Clinical characteristics and treatment patterns of ustekinumab in patients with Crohn's disease: Sub-group analysis from a one-year prospective nationwide K-STAR study in Korea

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Key takeaways

- **Key predictors of enhanced response to ustekinumab in Korean CD patients were identified.**
- **The results can guide clinicians in identifying patients most likely to benefit from ustekinumab and optimizing treatment strategies.**

Background

- Ustekinumab is approved for moderate-to-severe Crohn's disease (CD), however, real-world evidence on treatment patterns and patient characteristics among Korean patients is still limited.
- The previous findings from K-STAR study (Post-Mar**K**eting Surveill**A**nce for Crohn's Disease patients treated with **ST**EL**AR**A®) confirmed ustekinumab's effectiveness and safety in Korean CD patients, but gaps remain in understanding responder profiles and real-world treatment patterns.[1]

Objective

To identify patient profiles and characterize treatment patterns of ustekinumab in Korean patients with CD

Methods

- K-STAR is a prospective, multicenter, non-interventional study to demonstrate the safety and effectiveness of ustekinumab in Korean patients with CD under real clinical practice (ClinicalTrials.gov Identifier: NCT03942120).
- Adult CD patients treated with ustekinumab were prospectively enrolled in the K-STAR study from April 2018 to April 2022. Patients who were contraindicated with ustekinumab based on the product label in Korea were excluded.
- "Super-responders" were defined as patients maintaining clinical remission at all post-baseline visits.
- Data on demographics, disease characteristics, treatment patterns, and outcomes were collected and analyzed descriptively.

Results

Table 1. Baseline characteristics by clinical remission status

Variable	Non-Super-responder (N=151)	Super-responder (N=78)	*P*-value
Sex			0.7899
Male	98 (64.9)	52 (66.7)	
Female	53 (35.1)	26 (33.3)	
Age at enrollment (years)	35.1±11.9	36.7±13.6	0.5206
Age at diagnosis of CD (years)	**25.9±12.3**	**29.4±13.2**	**0.0371**
Body mass index (kg/m^2) (n=227)	**20.4±4.0**	**22.2±3.5**	**<0.0001**
Disease duration (months)	**111.1±77.0**	**88.8±83.2**	**0.0088**
Active smoker* (n=213)	**8 (5.8)**	**6 (7.9)**	**0.5738**
Disease location (n=200)			0.0565
L1, Ileum	**25 (18.5)**	**22 (33.8)**	
L2, Colon	12 (8.9)	5 (7.7)	
L3, Ileocolon	98 (72.6)	38 (58.5)	
L4, Upper disease	20 (14.8)	12 (18.5)	0.5100
Disease behavior (n=195)			0.8990
B1, Nonstricturing, nonpenetrating	46 (35.1)	24 (37.5)	
B2, Stricturing	57 (43.5)	28 (43.8)	
B3, Penetrating	28 (21.4)	12 (18.8)	
Perianal disease modifier	40 (30.5)	15 (23.4)	0.3011
Crohn's Disease Activity Index (n=223)	**298.8±69.2**	**270.4 ±41.0**	**0.0045**
C-Reactive Protein at baseline (mg/dL) (n=298)	**3.2±5.6**	**1.4±1.7**	**0.0121**
Fecal calprotectin (µg/g) (n=57)	2334.9 ±2270.1	1401.5 ±1657.3	0.0598
SIBDQ score (n=201)	**38.8±12.0**	**44.0±11.3**	**0.0096**
Prior exposure to biologic treatment(s) (n=229)	**105 (69.5)**	**32 (41.0)**	**<0.0001**
Number of prior biologics (n=229)			**0.0006**
1	62 (41.1)	20 (25.6)	
2	30 (19.9)	8 (10.3)	
3	13 (8.6)	4 (5.1)	
Type of biologics (n=229)			
Infliximab	**80 (53.0)**	**25 (32.1)**	**0.0026**
Adalimumab	**51 (33.8)**	**14 (17.9)**	**0.0118**
Vedolizumab	30 (19.9)	9 (11.5)	0.1120
Infliximab + Adalimumab	30 (19.9)	8 (10.3)	0.0639
Anti-TNF agent + Vedolizumab	26 (17.2)	8 (10.3)	0.1602
Prior intestinal resection(s)	54 (35.8)	23 (29.5)	0.3408
Concomitant medication			
5-ASA	67 (44.4)	44 (56.4)	0.0841
Systemic corticosteroids	**54 (35.8)**	**11 (14.1)**	**0.0006**
Immunomodulators	76 (50.3)	49 (62.8)	0.0720

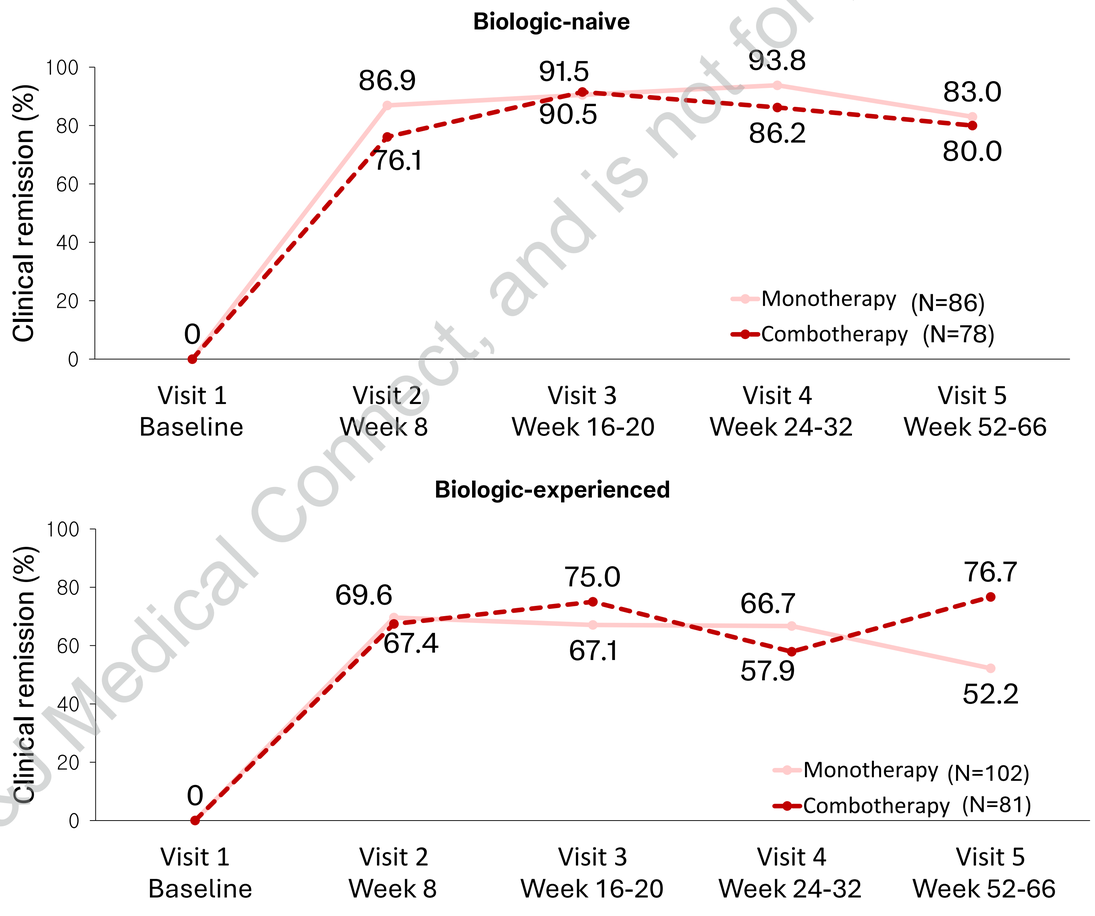
- Numerically more super-responders had L1 disease at baseline (33.8% vs. 18.5%) and fewer had L3 disease (58.5% vs. 72.6%) compared to non-super-responders.

Table 2. Baseline characteristics by treatment modality – Monotherapy and combination therapy (with immunomodulators)

Variable	Monotherapy (N=189)	Combination therapy (N=159)	*P*-value
Sex			0.7765
Male	124 (65.6)	102 (64.2)	
Female	65 (34.4)	57 (35.8)	
Age at enrollment (years)	**37.8±14.0**	**33.7±11.8**	**0.0080**
Age at the diagnosis of CD (years)	**29.9±13.9**	**25.6±11.4**	**0.0012**
Body mass index (kg/m^2) (n=345)	21.3±3.9	21.3±3.6	0.9957
Disease duration (months)	95.6±84.3	97.5±75.8	0.5726
Disease location (n=282)			0.7954
L1, Ileum	41 (26.5)	30 (23.6)	
L2, Colon	11 (7.1)	11 (8.7)	
L3, Ileocolon	103 (66.5)	86 (67.7)	
L4, Upper disease (n=282)	17 (11.0)	21 (16.5)	0.1731
Active smoker* (n=315)	**14 (8.0)**	14 (9.9)	0.5592
Disease behavior (n=277)			0.6695
B1, Nonstricturing, nonpenetrating	66 (43.1)	47 (37.9)	
B2, Stricturing	62 (40.5)	54 (43.5)	
B3, Penetrating	25 (16.3)	23 (18.5)	
Perianal disease modifier	**27 (17.6)**	**38 (30.6)**	**0.0111**
Crohn's Disease Activity Index (n=337)	289.2±61.1	282.0±60.8	0.1238
CRP at baseline (mg/dL) (n=284)	2.1±4.5	2.3±5.5	0.5331
Fecal calprotectin (µg/g) (n=64)	1758. 0±1693.0	1848.0 ±2148.8	0.9564
SIBDQ score (n=201)	41.4±13.4	43.3±11.2	0.2065
Prior exposure to biologic treatment(s) (n=347)	102 (54.3)	81 (50.9)	0.5381
Number of prior biologics (n=229)			**0.0006**
Naïve	86 (45.7)	78 (49.1)	
1	69 (36.7)	50 (31.4)	
2	25 (13.3)	25 (15.7)	
3	8 (4.3)	6 (3.8)	
Type of biologics (n=347)			
Infliximab	70 (37.2)	63 (39.6)	0.6484
Adalimumab	48 (25.5)	37 (23.3)	0.6255
Vedolizumab	25 (13.3)	18 (11.3)	0.5776
Infliximab + Adalimumab	21 (11.2)	22 (13.8)	0.4526
Anti-TNF agent + Vedolizumab	20 (10.6)	15 (9.4)	0.7105
Prior intestinal resection(s)	55 (29.1)	44 (27.7)	0.7687
Concomitant medication			
5-ASA	**65 (34.4)**	**102 (64.2)**	**<0.0001**
Immunomodulators	**0 (0.0)**	**159 (100.0)**	**<0.0001**

Values are presented as Mean±SD or number (%).
*Patients who have ever smoked within 6 months before enrollment or who were smoking at enrollment.

Figure 1. Clinical remission status by treatment modality throughout 1 year



- Higher proportion of biologic-naïve patients achieved clinical remission throughout the 1-year follow-up compared with biologic-experienced patients.
- Among biologic-experienced patients, those on combination therapy showed numerically higher rates of clinical remission V5 compared with those on monotherapy (76.7% vs. 52.2%) but did not reach statistical significance.

Table 3. Baseline characteristics of patients by dose group – Q12W and Q12W to Q8W

Variable	Q12W (N=193)	Q12W to Q8W (N=126)	*P*-value
Sex			0.4286
Male	125 (64.8)	87 (69.0)	
Female	68 (35.2)	39 (31.0)	
Age at enrollment (years)	35.2±12.9	36.3±12.3	0.3001
Age at the diagnosis of CD (years)	28.3±12.6	26.6±12.0	0.1988
Body mass index (kg/m^2) (n=316)	**21.9±3.7**	**20.8±4.1**	**0.0030**
Disease duration (months)	**83.3±74.5**	**116.3±76.4**	**<0.0001**
Active smoker* (n=294)	**17 (9.6)**	**11 (9.5)**	**0.9846**
Disease location (n=262)			0.8377
L1, Ileum	34 (22.5)	26 (23.4)	
L2, Colon	17 (11.3)	10 (9.0)	
L3, Ileocolon	100 (66.2)	75 (67.6)	
L4, Upper disease (n=262)	16 (10.6)	20 (18.0)	0.0847
Disease behavior at baseline (n=256)			**0.0068**
B1, Nonstricturing, nonpenetrating	71 (49.0)	36 (32.4)	
B2, Stricturing	55 (37.9)	46 (41.4)	
B3, Penetrating	19 (13.1)	29 (26.1)	
Perianal disease modifier (n=256)	**23 (15.9)**	**44 (39.6)**	**<0.0001**
Crohn's Disease Activity Index (n=311)	284.6±67.5	278.2±56.0	0.3892
C-Reactive Protein at baseline (mg/dL) (n=262)	**2.1±4.1**	**2.2±4.8**	**0.0934**
Fecal calprotectin (µg/g) (n=68)	**1278.5 ±1345.3**	**2313.3 ±2235.8**	**0.0352**
SIBDQ score (n=281)	42.9±11.9	41.7±11.9	0.5128
Prior exposure to biologic treatment(s) (n=318)	**70 (36.5)**	**95 (75.4)**	**<0.0001**
Number of prior biologics (n=318)			**<0.0001**
naïve	122 (63.5)	31 (24.6)	
1	47 (24.5)	49 (38.9)	
2	20 (10.4)	30 (23.8)	
3	3 (1.6)	16 (12.7)	
Type of biologics (n=318)			
Infliximab	**52 (27.1)**	**76 (60.3)**	**<0.0001**
Adalimumab	**31 (16.1)**	**51 (40.5)**	**<0.0001**
Vedolizumab	**13 (6.8)**	**30 (23.8)**	**<0.0001**
Infliximab + Adalimumab	**14 (7.3)**	**35 (27.8)**	**<0.0001**
Anti-TNF agent + Vedolizumab	**12 (6.3)**	**27 (21.4)**	**<0.0001**
Prior intestinal resection(s)	**47 (24.4)**	**48 (38.1)**	**0.0087**
Concomitant medication			
5-ASA	90 (46.6)	69 (54.8)	0.1557
Systemic corticosteroids	48 (24.9)	39 (31.0)	0.2331
Immunomodulators	100 (51.8)	76 (60.3)	0.1354

Values are presented as Mean±SD or number (%).
*Patients who have ever smoked within 6 months before enrollment or who were smoking at enrollment.

- Patients requiring dose escalation from Q12W to Q8W had longer disease duration (116.3 vs. 83.3 months), greater prior biologic exposure (75.4% vs. 36.5%), and more complicated disease behavior (stricturing: 41.4% vs. 37.9%; penetrating: 26.1% vs. 13.1%).

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5-ASA, 5-aminosalicylic acid; **anti-TNF,** anti-tumor necrosis factor; **CD,** Crohn's disease; **CRP,** C-reactive protein; **SD,** standard deviation; **SIBDQ,** Short Inflammatory Bowel Disease Questionnaire.

REFERENCE: 1. Lee CK, *et al. Inflamm Bowel Dis.* 2025 May 12;31(5):1306-1316.

CONFLICT OF INTEREST: *Jong Min Choi, Youngdoe Kim, and YoungJa Lee are employees of Jonhson & Johnson Korea. All other authors declare no conflict of interest.*