PGI50: THE RELATIONSHIP BETWEEN DISEASE SEVERITY AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ULCERATIVE COLITIS IN JAPAN

Hiroyo Kuwabara, Masafumi Kato, Kaoru Yamabe

Healthcare Policy and Access, Takeda Pharmaceutical Company Limited, Tokyo, Japan

BACKGROUND AND OBJECTIVE

- Patients with ulcerative colitis (UC) experience abdominal pain, frequent diarrhea, and bloody stool during the active phase of their disease, which significantly impact patients' health-related quality of life (HRQOL).
- Understanding a patient's HRQOL along with their disease severity is important for guiding discussions about choice of treatment and allowing shared decision-making between patients and physicians.
- The objective of this study was to assess the relationship between disease severity and HRQOL in patients with UC in Japan

METHODS

Study design

A multi-center, cross-sectional observational study

Patients

Patients meeting the following criteria were recruited during their routine clinical visits for the treatment of UC.

<Inclusion criteria>

- Aged ≥ 18 and ≤ 80 years at the time of informed consent
- Diagnosed with total or left-sided UC, based on the "Revised Diagnostic Criteria for UC"[1]

<Exclusion criteria>

- Had any disease except UC that an investigator determined may affect HRQOL
- Had a colectomy
- Participated in any other clinical studies within the preceding 12 weeks

This study was approved by independent ethics committees and written informed consent was obtained by participants at study enrollment.

Assessments and data collection

<Disease severity assessed by investigators>

The 3-item Partial Mayo (pMayo) score was used. Investigators interviewed patients about stool frequency, rectal bleeding, and general condition and evaluated each subscore. Patients were categorized by total pMayo score using thresholds from previous studies (remission: 0–2; mild disease: 3–4; moderate-to-severe disease: ≥ 5).[2,3]

<HRQOL assessed by patients>

Patients were requested to fill out three questionnaires before seeing investigators.

- Inflammatory Bowel Disease Questionnaire (IBDQ)
- European Quality of Life – 5 Dimensions Questionnaire (EQ-5D-5L)
- Work Productivity and Activity Impairment Questionnaire (WPAI)

<Others>

Patient demographics and disease characteristics

Statistical analysis

- Patient demographics and disease characteristics were summarized using descriptive statistics. To assess the relationships between UC disease severity, HRQOL measures (IBDQ and EQ-5D-5L), and WPAI scores, trend tests were used.
- $P < 0.05$ was considered to be statistically significant.

RESULTS

- A total of 319 outpatients were enrolled from 12 health facilities in Japan between July 2017 and December 2017.(Table 1) Of these, 59.9% of patients were in remission, 22.6% had mild disease severity, and 17.6% had moderate-to-severe disease severity. (Table 2)
- Mean IBDQ scores for patients in remission, with mild disease severity, and with moderate-to-severe disease severity were 190.5, 165.8, and 149.7, respectively. The differences between these scores were statistically significant ($p < 0.001$).
- All mean IBDQ subscores, EQ-5D utility and visual analog scores, and WPAI subscores were also significantly different between the disease severity groups. Patients are in an active disease phase, especially with moderate-to-severe disease, their HRQOL is substantially impaired (Figures 1&2, Table3)

Figure 2. Mean percentages of impairment of work productivity and activity impairment due to UC stratified by disease severity group

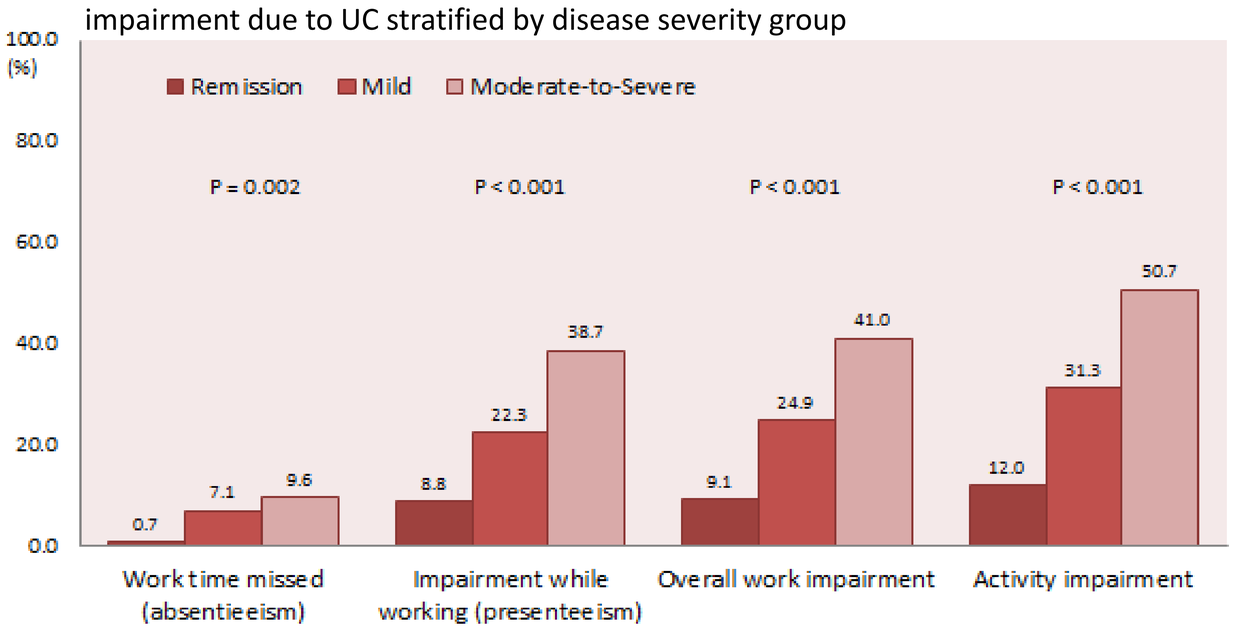


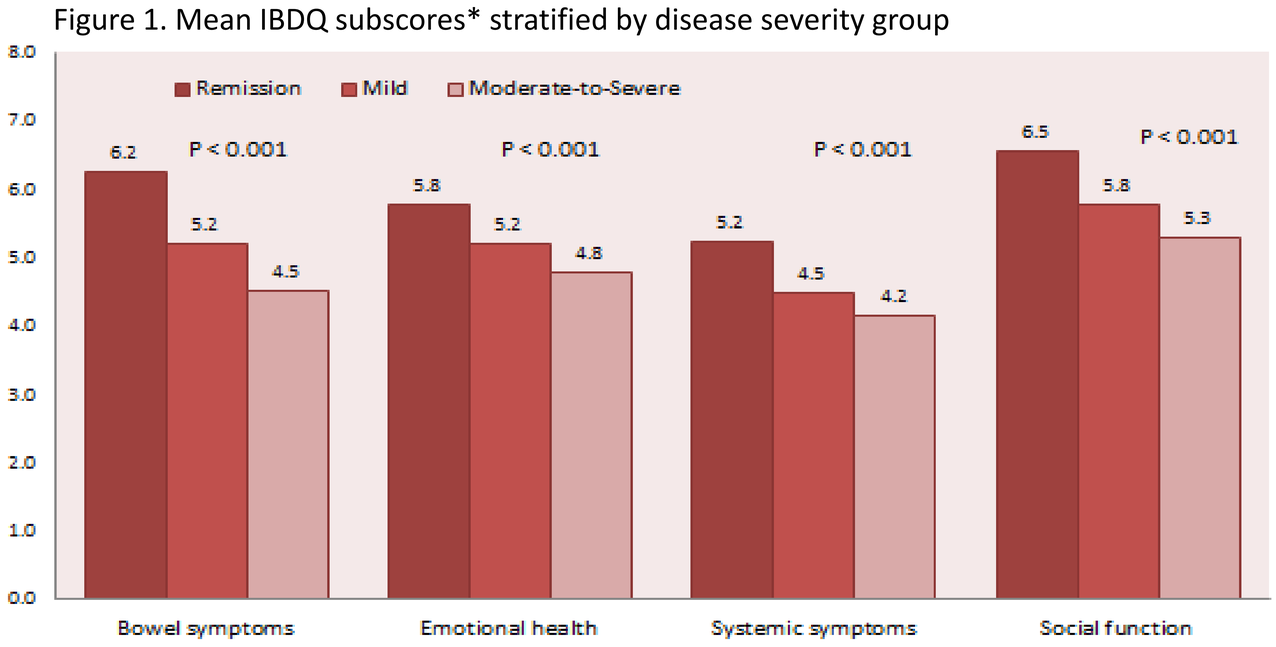
Table 1. Patient background

Characteristics	All patients (N = 319)
Age (years), mean (standard deviation: SD)	46.0 (15.4)
Male sex, %	53.6
Weight (kg), mean (SD)	60.4 (13.2)
Smoker, %	8.8
Current employment status, %	
Full-time	52.0
Part-time	16.3
Unemployed due to UC	0.9
Unemployed due to reasons other than UC	0.6
Other (student, retired, stay-at-home parent, etc)	30.1
Duration of disease (months), mean (SD)	120 (93.7)
Site of disease, n (%)	
Left-sided colitis	190 (59.6)
Total colitis	129 (40.4)
Steroid resistance, n (%)	33 (10.3)
Steroid dependence, n (%)	80 (25.1)
Treatment history with anti-TNF-alpha agonist, n (%)	132 (41.4)

Table 2. Summary of disease severity assessed by partial Mayo

pMayo			All patients
Stool frequency, n (%)	Normal	0	137 (42.9)
	1–2 stools/day more than normal	+1	93 (29.2)
	3–4 stools/day more than normal	+2	52 (16.3)
	> 4 stools/day more than normal	+3	37 (11.6)
Rectal bleeding, n (%)	None	0	219 (68.7)
	Visible blood with stool less than half the time	+1	67 (21.0)
	Visible blood with stool half of the time or more	+2	33 (10.3)
	Passing blood alone	+3	0 (0)
Physician rating, n (%)	Normal	0	146 (45.8)
	Mild	+1	117 (36.7)
	Moderate	+2	53 (16.6)
	Severe	+3	3 (0.9)
Score	Mean (SD)		2.1 (2.2)
Disease severity subgroup by pMayo, n (%)	Remission (0–2)		191 (59.9)
	Mild (3–4)		72 (22.6)
	Moderate-to-Severe (≥ 5)		56 (17.6)

Figure 1. Mean IBDQ subscores* stratified by disease severity group



* Higher scores indicate a better HRQOL

Table 3. Mean(SD) EQ-5D-5L scores stratified by disease severity group

	EQ-5D-5L	
	Utility score	Visual analog scale
Remission	0.935 (0.101)	80.5 (14.3)
Mild	0.856 (0.112)	71.4 (17.3)
Moderate to Severe	0.792 (0.132)	57.6 (16.5)
P-value	< 0.001	< 0.001

CONCLUSIONS

- The present study suggested that UC disease severity is associated with patients' HRQOL in Japan. The greater the disease severity the patients had, the greater impairment they experienced in terms of both disease-specific and general HRQOL, as well as work productivity and daily activity.
- HRQOL measures can be a useful tool for choosing treatments for patients and physicians. Further research is needed to assess the impact of treatment on HRQOL in patients with UC in order to maximize patients' HRQOL .

References: 1. "Diagnostic Criteria and Treatment Guideline for Ulcerative Colitis and Crohn's Disease," Research Group for Intractable Inflammatory Bowel Disease" Designated as Specified Disease by the MHLW of Japan (the Group of Dr. Watanabe), the additional volume of Assigned Study Report in 2012. 2. Lewis JD, et al. Use of the non-invasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis. 2008; 14: 1660-6. 3. Gibson PR, et al. Relationship between disease severity and quality of life and assessment of health care utilization and cost for ulcerative colitis in Australia: A cross-sectional, observational study. J Crohna Xoliria 2014;8:598-606.

This study was funded by Takeda Pharmaceutical Company Limited.