

Real world evidence of Ustekinumab on health-related quality of life in patients with Crohn's disease: A Prospective nationwide K-STAR study in Korea

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Key takeaways

- Ustekinumab treatment was associated with sustained improvements in QoL over one year in Korean CD patients.
- The correlation between clinical remission and quality of life improvement underscores the importance of disease control in enhancing patient-reported outcomes.

Background

- Ustekinumab has demonstrated clinical effectiveness in Crohn's disease (CD), but its impact on health-related quality of life (HRQoL) in real clinical practice in Korean patients were still limited.
- The previous findings from K-STAR study (Post-Marketing Surveillance for Crohn's Disease patients treated with **STELARA**) confirmed ustekinumab's effectiveness and safety in Korean CD patients. In this PMS study, QoL was measured with the SIBDQ, underscoring the significance of patient-focused outcomes in determining therapeutic effectiveness.

Objective To evaluate the long-term effect of ustekinumab on HRQoL in Korean patients with moderate-to-severe CD

Results

- Among 464 enrolled patients, 368 completed baseline SIBDQ assessments with 139 completing assessments through week 52-66.
- Baseline CDAI scores were significantly higher in patients with severely impaired QoL (298.7±72.6) versus moderately (269.6±44.2) or slightly (265.0±34.7) impaired QoL.

Table 1. Baseline characteristics by SIBDQ severity subgroup at baseline

Variable	Slightly (>60) (N=30)	Moderately (45-60) (N=133)	Severely (<45) (N=205)	P-value
Sex				0.2964
Male	23 (76.7)	92 (69.2)	131 (63.9)	
Female	7 (23.3)	41 (30.8)	74 (36.1)	
Age at enrollment (years)	36.2 ±12.1	36.2 ±13.1	33.8 ±12.2	0.1615
Age at the diagnosis of CD (years)	29.7 ±13.3	28.2 ±12.1	25.3 ±11.9	0.0149
BMI (kg/m²)	22.0 ±2.9	21.8 ±3.8	20.8 ±3.9	0.0046
Disease duration (months)	79.4 ±49.3	94.8 ±81.3	103.1 ±75.2	0.2006
Active smoker* (n=349)	2 (7.1)	16 (13.1)	17 (8.5)	0.3618
Disease Location at baseline (n=305)				0.2314
L1, Ileum	7 (25.9)	26 (24.3)	27 (15.8)	
L2, Colon	2 (7.4)	8 (7.5)	23 (13.5)	
L3, Ileocolon	18 (66.7)	73 (68.2)	121 (70.8)	
L4, Upper disease	2 (7.4)	20 (18.7)	24 (14.0)	0.2899
Disease behavior at baseline (n=300)				0.7766
B1, Nonstricturing, nonpenetrating	9 (34.6)	41 (38.7)	75 (44.6)	
B2, Stricturing	11 (42.3)	43 (40.6)	58 (34.5)	
B3, Penetrating	6 (23.1)	22 (20.8)	35 (20.8)	
Perianal disease modifier	4 (15.4)	22 (20.8)	52 (31.0)	0.0750
CDAI (n=357)	265.0 ±34.7	269.6 ±44.2	298.7 ±72.6	<0.0001
CRP at baseline (mg/dL) (n=298)	0.7 ±1.1	1.4 ±2.5	3.1 ±5.8	0.0002
Fecal calprotectin at baseline (µg/g) (n=72)	571.0 ±622.2	1864.1 ±1752.4	1828.4 ±2191.3	0.1868
SIBDQ score (n=368)	64.4 ±2.8	51.2 ±4.6	33.5 ±7.5	0.0096
Prior exposure to biologic treatment(s) (n=367)	15 (50.0)	67 (50.8)	119 (58.0)	0.3637
Number of prior biologics (n=367)				0.0318
1 biologic	14 (46.7)	46 (34.8)	64 (31.2)	
2 biologics	1 (3.3)	14 (10.6)	44 (21.5)	
3 biologics	0 (0.0)	7 (5.3)	11 (5.4)	
Type of biologics (n=367)				
Infliximab	9 (30.0)	52 (39.4)	92 (44.9)	0.2429
Adalimumab	6 (20.0)	27 (20.5)	58 (28.3)	0.2178
Vedolizumab	1 (3.3)	16 (12.1)	35 (17.1)	0.0919
Infliximab + Adalimumab	1 (3.3)	14 (10.6)	36 (17.6)	0.0430
Anti-TNF agent + Vedolizumab	0 (0.0)	14 (10.6)	30 (14.6)	0.0583
Prior intestinal resection(s)				
Yes	13 (43.3)	39 (29.3)	54 (26.3)	0.1563
Concomitant medication				
5-ASA	11 (36.7)	66 (49.6)	114 (55.6)	0.1228
Systemic corticosteroids	5 (16.7)	27 (20.3)	71 (34.6)	0.0058
Immunomodulators	15 (50.0)	77 (57.9)	117 (57.1)	0.7274

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

Table 2. SIBDQ score according to biologic experience by visit

Visit	SIBDQ		
	Total	Bio-Naïve	Bio-Experienced
Visit 1 (Baseline)	n=368	n=166	n=201
Median (range)	43 (13 to 70)	44 (15 to 70)	40 (13 to 70)
95% CI	41.13, 43.65	42.62, 46.20	38.91, 42.40
P-value	-		0.0051
Visit 3	n=284	n=130	n=153
Median (range)	53 (16 to 70)	56 (27 to 70)	50 (16 to 70)
95% CI	49.62, 52.35	52.23, 55.91	46.38, 50.19
P-value	-		<0.0001
Visit 5	n=139	n=54	n=85
Median (range)	51 (24 to 70)	55 (34 to 70)	49 (24 to 70)
95% CI	48.15, 51.85	51.11, 56.74	45.18, 49.83
P-value	-		0.0013

- Patients achieving clinical remission demonstrated significant SIBDQ improvements (from 45 to 53), while non-remitters showed minimal change.

Table 3. SIBDQ score according to 1-year clinical remission by visit

Visit	SIBDQ	
	Non-remission at Visit 5	Clinical remission at Visit 5
Visit 1 (Baseline)	n=70	n=196
Median (range)	37 (13 to 64)	45 (13 to 70)
95% CI	34.50, 40.18	42.61, 45.98
P-value		0.0001
Visit 3	n=64	n=147
Median (range)	45 (16 to 68)	55 (23 to 70)
95% CI	41.87, 47.95	51.19, 54.66
P-value		<0.0001
Visit 5	n=35	n=85
Median (range)	39 (24 to 66)	53 (33 to 70)
95% CI	40.04, 48.18	49.67, 53.91
P-value		0.0018

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.
- HRQoL was assessed using SIBDQ at baseline, visit 3 (weeks 16-20), and visit 5 (weeks 52-66). SIBDQ scores were categorized as severely (10-45), moderately (45-60), or slightly (60-70) impaired.

- In patients with severely impaired quality of life, median SIBDQ scores improved from 43 at baseline to 51 at visit 5.
- Biologic-naïve patients showed greater SIBDQ improvements than biologic-experienced patients (+10.0 vs +7.0).
- The proportion of patients with severely impaired QoL decreased from 55.7% to 30.2%.
- Baseline SIBDQ score ($p<0.0001$), BMI ($p=0.0233$), and disease duration ($p=0.0110$) emerged as clinical factors associated with SIBDQ improvement.

Figure 1. SIBDQ score change from baseline by visit (As observed)

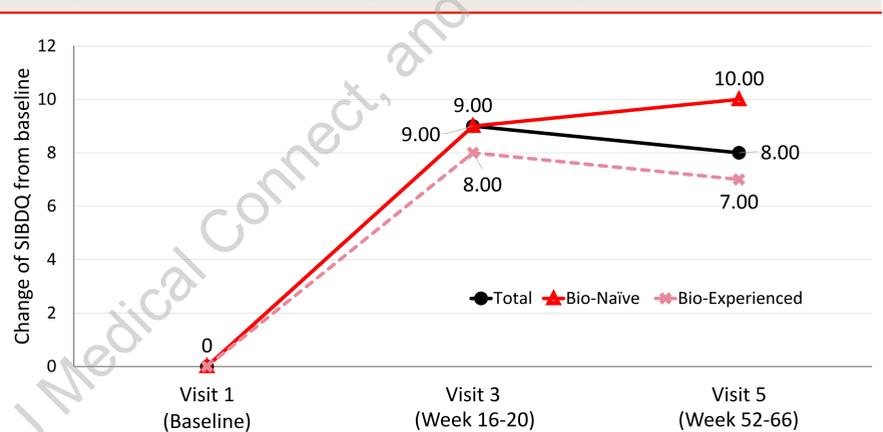


Figure 2. Proportion of patients with SIBDQ severity subgroup by prior biologics exposure

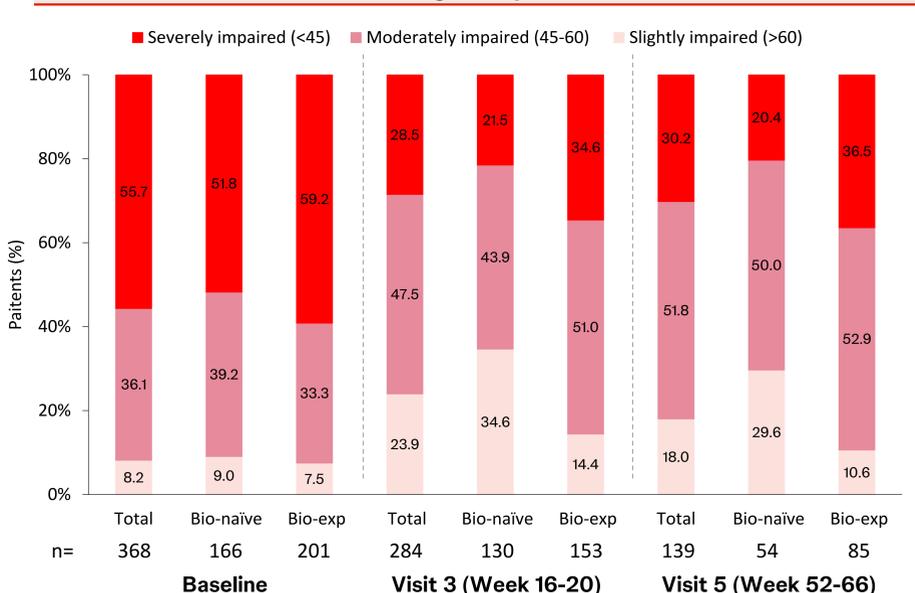


Table 4. Clinical factors associated with improvement in SIBDQ scores after ustekinumab treatment

Variable	Univariate				Multiple (Backward Selection)		
	Reference	Beta	SE	P-value	Beta	SE	P-value
SIBDQ at Baseline	-	-	-	-	0.47	0.082	<.0001
Sex=Female	Male	1.98	1.722	0.2524	3.13	1.911	0.1049
Age group at diagnosis: 17-40	0-16	3.40	2.470	0.1704	-	-	-
Age group at diagnosis: >40	0-16	4.60	3.134	0.1443	-	-	-
BMI (kg/m²)	-	0.46	0.215	0.0332	0.55	0.239	0.0233
Disease Duration (months)	-	-0.03	0.011	0.0141	-0.03	0.013	0.0110
Active smoker=Yes	No	-0.51	2.920	0.8606	-	-	-
CDAI score	-	-0.02	0.014	0.0856	-	-	-
Disease location: L2, Colon	L1, Ileum	-3.04	4.209	0.4714	-	-	-
Disease location: L3, Ileocolon		-0.25	2.272	0.9124	-	-	-
Disease location: L4, Upper disease = Yes	No	-3.92	2.447	0.1116	-	-	-
Disease location: B2, Stricturing	B1, nonstricturing, nonpenetrating	-1.98	1.999	0.3244	-	-	-
Disease location: B3, Penetrating	B1, nonstricturing, nonpenetrating	-5.62	2.443	0.0234	-	-	-
Disease location: p, Perianal disease modifier = Yes	No	0.15	2.005	0.9389	-	-	-
CRP at baseline (mg/dL)	-	0.37	0.340	0.2802	0.48	0.327	0.1488
Bio-Experienced	Bio-Naïve	-5.38	1.625	0.0012	-	-	-
Number of prior biologics = 1	0	-4.71	1.751	0.0081	-	-	-
Number of prior biologics ≥ 2	0	-6.98	2.246	0.0023	-	-	-
Prior intestinal resection(s): Yes	No	-3.47	1.682	0.0412	-	-	-

Baseline SIBDQ score was used as base-covariate.

5-ASA, 5-aminosalicylic acid; BMI, body mass index; CD, Crohn's disease; CDAI, Crohn's disease activity index; CI, confidence interval; CRP, c-reactive protein; HRQoL, health-related quality of life; QoL, quality of life; SD, standard deviation; SE, standard error; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; TNF, tumor necrosis factor.
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 Johnson & Johnson Korea. All other authors declare no conflict of interest.



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