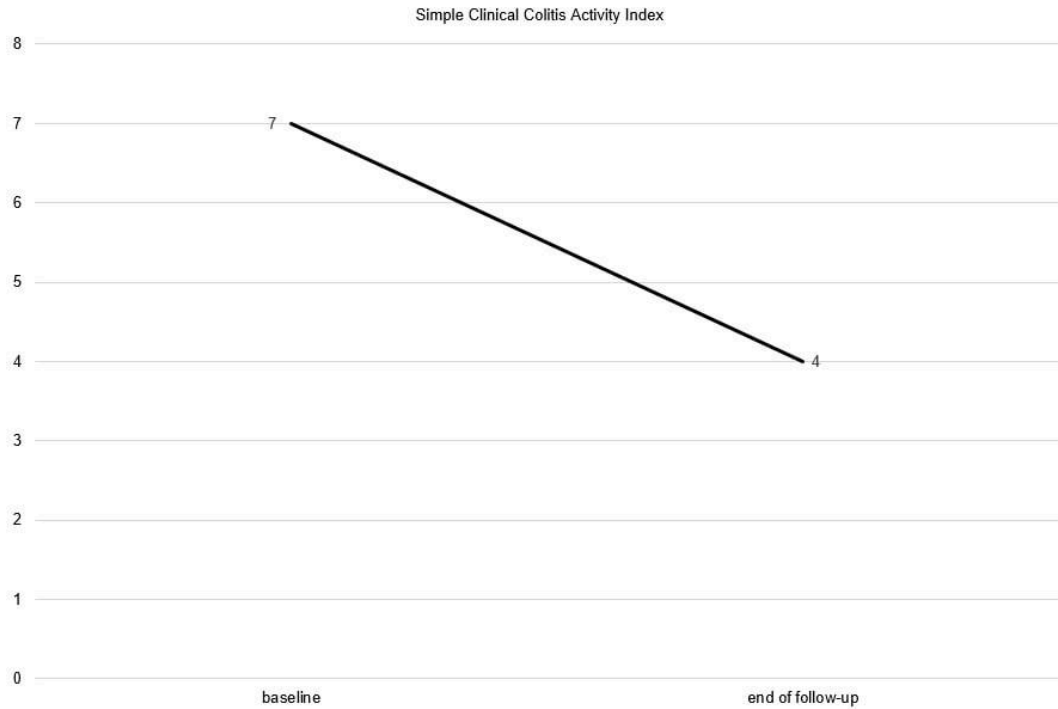


Figure 2. Simple clinical colitis activity index score in patients with ulcerative colitis

DISCUSSION

IBDs, including Crohn's disease and ulcerative colitis, are chronic inflammatory diseases of the gastrointestinal system that are characterised by abdominal pain, diarrhoea, blood in stools, weight loss, malnutrition, and fatigue. IBD progresses with remission and relapse. They present with varying severity from mild to severe activation due to inflammation (7).

For many years, many therapies have been implemented to treat IBD; however, there is still a challenge to manage the disease because there is no definite curative treatment. Drugs used for IBD treatment include 5-aminosalicylate, steroids, immunomodulators (azathioprine, methotrexate, and 6-mercaptopurine), biological agents, and JAK inhibitors (8). While immunomodulators are used only in remission maintenance, others are used in both remission induction and maintenance, and steroids are not used for a long time because of the side effects (9). In the present study, we evaluated the efficacy and safety of ustekinumab in patients with IBD. Our findings show that ustekinumab may represent an effective therapeutic option, with the potential to achieve both clinical and endoscopic remission. These results support the growing body of evidence regarding the role of biological therapies in optimising IBD management strategies.

Ustekinumab is a monoclonal antibody that targets the p40 subunit of interleukin 12 and interleukin 23 (IL12/23p40) (10). It is effective in both remission induction and maintenance for

both CD and UC (11, 12). In studies, ustekinumab was found to be superior to placebo in achieving clinical remission (11). In the study conducted by Engel et al. in 2019, examining 578 IBD patients, the response rate achieved in 1 year was found to be approximately 50%-60%. In another study conducted by Harris et al., the clinical response and remission rates were found to be 46% and 35%, respectively (13, 14). In our study, clinical remission was achieved at 71% in CD patients according to the CDAI score and 53.8% in UC patients according to the SCCAI score. While the response rates we received in CD patients are higher than those in the literature, our response rates in UC patients are similar to those in the literature.

In studies conducted, ustekinumab has also been shown to be very effective in endoscopic healing (15, 16). The administration of ustekinumab for both induction and maintenance therapy has a substantial SES-CD compared with the placebo (16). In our study, SES-CD was <4 in 46.2% of the CD patients who underwent control endoscopy. Likewise, ustekinumab was found to be superior to placebo in achieving endoscopic remission in UC patients (11). Ustekinumab was found to be effective in providing clinical and endoscopic remission in patients with anti-TNF failure (17).

Studies have evaluated the effectiveness of ustekinumab in IBD as well as its safety (18, 19). Ustekinumab demonstrated a relatively low level of immunogenicity when compared with the other biological agents. It has been observed that the development of antibodies against ustekinumab is quite low

Table 1. Clinical features of the study group

	All patients (n=48)	Crohn's disease (CD) (n=35)	Ulcerative colitis (UC) (n=13)	p
Gender (n, %)				
Female	26 (54.2)	22 (62.9)	4 (30.8)	0.098
Male	22 (45.8)	13 (37.1)	9 (69.2)	
Age (years) (mean±SD)	42.2±13.3	42.4±12	41.3±16.8	0.789
Disease age (months) (mean±SD)	136.8±92	125±65.5	168.5±139.5	0.298
Montreal classification of CD				
Age (years)				
A1 (<16) (n, %)		3 (8.6)		
A2 (17–40) (n, %)		23 (65.7)		
A3 (>40) (n, %)		9 (25.7)		
Disease localisation				
L1 (ileal) (n, %)		11 (31.4)		
L2 (colonic) (n, %)		4 (11.4)		
L3 (ileocolonic) (n, %)		20 (57.1)		
L4 (isolated upper disease) (n, %)		0		
Disease behaviour				
B1 (nonstructural, nonpenetrating) (n, %)		6 (17.1)		
B2 (structural) (n, %)		17 (48.6)		
B3 (penetrating) (n, %)		12 (34.3)		
p (perianal disease modifier) (n, %)		13 (37.1)		
Disease localisation for UC				
Proctitis (E1) (n, %)			0	
Left colon involvement (E2) (n, %)			3 (23)	
Pancolitis (E3) (n, %)			10 (77)	
Ustekinumab use duration (months) (mean±SD)	17.1±8	18.1±8.2	14.3±7.1	0.143
Using biological agents before ustekinumab (n, %)	48 (100)	35 (100)	13 (100)	
Reason for switching to ustekinumab (n, %)		Unresponsiveness to previous biologics (n=31, 88.6), development of allergy to previous biologics (n=3, 8.6), malignancy development with previous biologics (n=1, 2.8)	Unresponsiveness to previous biologics (n=12, 92.3), development of allergy to previous biologics (n=1, 7.7)	
Response to ustekinumab (clinical)				
CDAI <150 for CD		25 (71)	7 (53.8)	
SCCAI <5 for UC				
Response to ustekinumab (endoscopic)				
SES-CD <4 for CD (n=5)		3 (60)	6 (46.2)	
MAYO (0-1) for UC (n=13)				

CDAI: Crohn's Disease Activity Index, SCCAI: Simple Clinical Colitis Activity Index, SES-CD: Simple Endoscopic Score for Crohn's disease SD: Standard deviation

compared with other biological agents (20). In addition, the side effect profile of ustekinumab is quite low (21, 22). In our study, no side effects were observed in patients treated with ustekinumab.

Our study aimed to contribute to the literature by examining the effectiveness and safety of ustekinumab in patients with

IBD. However, the small number of patients and the short follow-up period are important limitations of this study. In this area, examining a larger number of patients and patients followed for a longer period will provide a more accurate analysis.



Table 2. Crohn's disease patients' laboratory changes

	Baseline	End of the follow-up [median 17, IQR (25- 75) (12 -23) months]	p
White blood cell (10 ³ /μl) (mean±SD)	7.3±2.9	7.4±1.3	0.970
Haemoglobin (g/dL) (mean±SD)	12.2±1.42	13.1±1.4	0.001
Platelet (10³/μl) (mean±SD)	339±140	280±114	0.026
Albumin (g/dL) (mean±SD)	4.1±0.4	4.39±0.3	0.011
C-reactive protein (mg/L) (mean±SD)	15.1±16.6	7.6±13.4	0.090
Erythrocyte sedimentation rate (mean±SD)	30.6±21.4	14.9±13.8	0.011
Crohn's Disease Activity Index (mean±SD)	218.4±45.9	123.1±54.1	<0.001

IQR: Interquartile range, μl: microliter, SD: Standard deviation, g/dL: grams/deciliter, mg/L: milligrammes/liter

Table 3. Ulcerative colitis patients' laboratory changes

	Baseline	End of the follow-up [median 15, IQR (25-75) (7- 20) months]	p
white blood cell (10 ³ /μl) (mean±SD)	9.3±3.3	8.55±3.5	0.477
Haemoglobin (g/dL) (mean±SD)	11.4±2.5	13.2±1.6	0.012
Platelet (10 ³ /μl) (mean±SD)	335.7±906.9	298.2±212.7	0.075
Albumin (g/dL) (mean±SD)	4.2±0.9	4.5±0.5	0.155
C-reactive protein (mg/L) (mean±SD)	14.2±15.4	10.9±17.4	0.374
Erythrocyte sedimentation rate (mean±SD)	35±23.2	19.1±22.5	0.027
Simple Clinical Colitis Activity Index (mean±SD)	7±2.2	4±4.6	0.058

IQR: Interquartile range, μl: microliter, SD: Standard deviation, g/dL: grams/deciliter, mg/L: milligrammes/liter

CONCLUSION

Ustekinumab appears to be highly effective, sustainable, and safe in achieving clinical and endoscopic remission in patients with difficult-to-treat IBD.



Ethics Committee Approval Ethics committee approval was received for this study from the ethics committee of İstanbul University, İstanbul Faculty of Medicine, Clinical Research Ethics Committee (Date: 15.12.2023, No: 25).

Informed Consent The requirement for written informed consent was waived due to the study's retrospective nature.

Peer Review Externally peer-reviewed.

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