Psychometric Evaluation of Patient-Reported Outcomes in Irritable Bowel Syndrome Randomized Controlled Trials: A Rome Foundation Report

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Abstract

BACKGROUND & AIMS: There is debate about how best to measure patient-reported outcomes (PROs) in irritable bowel syndrome (IBS). We pooled data to measure the psychometric properties of IBS end points, including binary responses (eg, "adequate relief") and 50% improvement in symptom severity. **METHODS:** We pooled data from 12 IBS drug trials involving 10,066 participants. We tested the properties of binary response and 50% improvement end points, including the impact of baseline severity on performance, and measured con- struct validity using clinical anchors. **RESULTS:** There were 9044 evaluable subjects (age, 44 years; 85% female; 58% IBS constipation-prominent [IBS-C]; 31% IBS diarrhea-prominent [IBS-D]). Using the binary end point, the proportion responding in the mild, moderate, and severe groups was 42%, 40%, and 38%, respectively (P □ .0008). There was no effect of baseline severity on binary response (odds ratio [OR], 0.99; 95% confidence interval [CI], 0.99–1.0; P □ .07). The proportions reaching 50% improvement in pain were 45%, 41%, and 41%, respectively; there was a small, yet significant, impact of base- line severity (OR, 1.04; 95% CI, 1.03–1.05; P □ .0001) that did not meet clinical relevance criteria. Both end points revealed strong construct validity and detected "minimally clinically important differences" in symptoms. Both provided better discriminant spread in IBS-D than IBS-C. **CONCLUSIONS:** Both the traditional binary and 50% improvement end points are equivalent in their psychometric properties. Neither is impacted by baseline severity, and both demonstrate excellent construct validity. They are optimized for the IBS-D population but also appear valid in IBS-C.

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