

# THE IMPACT OF MMX<sup>®</sup> MESALAMINE TREATMENT ON THE DISEASE-SPECIFIC, HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH ULCERATIVE COLITIS

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## Background

- Improving health-related quality of life (HRQoL) of patients with ulcerative colitis (UC) is a fundamental goal of treatment.
- 5-aminosalicylic acid (5-ASA), or mesalamine, is the recommended first-line therapy for mild-to-moderate UC, due to demonstrated efficacy and a good safety profile.
- No study has measured UC patients' disease-specific HRQoL following treatment with the recently developed multi-matrix (MMX) formulation of mesalamine, which provides a higher concentration per pill (1.2g) than any previous formulation.

## Objectives

- To examine changes in disease-specific HRQoL in mild-to-moderate active UC patients after receiving daily MMX mesalamine 2.4–4.8g/day for 8 weeks.
- To examine the association between changes in HRQoL and disease activity.

## Methodology

### Study population and design

- Data were collected from the Strategies in Maintenance for Patients Receiving Long-term Therapy (SIMPLE) trial, a phase IV, multi-center, single-arm, open-label trial that consisted of an 8-week acute phase and a 12-month maintenance phase.
- The data presented in the current analyses are from the acute phase, during which adult patients with active mild-to-moderate UC received MMX mesalamine 2.4–4.8g/day treatment for 8 weeks (dose titrated based on physician decision).
- Study outcome measures were assessed at the acute phase baseline and 8-week endpoint.

### Study outcomes

**HRQoL measure: SIBDQ** (Shortened version of the Inflammatory Bowel Disease Questionnaire)

- 10 item self-report IBD-specific health survey with a 2-week recall period.
- Includes 4 domains measuring impact of IBD on functional health and well-being
  - bowel symptoms
  - systemic symptoms
  - emotional function
  - social function.
- Provides a total score to measure overall impact of IBD on HRQoL.
- Each scale is the sum of responses to particular items; the total score is the sum of responses to all items.
- Higher scores indicate better health.

**Disease activity measures: stool frequency (SF) and rectal bleeding severity (RBS)**

- Both were single item patient-reported measures
  - stool frequency – scores ranged from 0 (≤1 more than usual) to 2 (≥4 more than usual)
  - rectal bleeding severity – scores ranged from 0 (≤1 streak of blood) to 3 (mostly blood).
- Each measured daily via IVRS reported.
- Averaged score from the 3 days prior to assessment point was used.
- Lower scores indicate less disease activity.

## Analysis

- Repeated-measures ANOVA tested for differences between baseline and endpoint SIBDQ, SF, and RBS scores.
- For each of the 10 SIBDQ items, the percentage of patients whose item scores improved, stayed the same, or got worse from baseline to endpoint was calculated.
- Pearson correlation coefficients were computed to assess the strength and direction of associations between baseline-endpoint change in SIBDQ scores with SF and RBS change scores.

## Results

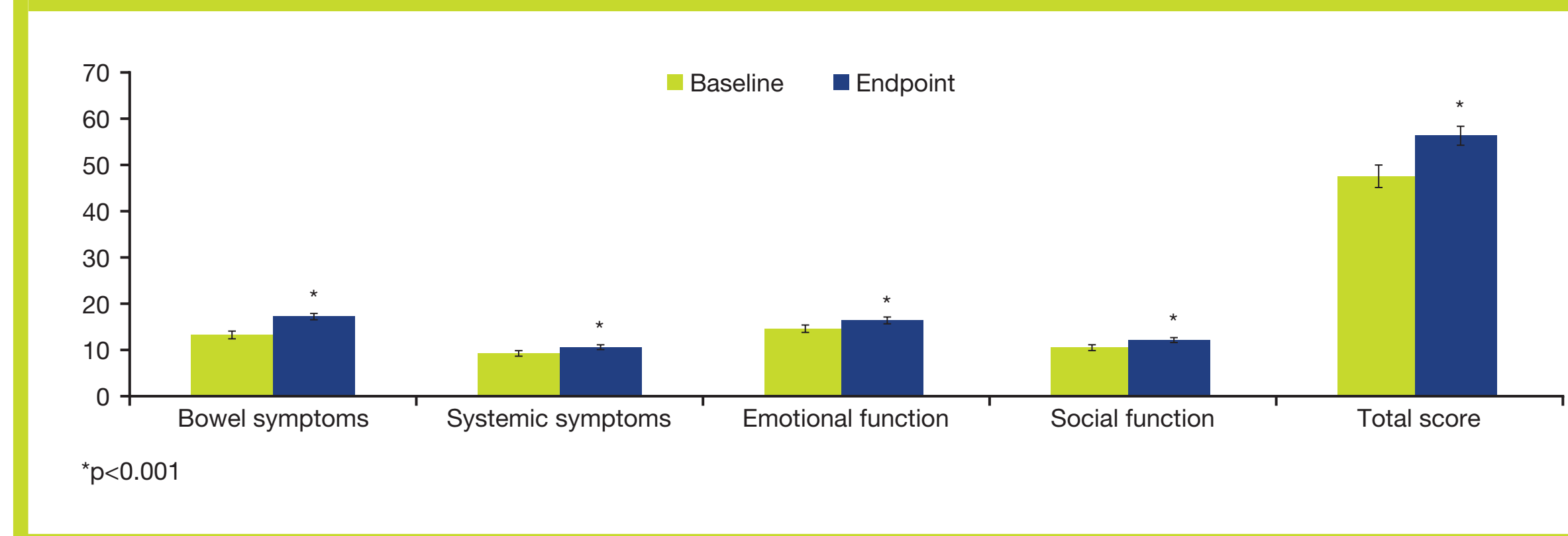
### Patient characteristics

**Table 1. Patient characteristics at baseline (n=132)**

	n	%
Gender		
Male	58	43.9
Female	74	56.1
	<b>Median</b>	<b>Min–Max</b>
Age	43	19–75
	<b>Mean</b>	<b>SD</b>
SIBDQ		
Bowel symptoms scale	12.83	4.34
Systemic symptoms scale	8.94	3.03
Emotional function scale	14.03	4.32
Social function scale	10.07	3.40
<b>Total score</b>	<b>45.87</b>	<b>12.86</b>
Disease activity		
Stool frequency	0.73	0.69
Rectal bleeding severity	0.88	0.78

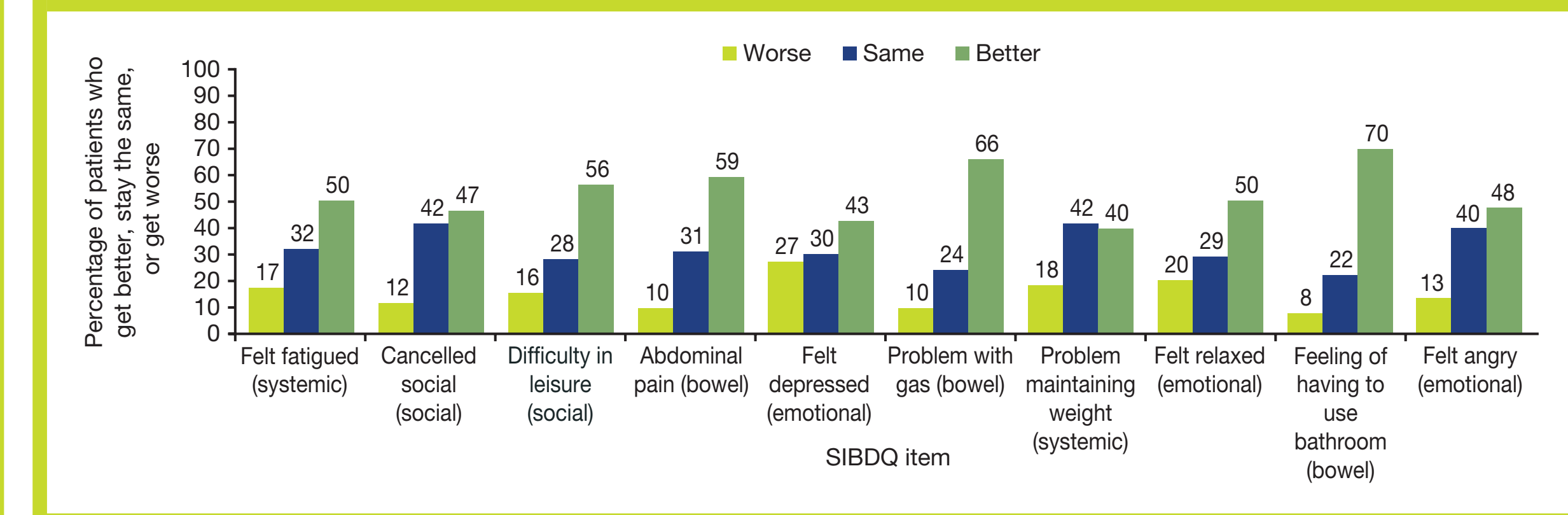
### Impact of MMX mesalamine on HRQoL of active mild-to-moderate UC patients

**Figure 1. Mean SIBDQ scores at baseline and 8-week endpoint (n=103). Error bars indicate 95% CIs**



### Responder level analysis: change in SIBDQ item scores from baseline to endpoint

**Figure 2. Percentage of patients who got better, stayed the same, or got worse for each SIBDQ item from baseline to 8-week endpoint**



### Correspondence between changes in disease activity and changes in HRQoL

**Table 2. Correlations between baseline-endpoint changes in SIBDQ scores and changes in disease activity (n=103)**

	Stool frequency	Rectal bleeding severity
Bowel symptoms	-0.47***	-0.56***
Systemic symptoms	-0.37***	-0.37***
Emotional function	-0.29**	-0.42***
Social function	-0.43***	-0.55***
<b>Total score</b>	<b>-0.48***</b>	<b>-0.59***</b>

\*\*p<0.01; \*\*\*p<0.001

## Main findings

- Following 8 weeks of daily MMX mesalamine treatment, the patient population showed small but statistically significant improvements in all SIBDQ scales and total score.
- Comparison of mean differences and examination of patient improvement across each item indicates that of the bowel symptoms scale of the SIBDQ showed greater responsiveness than did the other 3 scales.
- Improvement in all SIBDQ scales and total score was significantly associated with decreases in disease activity (i.e. decreases in both SF and RBS) at the end of 8 weeks' treatment.

## Conclusion

- Patients with active, mild-to-moderate UC who received 8 weeks of daily 2.4–4.8g MMX mesalamine treatment showed significant improvement in disease-specific HRQoL, and this improvement was significantly correlated to change in disease activity.

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