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Assessing Health Status in Inflammatory Bowel Disease using a Novel Single-Item Numeric Rating Scale

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Abstract

Background—Current instruments used to measure disease activity and health-related quality of life (HRQOL) in patients with Crohn’s disease (CD) and ulcerative colitis (UC) are often cumbersome, time-consuming, and expensive; although used in clinical trials, they are not convenient for clinical practice. A numeric rating scale (NRS) is a quick, inexpensive, and convenient patient-reported outcome (PRO) that can capture the patient’s overall perception of health.

Aims—To assess the validity, reliability, and responsiveness of an NRS and evaluate its use in clinical practice in patients with CD and UC.

Methods—We prospectively evaluated patient-reported NRS scores and measured correlations between NRS and a range of severity measures, including physician-reported NRS, Crohn’s disease activity index (CDAI), Harvey-Bradshaw index (HBI), inflammatory bowel disease questionnaire (IBDQ), and C-reactive protein (CRP) in patients with CD. Subsequently, we evaluated the correlation between the NRS and standard measures of health status (HBI or simple colitis clinical activity index [SCCAI]) and laboratory tests (sedimentation rate [ESR], CRP, and fecal calprotectin) in patients with CD and UC.

Results—The patient-reported NRS showed excellent correlation with CDAI ($R^2=0.59$, $p<0.0001$), IBDQ ($R^2=0.66$, $p<0.0001$), and HBI ($R^2=0.32$, $p<0.0001$) in patients with CD. The NRS showed poor, but statistically significant correlation with SCCAI ($R^2=0.25$, $p<0.0001$) in patients with UC. The NRS did not correlate with CRP, ESR, or calprotectin. The NRS was reliable and responsive to change.

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Conclusions—The NRS is a valid, reliable, and responsive measure that may be useful to evaluate patients with CD and possibly UC.

INTRODUCTION

Assessment and treatment of patients with Crohn's disease (CD) or ulcerative colitis (UC) requires a comprehensive evaluation including biologic, clinical, and psychosocial aspects of disease activity and health-related quality of life (HRQOL). Increasingly, patient-reported outcomes (PROs) are being emphasized in the development of instruments that assess health status. PROs encompass health concepts such as pain, fatigue, depression, and physical function that are meaningful and important to patients.^{1,2} A fundamental attribute of PROs is that they provide the patient's perspective to health assessment. The measurement of PROs has been demonstrated to improve the management of patient conditions, provider behaviors, patient-provider communication, and patient health status.^{3,4,5}

Multiple disease-specific instruments have been developed to assess disease activity and HRQOL in patients with CD or UC. The Crohn's disease activity index (CDAI) is considered the gold standard for the assessment of clinical disease activity for clinical trials.⁶ The CDAI consists of 8 items, and requires a 7-day symptom diary, physical examination, laboratory tests, and a complex calculation to generate a final score, making it difficult to perform quickly. There is no uniformly accepted measure of UC disease activity, although many indices are widely used, including the Mayo Score and the Simple Clinical Colitis Activity Index (SCCAI). The IBD-Quality of Life index (IBD-Q) is a 32-item disease-specific instrument used to evaluate HRQOL among patients with both CD and UC. These and other instruments have primarily been developed for use in research and clinical trials, and none are widely used in clinical practice possibly because they are time-consuming, cumbersome, require complex calculations, and/or are costly.

Numeric rating scales (NRS) have been used as a PRO in clinical trials and practice in a wide range of conditions including acute and chronic pain,^{7,8,9,10,11,12} patient well-being and satisfaction after head and neck surgery,¹³ impact of rheumatoid arthritis,¹⁴ and postoperative nausea,¹⁵ among others. The EQ-5D (EuroQol), a generic measure of health status, utilizes a vertical visual analog scale ranging from 0 to 100 to evaluate health status.¹⁶ In gastroenterology, NRS have been used to assess analgesia during colonoscopy,¹⁷ abdominal pain in irritable bowel syndrome,¹⁸ and distress and depression in colorectal cancer survivors.¹⁹ The NRS has not been well-studied in patients with inflammatory bowel disease (IBD), however a recent study measured disease burden in CD using a "feeling thermometer", by employing a visual analog scale ranging from 0 to 100.²⁰

We further explored the utility of a novel NRS in a large cohort of patients with both CD and UC, and compared the NRS with disease activity indices, HRQOL measurements, and inflammatory markers. We hypothesized that an 11-point NRS (0 to 10) is a quick, inexpensive, and convenient PRO that can capture patients' perceptions of overall health status and general well-being in both CD and UC. The specific aims of our study were to assess the validity, reliability, and responsiveness of the NRS as well as to evaluate its use in clinical practice in patients with IBD.

MATERIALS AND METHODS

Our study consisted of two stages, referred to as Study A and Study B. Study A was a prospective evaluation of the correlation between the patient-reported 11-point NRS score and physician-reported NRS score, standard measures of health status (CDAI, IBDQ, and Harvey-Bradshaw Index [HBI]), and CRP in patients with CD. Study B involved a retrospective evaluation of the NRS in the clinical setting by assessing correlation with standard disease measurement instruments (HBI and SCCAI) and laboratory tests (CRP, ESR, and/or fecal calprotectin) in a larger cohort among patients with either CD or UC. Both protocols were approved by the Cedars-Sinai Medical Center institutional review board.

STUDY POPULATION

Consecutive adult patients seen at the IBD Center at Cedars-Sinai Medical Center between February, 2007 and July, 2008 were invited to participate. All patients had CD or UC that was diagnosed by standard clinical, radiographic, endoscopic, and/or histopathologic criteria. Patients who had surgery within 3 months were excluded from the studies as HRQOL assessment may be confounded by recent surgery. Patients with an ostomy or ileal pouch-anal anastomosis were also excluded since the CDAI has not been validated in these circumstances.

DEVELOPMENT OF THE PATIENT-REPORTED OUTCOMES (PROs)

We developed two PROs for this study, an 11-point NRS and a single self-reported “remission” item, with input from experts in qualitative HRQOL methodology and gastroenterologists. Test-retest reliability of both questions was assessed in 10 patients who completed these questions twice, 1 week apart. Perfect intraobserver reliability was determined with a kappa of 1.0. All 10 patients reported that the NRS was easy to understand and use.

MEASURES OF DISEASE ACTIVITY

Numeric rating scale (NRS)—The primary measure of this study was the generic PRO of health status as measured by an 11-point NRS. This was anchored at each end (0=“As bad as being dead”, 10=“Perfect health”). The wording of the anchors was chosen based on that used in health utilities and the clarity of the meaning of both ends of the scale.²¹ A secondary measure was the physician’s assessment of the patient’s health status using the same NRS. (Figure 1) Physicians and patients were blinded to each others’ NRS scores.

Remission rating—Both the patient and physician rated whether or not the patient was in remission at each visit, by respectively answering the following disease-specific yes/no question: “Do you feel your disease is in remission?” or “Do you feel your patient’s disease is in remission?” Physicians and patients were blinded to the others’ remission ratings.

Crohn’s Disease Activity Index (CDAI)—The CDAI scores range from 0 (best) to 600 (worst). Score interpretations (mild, moderate, and severe disease activity) and remission are derived from physician assessments of health status. Patients with a score of less than 150 are considered to be in clinical remission.²² (Supplemental Table 1)

Harvey-Bradshaw Index (HBI)—The HBI was developed as a simplified version of the CDAI and consists of 5 items that the patient and physician complete. Scores range from 0 (best) to 40 (worst).²³ (Supplemental Table 2)

Inflammatory Bowel Disease Quality of Life Questionnaire (IBDQ)—The IBDQ assesses the patient's status during the previous 2 weeks prior to administration and is responsive to changes in disease activity as determined by the CDAI in patients with CD.²⁴ It encompasses 4 domains: bowel symptoms (10 items), systemic symptoms (5 items), social function (5 items), and emotional status (12 items). Scores range from 32 to 224, with higher scores representing better quality of life.²⁵ The IBDQ is a reliable, valid, and sensitive instrument for assessing HRQOL in both CD and UC.²⁶

Simple Clinical Colitis Activity Index (SCCAI)—The SCCAI is a 6-item measure that the patient and physician complete to assess UC disease activity.²⁷ (Supplemental Table 3)

DATA COLLECTION

Study A—Eligible patients were sent a letter by their treating physician, which explained the nature of the study. Those interested in participating provided written informed consent and were asked to keep a 7-day symptoms diary immediately prior to their next visit for CDAI calculation. The CDAI, HBI, and IBDQ scores were calculated at each visit. CRP and hemoglobin were measured at the clinic visit. Blood measurements of ESR and CRP were collected on the day of the visit. Fecal calprotectin was measured within 1 week of the visit. Patients who were seen in follow-up were assessed with NRS, CDAI, HBI, and IBDQ to assess the responsiveness of the NRS score.

Study B—From January 2010 through March, 2011, the NRS, HBI, and SCCAI were routinely collected at each patient visit at the Cedars-Sinai IBD Center. All laboratory studies (ESR, CRP, and/or fecal calprotectin) were obtained within 30 days of the clinic visit. The patient and physician also independently reported remission status of the patient at each visit.

ANALYSIS

We applied the principles of criterion and construct validity to determine how well the NRS assesses disease activity and health status in patients with IBD. We analyzed the correlation between the patient-reported NRS score and CDAI, HBI, IBDQ, SCCAI as well as CRP, ESR, and/or fecal calprotectin using Pearson's correlation coefficient, and utilized a p-value of <0.05 as evidence of statistical significance. We also analyzed the correlations between the NRS and each of the 4 domains of the IBDQ and examined the correlation between the patient-reported and physician-reported NRS scores. NRS score means were correlated with remission status using student's t-tests. We determined the optimal cutoff of CDAI scores correlating best with patient-reported remission using classification and regression tree (CART) analysis. This statistical tool allows for the unbiased determination of the optimal split (i.e. cutoff point) among observations of the independent variable (i.e. CDAI score) based on the dependent variable (i.e. patient-reported remission).

We assessed the responsiveness of the NRS and activity indices by evaluating and comparing the changes over two time points in NRS score, CDAI, HBI, and IBDQ.

We estimated 45 patients would provide 90% power at $\alpha=0.05$ to detect a large correlation ($r = 0.5$) between the NRS and the IBD-Q, based on Cohen's standardized interpretation of effect sizes.²⁸

RESULTS

PATIENT CHARACTERISTICS

Forty six patients with CD completed at least 1 time point and 21 patients completed 2 time points in the prospective Study A. The mean number of days between time points was 108, ranging from 24 to 243 days. (Table 1)

We evaluated a total of 216 patients in Study B, of which 135 patients had CD and 81 patients had UC. (Table 1) Fifty-five percent were female. The mean age was 43 years in the CD group and 46 years in the UC group. Among the 135 patients with CD, 56 (41%) had prior intestinal surgery, and the mean duration of disease was 13.5 years (range 1 to 47 years). Among the 81 patients with UC, 3 (4%) had prior resection and the mean duration of disease was 10.2 years. (Table 1) A summary of health status assessments is presented in Table 2.

NRS CORRELATION WITH DISEASE ACTIVITY, HRQOL, AND INFLAMMATORY MARKERS

In the prospective Study A, the NRS showed excellent correlation with IBDQ ($R^2=0.66$, $p<0.0001$), CDAI ($R^2=0.59$, $p<0.0001$), and HBI ($R^2=0.32$, $P<0.0001$) (Figure 2). The NRS showed excellent correlation with each IBDQ domain: bowel domain ($R^2 = 0.55$, $p<0.0001$), systemic domain ($R^2 = 0.55$, $p<0.0001$), social domain ($R^2 = 0.60$, $p<0.0001$), and emotional domain ($R^2 = 0.50$, $p<0.0001$). The NRS also correlated with the patient-reported remission ($R^2 = 0.34$, $p<0.0001$).

Among the 135 patients with CD in Study B, there were 230 patient-reported NRS ratings. The mean NRS rating was 5.50. Among the 81 patients with UC in Study B, there were 93 patient-reported NRS ratings, with a mean NRS rating of 5.59. The patient-reported NRS showed a modest, but statistically significant correlation with HBI ($R^2=0.25$, $p<0.0001$) and SCCAI ($R^2=0.25$, $p<0.0001$). (Supplemental Figure 1)

Serum and stool inflammatory markers (ESR, CRP, and fecal calprotectin) did not correlate with the patient-reported NRS or remission status. (Figure 2, Supplemental Figure 2)

RESPONSIVENESS OF THE NRS

Changes in the patient-reported NRS ratings correlated well with changes in IBDQ ($R^2 = 0.67$, $p=0.0002$), but not with changes in CDAI ($R^2 = 0.04$, $p=0.36$) or HBI ($R^2 = 0.11$, $p=0.23$).

PATIENT-DEFINED REMISSION

Patient-defined remission correlated well with the IBDQ, CDAI, and HBI. (Figure 3) All patients who felt they were in remission had a self-reported NRS rating of 6 or higher and self-reported remission correlated both with patient and physician-reported NRS ratings. (Supplemental Figure 3) Mean CDAI and HBI scores were significantly lower in patients who reported being in remission. (Figure 3) CRP did not correlate with self-reported remission ($p=0.72$). (Figure 3) CART analysis showed that the optimal CDAI cut-off score that correlated best with patient-reported remission was 170 (data not shown).

PHYSICIAN AND PATIENT AGREEMENT

In Study A, physician NRS ratings correlated significantly with patient-reported NRS ($R^2 = 0.44$, $p<0.0001$) ratings as well as remission status. (Figure 4) There was statistically significant correlation between patient-reported NRS and physician-reported NRS in patients with CD in the retrospective Study B ($R^2 = 0.22$, $p<0.0001$). Among patients with UC, there was little correlation between patient-reported NRS and physician-reported NRS ($R^2 = 0.09$, $p=0.02$). (Supplemental Figure 4)

DISCUSSION

The clinical manifestations of IBD and their impact on quality of life are highly individual. Biologic data and physician assessment may not adequately capture the patient's perspective of their overall health and well-being. Studies examining the correlation between disease activity indices and patient-reported well-being and HRQOL have demonstrated variable results, with some showing small to moderate associations and others showing none.^{29,30,31} This disassociation between disease activity indices and patient-derived estimates of HRQOL has also been shown in cirrhosis,³² rheumatoid arthritis,³³ diabetes,³⁴ hypertension,³⁵ and renal failure requiring hemodialysis.³⁶

A patient's perception of overall health status and general well-being includes several aspects of life that are difficult to measure: family life, friends, hobbies, social support, education, etc.³⁷ Because these variables are not easily measurable, they cannot be factored into disease activity indices and may explain the poor correlation between disease activity and HRQOL. The NRS provides a surrogate, tangible value that may at least superficially embody these characteristics and allow the physician to get a general sense of how the patient is doing at a point in time. Compared to the general well-being component (rated 0 to 4) of the HBI and SCCAI, the NRS provides several advantages including a larger range (0 to 10) to be able to capture nuances, a visual numberline for easy use, and specific anchors based on health utilities ("as bad as being dead" and "perfect health"). Our study examined several aspects of the NRS for the evaluation of patients with IBD and demonstrated several important findings.

First, the NRS showed excellent correlation with standard instruments of IBD activity and HRQOL including CDAI, HBI, and IBDQ in patients with CD. The patient-reported NRS showed statistically significant, albeit lower correlation with the SCCAI in patients with UC. This difference in patients with CD and UC has been described previously, and may in part

relate to the instrument used to measure disease activity. Approximately 25% of the CDAI score is derived from the patient's subjective report of symptoms and perception of well-being. The (inverse) correlation between the CDAI and the IBDQ is therefore high, $r = -0.67$.²⁷ The heterogeneity in clinical manifestations, complications, and long term outcomes between CD and UC may also account for this difference. Drossman et al. demonstrated several differences in concerns that patients with UC have compared with patients with CD. For example, CD patients have more chronic symptoms and complications causing concern about pain and suffering, being a burden on others, and financial differences.³⁸ Patients with active UC were more concerned with the greater risk of developing cancer than patients with CD.³⁶

Second, the NRS did not correlate with biologic markers (CRP, ESR, and fecal calprotectin). The correlation between biologic markers and disease activity scores in previous studies has been variable, with most showing little or no correlation.^{39,40,41,42} It is reasonable that inflammatory markers may not necessarily correlate with the NRS since this score reflects overall self-perceived health status and not necessarily mucosal or systemic inflammation which may be clinically silent. Furthermore, the origin of symptoms such as diarrhea, fatigue, and abdominal pain in patients with IBD is multifactorial and may not always be due to inflammation.³⁷

Third, the NRS was responsive to change in the limited group in whom change was assessed. Changes in patient-reported NRS score correlated with changes in IBDQ, however not with CDAI or HBI. This is consistent with prior findings demonstrating that functional status correlates with ratings of health status more than disease activity.⁴³ The IBDQ has been shown to reflect short-term changes in the quality of life of patients with CD, making it a useful measure in clinical practice to assess patients' response to therapy.²³ However the IBDQ is a much more cumbersome and expensive instrument compared to the NRS, making the NRS an easier and more practical score to use in routine clinical practice. Further assessment of NRS responsiveness should include a larger cohort of patients with evaluations at 2 timepoints.

Fourth, patient-defined disease-specific remission correlated with IBDQ, CDAI, and HBI. Our study showed that a CDAI score of less than or equal to 170 correlated best with remission and optimally separated patients who felt they were in remission (CDAI less than or equal to 170) from those who did not feel they were in remission (CDAI greater than 170). All patients who felt they were in remission had an NRS score of 6 or higher. The standard measurements of disease activity and definitions of remission are based on scores that involve lengthy questionnaires, laboratory values, and endoscopic activity. The NRS is a quick and convenient measure that adds the patient's perspective to the assessment of remission.

Finally, we found mixed results with regards to physician and patient agreement. In our prospective study, there was correlation between physician and patient-reported NRS ratings. However in our retrospective study, there was weak correlation between physician and patient-reported NRS ratings in patients with CD, and no correlation in patients with UC. Wilcox et al. demonstrated that physicians' perception of current health and burden of

disease in 113 patients with CD correlated to their patients' perception ($\rho = 0.73$ and 0.69 respectively) based on a feeling thermometer.²⁰ However, many studies have shown that patients' perception of their disease severity, physical impact of their disease, disruptive impact on daily activities, and psychological distress was worse than that reported by physicians.^{44,45} Other studies have found that perceptions of disease burden as well as acceptable risk versus benefit differed between patients with IBD and their physicians.^{46,47} A lack of agreement between patients' and physicians' perspectives of disease and health status has also been shown in other chronic diseases such as rheumatoid arthritis,⁴⁸ multiple sclerosis,⁴⁹ lupus,⁵⁰ and cancer.⁵¹ A lack of communication as well as limitations of available measures used to assess patients with IBD may partially explain the differences in health perception between patients and physicians. Disease-specific indices and physicians may be focusing on specific IBD-related symptoms, whereas other factors that are important to patients and contribute to their overall health status may be better understood in the context of a generic assessment of health status, such as the NRS. In a content analysis of patient responses, Wolfe et al. revealed that there were several dimensions of HRQOL, such as cognitive, self-regulation, and practical functioning, that are not incorporated in current measures of HRQOL in patients with IBD.⁴⁵ By incorporating a PRO such as the NRS, physicians may be able to get a better sense of how their patients are doing overall by prompting further discussion and elucidating these other relevant factors, particularly if the scores do not agree.

In order to effectively utilize the NRS in clinical practice, several limitations should be recognized. First, a single item score does not provide insight into the factors that determine the patient's response and the score is a simple representation of a more complex process. However, a change in the score or a low score can prompt further discussion to elucidate issues of concern to the patient. Given the lack of absolute reference standards for the NRS, there may be inter-person variability with regards to the meaning of an individual's score. Second, the generalizeability of our study may be limited given that our cohort is from a single, tertiary referral center. Third, we did not have resources to assess for endoscopic correlates of self-reported health status; endoscopic endpoints are increasingly recognized as important endpoints for purposes of demonstrating therapeutic effects. Finally, it should be recognized that the NRS is not disease-specific but rather assesses general health status. It does not specify a timeframe, which may also limit its ability to correlate with standard assessments of health status. However, despite these limitations, we have found that the NRS has proven to be a useful measure in the evaluation of patients.

In conclusion, the NRS may help provide insight into one of the most important endpoints in clinical practice as well as in clinical trials, which is how the patient feels. As demonstrated in our study, the NRS is a valid, reliable, and responsive PRO that can be used to assess patients with CD. Its utility in patients with UC is less clear and further prospective studies with a large number of patients are needed. Despite its limitations, the NRS is an inexpensive, time-saving, and convenient measure that can be used to complement the assessment and monitoring of overall health status in patients with IBD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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REFERENCES

1. Magasi S, Ryan G, Revicki D, et al. Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. *Qual Life Res.* 2011 [Epub ahead of print].
2. Fiscella K, Ransom S, Jean-Pierre P, et al. Patient-reported outcome measures suitable to assessment of patient navigation. *Cancer.* 2011; 117(15 Suppl):3601–3615.
3. Marshall S, Haywood K, Fitzpatrick R. Impact of patient-reported outcome measures on routine practice: a structured review. *J Eval Clin Pract.* 2006; 12(5):559–568. [PubMed: 16987118]
4. Velikova G, Booth L, Smith AB, et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. *J Clin Oncol.* 2004; 22(4):714–724. [PubMed: 14966096]
5. Detmar SB, Muller MJ, Schornagel JH, et al. Health-related quality-of-life assessments and patient-physician communication: a randomized controlled trial. *JAMA.* 2002; 288(23):3027–3034. [PubMed: 12479768]
6. Sandborn WJ, Feagan BG, Hanauer SB, et al. A review of activity indices and efficacy endpoints for clinical trials of medical therapy in adults with Crohn's disease. *Gastroenterology.* 2002; 122:512–530. [PubMed: 11832465]
7. Salaffi F, Stancati A, Silvestri CA, et al. Minimally clinically important changes in chronic musculoskeletal pain intensity measured on a numeric rating scale. *Eur J Pain.* 2004; 8(4):283–291. [PubMed: 15207508]
8. Samulak D, Michalska M, Gaca M, et al. Efficiency of postoperative pain management after gynecologic oncological surgeries with the use of morphine + acetaminophen + ketoprofen versus morphine + metamizol + ketoprofen. *Eur J Gynaecol Oncol.* 2001; 32(2):168–170. [PubMed: 21614906]
9. Van Seventer R, Serpell M, Bach FW, et al. Relationships between changes in pain severity and other patient-reported outcomes: an analysis in patients with posttraumatic peripheral neuropathic pain. *Health Qual Life Outcomes.* 2011; 9:17. [PubMed: 21439051]
10. Eckmann MS, Ramamurthy S, Griffin JG. Intravenous regional ketorolac and lidocaine in the treatment of complex regional pain syndrome of the lower extremity: a randomized, double-blinded, crossover study. *Clin J Pain.* 2011; 27(3):203–206. [PubMed: 21358290]
11. Simpson DM, Schifitto G, et al. 1066 HIV Neuropathy Study Group. Pregabalin for painful HIV neuropathy: a randomized, double-blind, placebo-controlled trial. *Neurology.* 2010; 74(5):413–420. [PubMed: 20124207]
12. Birnbaum J, Kip M, Spies CD, et al. The effect of stimulation versus nonstimulating catheters for continuous interscalene plexus blocks in short-term pain management. *J Clin Anesth.* 2007; 19(6):434–439. [PubMed: 17967672]
13. Funk W, Podmelle F, Guiol C, et al. Aesthetic satisfaction scoring- Introducing an aesthetic numeric analogue scale (ANA-scale). *J Craniomaxillofac Surg.* 2011 [Epub ahead of print].
14. Gossec L, Paternotte S, Aanerud GJ, et al. Finalisation and validation of the rheumatoid arthritis impact of disease score, a patient-derived composite measure of impact of rheumatoid arthritis: a EULAR initiative. *Ann Rheum Dis.* 2011; 70(6):935–942. [PubMed: 21540201]
15. Wig J, Chandrashekhara KN, Yaddanapudi LN, et al. Effect of prophylactic odansetron on postoperative nausea and vomiting in patients on preoperative steroids undergoing craniotomy for supratentorial tumors. *J Neurosurg Anesthesiol.* 2007; 19(4):239–242. [PubMed: 17893575]
16. Rabin R, De Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med.* 2001; 33(5):337–343. [PubMed: 11491192]

17. Stermer E, Gaitini L, Yudashkin M, et al. Patient-controlled analgesia for conscious sedation during colonoscopy: a randomized controlled study. *Gastrointest Endosc.* 2000; 5(3):278–281. [PubMed: 10699771]
18. Spiegel B, Bolus R, Harris LA, et al. Measuring irritable bowel syndrome patient-reported outcomes with an abdominal pain numeric rating scale. *Aliment Pharmacol Ther.* 2009; 30(11–12):1159–1170. [PubMed: 19751360]
19. Livingston PM, Craike MJ, White VM, et al. A nurse-assisted screening and referral program for depression among survivors of colorectal cancer: feasibility study. *Med J Aust.* 2010; 193(5 Suppl):S83–S87. [PubMed: 21542453]
20. Wilcox AR, Dragnev MCC, Darcey CJ, et al. A new tool to measure burden of Crohn's Disease and its treatment: Do patient and physician perceptions match? *Inflamm Bowel Dis.* 2010; 16:645–650. [PubMed: 19714751]
21. Torrance GW. Measurement of health state utilities for economic appraisal. *J Health Econ.* 1986; 5(1):1–30. [PubMed: 10311607]
22. Best WR, Becktel JM, Singleton JW, et al. *Gastroenterology.* 1976; 70(3):439–444. [PubMed: 1248701]
23. Harvey RF, Bradshaw JM. A simple index of Crohn's disease activity. *Lancet.* 1980; 1:514. [PubMed: 6102236]
24. Hlavaty T, Persoons P, Vermeire S, et al. Evaluation of short-term responsiveness and cutoff values for inflammatory bowel disease questionnaire in Crohn's Disease. *Inflamm Bowel Dis.* 2006; 12(3):199–204. [PubMed: 16534421]
25. Guyatt G, Mitchell A, Irvine EJ, et al. A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology.* 1989; 96:804–810. [PubMed: 2644154]
26. Pallis AG, Mouzas IA, Vlachonikolis IG, et al. The inflammatory bowel disease questionnaire. A Review of its national validation studies. *Inflamm Bowel Dis.* 2004; 10(3):261–269. [PubMed: 15290922]
27. Walmsley RS, Ayres RC, Pounder RE, et al. A simple clinical colitis activity index. *Gut.* 1998; 43(1):29–32. [PubMed: 9771402]
28. Cohen J. A power primer. *Psychological Bulletin.* 1992; 112:155–159. [PubMed: 19565683]
29. Irvine EJ, Feagan B, Rochon J, et al. Quality of life: a valid and reliable measure of therapeutic efficacy in the treatment of inflammatory bowel disease. Canadian Crohn's relapse prevention trial study group. *Gastroenterology.* 1994; 106(2):287–296. [PubMed: 8299896]
30. Gray WN, Denson LA, Baldassano RN, et al. Disease activity, behavioral dysfunction, and health-related quality of life in adolescents with inflammatory bowel disease. *Inflamm Bowel Dis.* 2011; 17(7):1581–1586. [PubMed: 21674715]
31. Banovic I, Gilibert D, Cosnes J. Crohn's disease and fatigue: constancy and co-variations of activity of the disease, depression, anxiety, and subjective quality of life. *Psychol Health Med.* 2010; 15(4):394–405. [PubMed: 20677078]
32. Kanwal F, Hays RD, Kilbourne AM, et al. Are physician-derived disease severity indices associated with health-related quality of life in patients with end-stage liver disease? *Am J Gastroenterol.* 2004; 99:1726–1732. [PubMed: 15330910]
33. Borstlap M, van de Laar M, Zant J, et al. Components of health: an analysis in rheumatoid arthritis using quality of life questionnaires and clinical and laboratory variables. *Ann Rheum Dis.* 1993; 52:650–654. [PubMed: 8239759]
34. Bardsley MJ, Astell S, McCallum A, et al. The performance of three measures of health status in an outpatient diabetes population. *Diabet Med.* 1993; 10:619–626. [PubMed: 8403822]
35. Beto JA, Bansal VK. Quality of life in treatment of hypertension: a metaanalysis of clinical trials. *Am J Hypertens.* 1992; 5:1250133.
36. Laupacis A, Wong C, Churchill D. The use of generic and specific quality of life measures in hemodialysis patients treated with erythropoietin. The Canadian Erythropoietin Study Group. *Control Clin Trials.* 1991; 12:168S–179S. [PubMed: 1663853]
37. Hjortswang H, Almer S, Strom M. The network: a strategy to describe the relationship between quality of life and disease activity. The case of inflammatory bowel disease. *Eur J Gastroenterol Hepatol.* 1999; 11(10):1099–1104. [PubMed: 10524638]

38. Drossman DA, Leserman J, Li Z, et al. The rating form of IBD patient concerns: a new measure of health status. *Psychosomatic Medicine*. 1991; 53:701–712. [PubMed: 1758953]
39. Denis MA, Reenaers C, Fontaine F, et al. Assessment of endoscopic activity index and biological inflammatory markers in clinically active Crohn's disease with normal C-reactive protein serum level. *Inflam Bowel Dis*. 2007; 13(9):1100–1105.
40. Lewis JD. The utility of biomarkers in the diagnosis and therapy of inflammatory bowel disease. *Gastroenterology*. 2011; 140:1817–1826. [PubMed: 21530748]
41. Cakal B, Akoz AG, Ustundag Y, et al. Red cell distribution width for assessment of activity of inflammatory bowel disease. *Dig Dis Sci*. 2009; 54:842–847. [PubMed: 18716874]
42. Rodgers AD, Cummins AG. CRP correlated with clinical score in ulcerative colitis but no in Crohn's disease. *Dig Dis Sci*. 2007; 52:2063–2068. [PubMed: 17436102]
43. Drossman DA, Patrick DL, Mitchell CM, et al. Health related quality of life in inflammatory bowel disease: functional status and patient worries and concerns. *Dig Dis Sci*. 1989; 34:1379–1386. [PubMed: 2766905]
44. Rubin DT, Siegel CA, Kane SV, et al. Impact of ulcerative colitis from patients' and physicians' perspectives: Results from the UC: NORMAL survey. *Inflamm Bowel Dis*. 2009 Apr; 15(4):581–588. [PubMed: 19067414]
45. Sewitch MJ, Abrahamowicz M, Dobkin PL, et al. Measuring differences between patients' and physicians' health perceptions: the patient-physician discordance scale. *J Behav Med*. 2003; 26(3): 245–264. [PubMed: 12845937]
46. Westwood N, Travis SPL. Review article: what do patients with inflammatory bowel disease want for their clinical management? *Aliment Pharmacol Ther*. 2008; 27(Suppl 1):1–8. [PubMed: 18307643]
47. Wolfe BJ, Sirois FM. Beyond standard quality of life measures: the subjective experiences of living with inflammatory bowel disease. *Qual Life Res*. 2009; 17(6):877–886. [PubMed: 18521720]
48. Leeb BF, Sautner J, Leeb BA, et al. Lack of agreement between patients' and physicians' perspectives of rheumatoid arthritis disease activity changes. *Scand J Rheumatol*. 2006; 35(6): 441–446. [PubMed: 17343251]
49. Rothwell PM, MacDowell Z, Wong CK, et al. Doctors and patients don't agree: cross sectional study of patients' and doctors' perceptions and assessments of disability in multiple sclerosis. *Br Med J*. 1997; 314:1580–1583. [PubMed: 9169401]
50. Leong KP, Chong EY, Kong KO, et al. Discordant assessment of lupus activity between patients and their physicians: the Singapore experience. *Lupus*. 2010; 19(1):100–106. [PubMed: 19880553]
51. Slevin ML, Plant H, Lynch D, et al. Who should measure quality of life, the doctor or the patient? *Br J Cancer*. 1988; 57:109–112. [PubMed: 3348942]

Figure 1.

Numeric rating scale (NRS) On the numerical scale below, please rate your overall impression of your health status; 0 is worse (as bad as being dead), 10 is best (perfect health). (circle one)

IBDQ: $R^2=0.66$, $p<0.0001$

CDAI: $R^2=0.59$, $p<0.0001$

HBI: $R^2=0.32$, $p<0.0001$

$p=0.24$

Figure 2.

Patient-reported NRS correlation with standard instruments of disease activity, HRQOL, and CRP. TOP (IBDQ, CDAI, HBI), BOTTOM (CRP)

Figure 3.
Patient-defined remission correlated with IBDQ, CDAI, and HBI, but not CRP.

$$R^2=0.44, p<0.0001$$

$$p=0.0002$$

Figure 4.
Patient-physician agreement.

Table 1

Baseline characteristics

	Crohn's Disease (Study A)	Crohn's Disease (Study B)	Ulcerative Colitis (Study B)
Total patients, n	46	135	81
Age, mean (range), years	45.7 (23 – 81)	43 (20 – 79)	46.8 (22 – 83)
Duration of disease, mean (range), years	14.8 (3 – 46)	13.5 (1 – 47)	10.2 (1 – 49)
Gender (female), n (%)	29 (63%)	74 (55%)	46 (57%)

Table 2

Summary of Indices

	Crohn's Disease (Study A, Time point 1)	Crohn's Disease (Study A, Time point 2)	Crohn's Disease (Study B)	Ulcerative Colitis (Study B)
Patient-reported NRS score, mean $\pm$ SD, (median, range) n	5.45 $\pm$ 2.04 (5, 2 – 9) 22	5.59 $\pm$ 2.13 (5.5, 2 – 9) 22	5.5 $\pm$ 2.18 (5, 1 – 10) 230	5.59 $\pm$ 1.95 (5, 2 – 10) 93
Physician-reported NRS score, mean $\pm$ SD, (median, range) n	7.27 $\pm$ 1.78 (7.5, 3 – 10) 22	6.82 $\pm$ 1.82 (7, 2 – 9) 22	6.5 $\pm$ 1.95 (7, 0 – 10) 165	6.98 $\pm$ 1.87 (7, 1 – 10) 59
CDAI, mean $\pm$ SD, (median, range) n	174 $\pm$ 118 (150, 21 – 495) 22	178 $\pm$ 142 (142, 34 – 621) 22	NA	NA
IBDQ, mean $\pm$ SD, (median, range) n	158 $\pm$ 39 (168, 80 – 219) 22	153 $\pm$ 38 (160, 76 – 207) 22	NA	NA
HBI, mean $\pm$ SD, (median, range) n	6.54 $\pm$ 6.2 (4.5, 0 – 25) 22	5.54 $\pm$ 3.72 (5, 0 – 15) 22	3 $\pm$ 3.29 (2, 0 – 10) 209	NA
SCCAI, mean $\pm$ SD, (median, range) n	NA	NA	NA	2.85 $\pm$ 2.54 (2, 0 – 12) 60
C-reactive protein (CRP), mg/dl mean $\pm$ SD, (median, range) n	0.41 $\pm$.042 (0.34, 0.02 – 1.37) 17	0.41 $\pm$ 0.42 (0.34, 0.02 – 1.37) 17	1.27 $\pm$ 2.80 (0.44, 0 – 20.25) 93	0.79 $\pm$ 1.50 (0.21, 0.02 – 8.45) 47
Erythrocyte sedimentation rate (ESR), mm mean $\pm$ SD, (median, range) n	NA	NA	22.6 $\pm$ 21.8 (13.5, 3 – 101) 96	22.9 $\pm$ 21.3 (14, 2 – 90) 48
Fecal calprotectin, mcg/g mean $\pm$ SD, (median, range) n	NA	NA	459 $\pm$ 614 (279, 22 – 2879) 20	1046 $\pm$ 2103 (307, 62 – 5808) 7

Normal CRP < 0.80 mg/dl. Normal ESR 0–15 mm. Normal calprotectin 162.9 mcg/g.