Development and validation of a new domain structure for the IMPACT-III Health Reported Quality of Life (HRQOL) tool for pediatric patients with Inflammatory Bowel Disease (IBD)

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Background: The IMPACT-III is a validated, disease-specific HRQOL questionnaire for IBD patients ages 9-17. Items within IMPACT are grouped by domains, which cover different aspects of HRQOL. The domain structure has not been changed since validation, although two alternate domain structures have been proposed using different methodologies. Using a large, diverse cohort, the aim of this study was to develop the optimal domain structure for IMPACT.

Methods: Three prospectively collected datasets of adolescents with IBD were used: 1) an internet-based cohort of children with IBD from the Crohn’s and Colitis Foundation of America (CCFA) Partners Kids & Teens study, 2) the REACH infliximab trial for pediatric Crohn’s Disease (CD), and 3) the T72 infliximab trial in pediatric Ulcerative Colitis (UC). Model development used a random sample of 75% of the data. Exploratory factor analyses were run in SPSS using Principal Axis Factoring. Confirmatory Factor Analysis compared previously developed and new factor models, using the full dataset. The Comparative Fit Index (CFI) determined model fit. Data from the CCFA dataset examined the psychometric properties of the new domain structure. Cronbach’s alphas were calculated for reliability, while Pearson correlations measured construct validity between new IMPACT domains and PROMIS measures of anxiety, depression, fatigue, pain and peer relationships. The Pediatric Ulcerative Colitis Activity Index (PUCAI) and Pediatric Crohn’s disease activity index (PCDAI) defined disease activity.

Results: The sample included 502 patients, 125 with UC, 377 with CD (44% female, mean age = 13.4±2.4 years, 37% female, mean age of diagnosis = 10.6±3.0 years). 56% were in remission, 13% had mild disease, and 28% had moderate/severe disease (3% missing). The original IMPACT and the Abdovic et al. domain structures had poor model fit (CFI = .60 and .70), while the Perrin et al. IMPACT-II model had reasonable model fit (CFI = .84). The new 4-factor IMPACT-III model was parsimonious and had good fit (CFI = .90). The new domains were: 1. General well-being (daily functioning, and “internal” symptoms such as stomach pain); 2. Social Functioning (social well-being, and “external” disease symptoms such as fecal urgency, which have a direct social impact); 3. Emotional functioning; 4. Body Image. The new domains and total scale had high internal consistency (Cronbach’s alphas .92, .85, .86, .75, respectively, total scale .95). General well-being was most highly correlated with PROMIS pain and fatigue scales (Pearson’s both -.74), Social was highly related to anxiety and depression scales (both -.64), Emotional was also highly related to the anxiety and depression scales (-.54, -.60), while Body Image was similarly related to all PROMIS instruments (.44 for Peer Relations to -.61 for depression). All correlations were highly significant (p < .001).

Conclusions: The new domain structure of the IMPACT-III questionnaire exhibited reliable and valid domains, demonstrated better model fit and higher reliability than the original IMPACT domain structure, and showed construct validity with PROMIS instruments. These results have important applications both clinically and in large-scale clinical trials, particularly with interventions which may have differential effects on specific aspects of HRQOL.