An Association Between Irritable Bowel Syndrome Quality of Life Score and Symptoms of Abdominal Pain, Bloating, and Cramping in IBS With Constipation: A Pooled Phase 3 Trial Correlation Analysis

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INTRODUCTION

- Although recurrent abdominal pain and altered stool consistency/frequency are irritable bowel syndrome (IBS) diagnostic criteria,[1] other symptoms such as bloating are among the most common and bothersome[2,3]
  - The Rome Foundation has suggested that symptom bothersomeness (eg, severe enough to impact patient quality of life) should be included as a clinical criterion for diagnosis of disorders of gut-brain interaction, such as IBS[4]
- Despite these notions, data suggest that these bothersome symptoms have limited ability to predict the burden and impact of IBS[2]

AIM

- To assess potential relationships between the IBS with constipation (IBS-C) symptoms of abdominal pain, bloating, and cramping, and irritable bowel syndrome quality of life (IBS-QOL) and treatment satisfaction using data from two phase 3 trials of plecanatide

METHODS

- Data were pooled and analyzed post hoc from 2 identically designed, phase 3, randomized, placebo-controlled trials[5]
- Patient population included adults with IBS-C (Rome III criteria) with a worst abdominal pain intensity mean score ≥3 (score range, 0 [none] to 10 [worst possible]) during a 2-week pretreatment (baseline) period who were randomly assigned to receive plecanatide (Trulance®, Salix Pharmaceuticals, Bridgewater, NJ) 3 mg, plecanatide 6 mg, or placebo for 12 weeks
- Assessments
  - Abdominal pain, bloating, and cramping (score range for each, 0 ["no"] to 10 ["worst possible"]) were assessed daily via an electronic diary
  - The IBS-QOL questionnaire (total score range, 0-100) was completed on Day 1 (Week 0) and Weeks 4, 8, 12 (end of treatment), and Week 14 (2-week post-treatment follow-up)
  - Treatment satisfaction (score range, 1 [not at all satisfied] to 5 [very satisfied]) was determined on Weeks 4, 8, and 12
- Pearson correlation analyses compared IBS-QOL total score and treatment satisfaction score with abdominal pain, bloating, and cramping weekly mean scores (over 12-week treatment period and by week)
- A coefficient (r) value (positive or negative) of 0.40 to < 0.70 was considered of moderate strength (0.10 to < 0.40 [weak]; ≥ 0.70 [strong to very strong])

RESULTS

- Data from 2176 patients with IBS-C were included in the analysis (Table 1)

Table 1. Demographics and Baseline Characteristics

Characteristic	Plecanatide 3 mg (n=724)	Plecanatide 6 mg (n=723)	Placebo (n=729)
Age, y, mean (SD)	43.5 (14.2)	43.1 (13.8)	43.9 (14.2)
Female, n (%)	534 (73.8)	536 (74.1)	540 (74.1)
Race, n (%)			
White	527 (72.8)	515 (71.2)	536 (73.5)
Black	155 (21.4)	177 (24.5)	160 (21.9)
Asian	33 (4.6)	25 (3.5)	25 (3.4)
Other	9 (1.2)	6 (0.8)	8 (1.1)
Abdominal pain score, mean (SD)*	6.3 (1.7)†	6.2 (1.8)‡	6.3 (1.7)§
Bloating score, mean (SD)*	6.5 (1.7)†	6.4 (1.8)‡	6.5 (1.8)§
Cramping score, mean (SD)*	6.0 (1.9)†	5.9 (2.0)‡	6.0 (2.0)‡
IBS-QOL total score, mean (SD)	46.5 (24.5)¶	45.3 (24.4)#	44.4 (24.9)¶

*Abdominal pain, bloating, and cramping were measured using an 11-point scale (range, 0 ["no"] to 10 ["worst possible"]). †n=719. ‡n=716. §n=717. ¶n=691. #n=687.
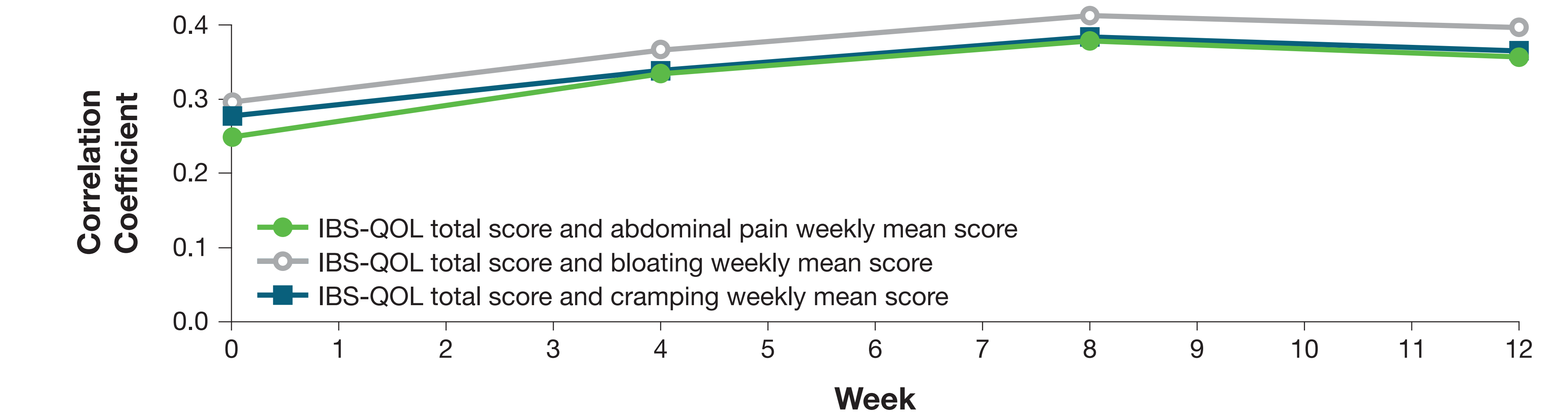
- A positive correlation between IBS-QOL total score and each of the 3 IBS-C symptoms (abdominal pain, bloating, cramping) was observed over the 12-week treatment period (r ≤ 0.41; Table 2) and when assessed by week (r ≤ 41; Figure 1)

Table 2. Correlations Between Symptoms and IBS-QOL or Treatment Satisfaction*

	Pearson Correlation Coefficient, r	
IBS-C Symptom	IBS-QOL Total Score	Treatment Satisfaction
Abdominal pain weekly mean score	+0.38	−0.30
Bloating weekly mean score	+0.41	−0.30
Cramping weekly mean score	+0.39	−0.27

*Over 12-week treatment period.
IBS-C = irritable bowel syndrome with constipation; IBS-QOL = irritable bowel syndrome quality of life.

Figure 1. Correlation Coefficients for Comparisons Between IBS-QOL and Weekly Mean Symptom Scores, by Week

IBS-QOL = irritable bowel syndrome quality of life.

- A negative correlation between treatment satisfaction and each of the 3 IBS-C symptoms (abdominal pain, bloating, cramping) was observed over the 12-week treatment period (r ≤ −0.30; Table 2) and when assessed by week (r ≤ −0.32; Figure 2)

Figure 2. Correlation Coefficients for Comparisons Between Treatment Satisfaction and Weekly Mean Symptom Scores, by Week*
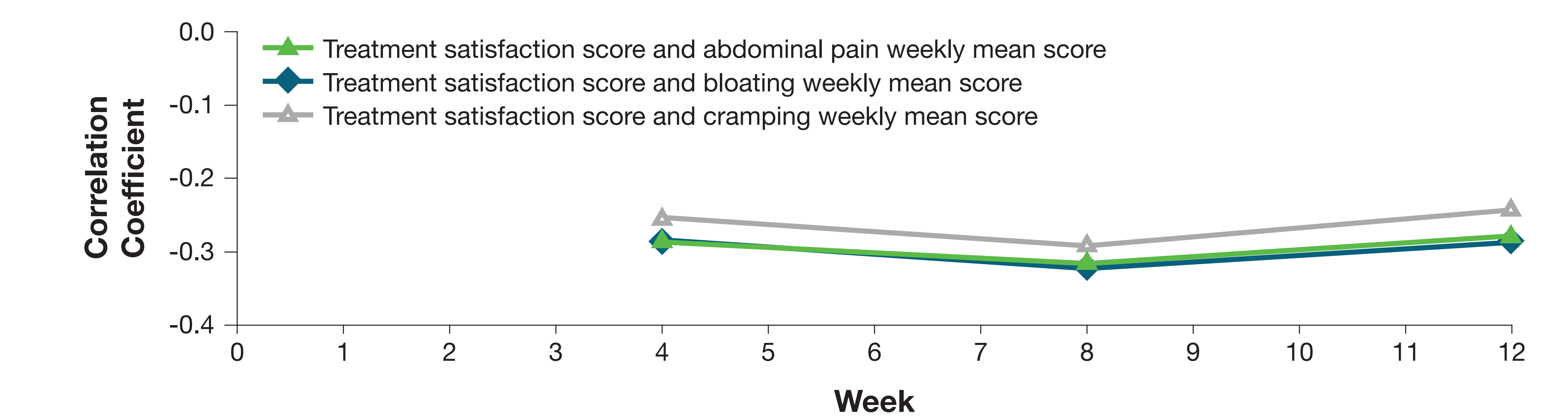
*First treatment satisfaction assessment occurred at Week 4.

CONCLUSIONS

- All three IBS-C symptoms of abdominal pain, bloating, and cramping correlated, albeit weakly/moderately, with IBS-QOL and treatment satisfaction
- Data pooled from plecanatide phase 3 trials support that it is important to effectively treat multiple symptoms of IBS-C, not just abdominal pain and altered stool frequency

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