Patient activation and its association with health indices among patients with inflammatory bowel disease

Ola Haj [ID], **Miri Lipkin, Uri Kopylov** [ID], **Sina Sigalit and Racheli Magnezi**

Abstract

Background: Patient activation refers to patients' independence in daily activities, involvement in the therapeutic process, and ability to manage their health. This study examined the association between the activation of patients with inflammatory bowel disease (IBD) and its effect on health indices.

Objectives: To evaluate the association between the activation of patients with IBD measured by patient activation measure (PAM-13) questionnaire with disease activity and quality of life in IBD.

Design: A retrospective cross-sectional study.

Methods: This study included patients with Crohn's Disease (CD) or ulcerative colitis (UC) followed at a large medical center in Israel, who were recruited during routine visits. They answered weekly questionnaires using a mobile smartphone application that included clinical and emotional disease parameters, including IBD control, quality of life [short IBD quality of life questionnaire (SIBDQ)], patient-reported outcomes measurement information system (PROMIS-10) and PAM-13. Additional clinical parameters were collected from electronic medical records.

Results: Among 201 patients (113 females) who responded to the questionnaires, 152 (75.6%) had CD and 49 (24.4%) UC. For PAM-13, 158 (79%) patients were at PAM-13 levels 3–4 (mean score: 68.5, range: 60.0–73.1) and 43 (21%) were at levels 1–2 (mean score: 45.2, range: 40.9–49.9). PAM-13 levels were correlated with IBD control ($r = 0.19$, $p = 0.023$), SIBDQ ($r = 0.20$, $p = 0.010$), and PROMIS-10 score ($r = 0.24$, $p = 0.017$).

Conclusions: Our findings demonstrate the importance of patient activation and engagement in IBD. Knowledge of patient activation may enable caregivers to predict levels of self-care and the likelihood of compliance with health behavior recommendations.

Keywords: Crohn's disease, inflammation, patient activation measure, quality of life, ulcerative colitis

Correspondence to:
Ola Haj
IBD Clinic,
Gastroenterology
Department, Sheba
Medical Center, Derech
Sheba 2, Ramat Gan 52621
Israel

Department of
Management, Health
Systems Management,
Bar Ilan University, Ramat
Gan, Israel
**ola.haj@sheba.health.
gov.il**

Miri Lipkin
Sina Sigalit
IBD Clinic,
Gastroenterology
Department, Sheba
Medical Center, Ramat
Gan, Israel

Uri Kopylov
IBD Clinic,
Gastroenterology
Department, Sheba
Medical Center, Ramat
Gan, Israel

Sackler Faculty of
Medicine, Tel Aviv
University, Tel Aviv, Israel

Racheli Magnezi
Department of
Management, Health
Systems Management,
Bar Ilan University, Ramat
Gan, Israel

Introduction

The prevalence of inflammatory bowel disease (IBD) is increasing dramatically worldwide.[1] In Israel, there are currently over 46,000 patients with IBD corresponding to a national prevalence of 519/100,000 (0.52%). As of 2019, 54.1% had Crohn's disease (CD) and 45.9% had ulcerative colitis (UC).[2]

Optimal management of IBD relies on understanding and tailoring evidence-based interventions through shared decision-making of physicians and patients. Traditional approaches to the management of IBD care, based on treating symptoms alone and managing disease flares, have not changed the natural history of the disease. A more proactive rather than reactive

treatment approach to disease management is required. Engaging patients in their self-care using novel approaches, such as participatory healthcare models, may facilitate a more proactive approach to management.[3] Studies indicate that patient-centric self-management strategies in which patients receive adequate informational support and actively identify challenges and solve them are far more likely to foster adherence to complex treatment regimens of chronic diseases.[4]

Patients' understanding of their role in the care process and having the knowledge, skills, and confidence to manage their health and care is crucial for treatment success.[5,6] Over the past decade, evidence supporting the importance of patient activation, defined as the willingness to take autonomous actions to become managers of their healthcare, in chronic illness has grown, revealing improved health outcomes, enhanced patient experiences, and lower overall costs.[6–10] Patient activation can be measured, and interventions have been shown to improve levels of activation over time and influence health outcomes. A focus on patient activation is important for patients with IBD, as it may potentially serve as a tool for IBD providers to improve patient outcomes and experience, as well as reduce healthcare costs.[11,12]

The patient activation measure (PAM) is a psychometric instrument used to measure activation. The short version is reliable and valid[9] and appears to tap into the developmental nature of activation.[13] Each item on the PAM has a calibrated value that represents the amount of patient activation required to endorse the item. The PAM score places the patient at one of the four stages of activation, providing insight into a patient's health status.[8,13] One of the strengths of the PAM is that it can be used to develop individually tailored care plans. As the PAM maintains precision and provides consistent results across different levels of health, it can be used for a broad range of demographic and health status groups. In a study of patients with a variety of chronic medical conditions, patients with high PAM scores were significantly more likely to demonstrate better self-reliance and manage their health, follow preventive behaviors, and report high medication adherence, compared to patients with low PAM scores.[9]

To date, very few studies have addressed the utility of PAM in IBD. In a primary care setting, higher PAM scores were positively associated with improved health outcomes, such as metabolic parameters, smoking cessation, involvement in cancer screening programs, and lower risk of hospitalization and overall healthcare costs.[14] We hypothesized that patients with higher levels of patient engagement are more likely to exhibit improved quality of life and improved patient-reported measures of disease activity.

Methods

Patients
From December 2020 until August 2021, patients (≥18 years) who visited the IBD clinic or infusion center visit at Sheba Medical Center, Israel for a routine visit were offered to be enrolled in the study.

Measures
Patients' disease characteristics were classified based on the Montreal classification for UC or CD for age, location, and behavior.[15] Clinical and demographic characteristics [age, gender, years since IBD diagnosis, history of IBD-related surgeries, personal habits (smoking), and the last biological medication taken, fecal calprotectin, and C-reactive protein (CRP) levels] were collected from electronic medical records. These were available for only a small proportion of the study patients.

The patients received questionnaires *via* the specialized smartphone app (Datos Health, Tel Aviv, Israel) that was customized specifically for the needs of IBD patients at the Sheba Medical Center gastroenterology department. The questionnaires were delivered *via* the app and addressed several clinical and emotional disease domains including patient's sense of disease control (IBD-control), quality of life (short IBD quality of life questionnaire (SIBDQ),[16,17] and patient-reported outcomes measurement information system (PROMIS-10).[18] The questionnaires were delivered during or shortly after their visit to the clinic. If the patients' questionnaires were not answered and completed simultaneously during their visit, offline responses within 30 days from one set of questionnaires to another were

used for correlation analysis. The CRP and fecal calprotectin were collected from the medical records from 90 days from PAM result. Supplemental Table 1 shows the results of the questionnaires.

In addition to the questionnaires, we collected data on disease severity scores (Harvey Bradshaw score for CD, simple colitis clinical activity index (SCCAI) for UC) from the medical records. For IBD control, the original surveys were comprised of 13 questions related to disease activity (including bowel activity and sense of control) and the SIBDQ disease control (including 10 questions about abdominal pain and mental and physical aspects). Clinical activity was measured using SCCAI for UC, patient-reported outcome 2 (PRO-2) for symptom severity, and the HBI for CD indices, and the PROMIS-10.

PAM-13, previously validated Hebrew version of the PAM tool, was used in this study.[5,6] Responses were rated on a Likert Scale of 1–5, according to the degree of agreement with health management statements. PAM-13 consists of 13 statements about managing one's health, for example, 'I am confident that I can tell a doctor my concerns, even when he or she does not ask', 'I know how to prevent problems with my health', or 'I am confident that I can tell a doctor my concerns, even when he or she does not ask'. The five response categories were as follows: (1) strongly disagree, (2) disagree, (3) agree, (4) strongly agree, and (5) not applicable.[13] The common ranges of the PAM score were used to map the final score into four levels (Insignia Health, LLC. PAM-13: License Materials; 2021). Level 1 (indicated by a score of 0.0–47.0) reflects a lack of or low level of understanding about the importance of patient involvement. Level 2 (47.1– 55.1) represents a low confidence level and knowledge to take action. Level 3 (55.2–72.4) indicates that a person is starting to follow the healthcare recommendations and a positive behavioral change. Level 4 (72.5– 100) implies a proactive approach taken toward self-health management and engagement in recommended health behaviors (Supplemental Table 1). In our analysis, we considered PAM-13 levels of 3–4 as high and 1–2 as low PAM-13 scores.

SCCAI was used to measure UC activity. It includes six items: bowel frequency during the day and night, the urgency of defecation, blood in the stool, general well-being, and extracolonic manifestations. Higher scores indicate more active disease.[19]

PRO-2 questionnaire consists of two questions (stool frequency and rectal bleeding), with four response options each, scored from normal (no disease symptoms) to most severe symptoms (0–3).[20] SIBDQ is a well-validated questionnaire for assessing health-related quality of life (HRQoL) in IBD patients. It measures physical, social, and emotional status (scores range from 10 to 70), indicating poor to good HRQoL.[17]

The IBD Control Questionnaire (IBD CONTROL) consists of five sections. It contains 13 questions and a visual analog scale. Responses are allocated a score of 0 for the least favorable response, 1 for the intermediate response or not sure, and 2 for the most favorable response. The scores are simply added to produce a total score. This questionnaire scores range from 0 to 26 and IBD control 8 scores from 0 to 16. Low scores indicate poor patient-reported control of IBD and high scores indicate good control.[21]

PROMIS-10 are standardized, validated questionnaires intended for completion by patients to measure their perceptions of their functional status and well-being.[22]

Statistical Analysis
Descriptive statistics were reported for all patient characteristics using means and standard deviations for continuous variables and counts with percentages for categorical variables (Supplemental Table 2). Qualitative summary statistics were used to describe demographic characteristics. Cronbach's alpha was used to calculate internal consistency between the 13 items on the PAM questionnaire. Continuous variables were compared using either the unpaired t-test for two variables or the Kruskal–Wallis test, a one-way analysis of variance for more than two variables. Categorical variables were compared using the chi-squared test. We tested the Pearson correlation of the different variables with the final PAM level score and constructed a correlation matrix to assess the possible collinearity between covariates. We also attempted to create a model to predict high PAM-13 levels using the Pearson correlation of the different variables tested with the final PAM level score and constructing a correlation matrix to assess the possible collinearity

between covariates. Two-tailed value <0.05 was considered significant. The analyses were performed using the R statistical software package.

Ethical considerations

This study was approved by the Institutional Review Board of Sheba Medical Center. All participants provided informed consent for using the application and the data privacy policy of the app by marking 'I have read the app usage conditions and privacy policy and agree to install the app'.

The Strengthening the Reporting of Observational Studies in Epidemiology Statement: guidelines for reporting observational studies for reports of *cross-sectional studies* were followed.[23]

Results

Patients characteristics

During the study period, 201 of the 356 IBD patients (56%) responded to the questionnaires and were included in the study. Nearly 75% ($n=152$) were diagnosed with CD and the rest had UC ($n=49$). Of the 201 study patients, 96% were treated with at least one biological therapy; infliximab was the most frequently used medication (35.3%, $n=71$), followed by vedolizumab (29.4%, $n=59$), ustekinumab (13.9%, $n=28$), adalimumab (12.9%, $n=26$), xeljantz (2.5%, $n=5$), certolizumab (1%, $n=2$) and golimumab (1%, $n=2$).

The mean disease duration at baseline with respect to PAM level was 5.7 years (2–12 years corresponding to low PAM levels of 1 and 2 and 3–15.8 years corresponding to higher PAM levels of 3 and 4, $p=0.012$). Baseline characteristics are summarized in Supplemental Table 1.

Correlation of PAM-13 with clinical and demographic characteristics

In all, 43 (21%) patients had level 1 and 2 scores (mean: −45.2, range: 40.9–49.9) signifying low patient activation, and 158 (79 %) – levels 3 and 4 (mean: 68.5, range: 60.0–73.1) (high activation). None of the clinical and demographic characteristics, including inflammatory biomarker levels or clinical activity scores (SCCAI and PRO-2), differed between groups (Supplemental Table 3). We attempted to create a multivariate predictive model for PAM. The model coefficients were significant (Supplemental Table 4).

Correlation between PAM-13 levels, quality of life, and emotional status

There was a weak but significant correlation of PAM-13 levels with IBD control ($r=0.19$, $p=0.023$) and SIBDQ ($r=0.20$, $p=0.010$). A moderate significant correlation was found between PAM-13 levels and PROMIS-10 score ($r=0.24$, $p=0.017$) (Supplemental Table 2). PAM scores were positively correlated with IBD control ($r=0.19$, $p=0.023$). The psychological and mental health sub-scores [SIBDQ-psychological ($r=0.28$, $p=0.0006$), PROMIS-mental health ($r=0.3$, $p=0.0024$)] demonstrated significant correlation with PAM-13 scores (Supplemental Table 3).

Discussion

This study used several self-reported questionnaires to evaluate the association between patient activation, as reflected in the PAM, and its effect on health indices among patients with IBD. We found positive correlations between PAM and the SIBDQ, IBD CONTROL, and PROMIS outcomes in an IBD population.

Our findings suggest the potential importance of patient activation on disease management. Our findings have implications beyond the PAM score itself, as the PAM is a parameter that might change using specific interventions. The findings demonstrate that PAM-13 scores were significantly correlated with parameters associated with overall well-being, emotional status, and quality of life (SIBDQ, IBD CONTROL, and PROMIS). Overall, 158 (79%) respondents demonstrated high levels of patient activation, defined as PAM level 3 or 4. In similarity to our findings, in a study by Munson *et al.*,[24] a significant correlation of PAM levels SIBDQ was demonstrated in a cohort of 260 IBD patients from the Veteran's healthcare system in the United States.

Due to the complexity and the long-term nature of this disease condition, patients' ownership and involvement in managing their disease are of utmost importance to improve quality of life, preventing complications of the disease, and providing better functional and disease self-management. Patient activation is a relatively novel concept in IBD and these findings suggest that patient

activation may play an important role in disease outcomes.[11]

However, there was no significant correlation between objective or subjective disease activity parameters, such as activity scores and inflammatory biomarker levels. This is in contrast to Magadi *et al.*,[25] who described lower activation levels with a higher symptom burden and reduced HRQoL among patients with chronic kidney disease. Previous studies that examined PAM in patients with chronic conditions demonstrated that those with high PAM scores were significantly more likely to display self-management behavior, use self-management services, and report high medication adherence, as compared with patients with the lowest PAM scores.[12] The possible explanation for this discrepancy is that clinical presentation of IBD can be highly variable and multifactorial, affecting a heterogeneous patient population, with a vast array of coping, adjustment techniques and abilities. Thus, objective or perceived disease activity is just one of the factors that may be affected or correlated with patient engagement, while a patient's ability to cope with a disease is an additional variable that is not easy to quantify.

An important aspect of the current study was the use of a specific electronic platform and smartphone application that was developed and customized for our patient cohort. While such a platform is easy and intuitive, it creates a bias toward younger and more 'digitally agile' patients, while older patients, as well as those with a conservative lifestyle (e.g. ultraorthodox Jews who generally avoid using the internet and smartphones), were less likely to participate in the study.

Our results propose that patient engagement may potentially serve as a treatment target in IBD patients. However, currently, there is no prospective data to support patient activation as a therapeutic target, we suggest that an intervention to increase patient engagement may result in improvements in quality of life and sense of disease control. This hypothesis will need to be tested in a prospective trial using an interventional tool. Examples of interventions include participation in specialized support groups, patient education-focused coaching activities, self-management techniques such as mindfulness, and other stress-mitigating techniques. These interventions (patient-tailored treatment package) should be specifically targeted at patients with low baseline PAM levels.[11] The magnitude of the impact on PAM-13 levels should be evaluated for its predictive ability to improve long-and short-term disease outcomes, such as the need for surgery, rate of hospitalization, and need for advanced medical treatments, such as biologics. Investigating the needs of patients and making information sources accessible among patients with IBD in tertiary centers and the community can also contribute to better mapping of the specific profile of IBD patients in the Israeli population and their needs. By doing so, these types of studies can direct how patients' cognitive perceptions can be influenced or adjusted to better adapt to their disease situation and create better-coping strategies. Providing planned and customized guidance incorporating both the physical and emotional needs, as well as personal data gaps for each patient is expected to improve their understanding of the disease state and achieve better control and engagement through enhancement of personal independence and empowerment.

This study had several limitations. Primarily, the associations detected in our study were rather weak even when significant. This likely reflects a diverse and multifactorial nature of IBD, with no single factor being a single driver or response, quality of life, or any other activity metric .In addition, patient-reported outcomes and clinical scores are limited as a tool for assessment of disease burden. Unfortunately, in our study, inflammatory biomarkers were not widely available. Most of the patients were already on biological therapy, implying an overall significant disease burden, possibly with less variability than would be expected in a community practice or a non-referral center clinic. In addition, as biomarker levels were not a predefined component of the study protocol, these were available in only a small proportion of the participants, due to administrative issues (as the medical insurance only approves calprotectin test once a year) potentially affecting the magnitude of the association. An additional limitation is the number of patients declining to respond to participate in the study it is possible that there could have been a bias toward higher PAM scores in patients that complied with the questionnaire, as opposed to those that were not interested. Unfortunately, the data for patients that opted to ignore the questionnaire are not available to us. Finally, although we aimed to construct a predictive model for high PAM levels, this was not successful, probably due to insufficient sample size.

We recommend further research on patient activation in IBD and to actively take measures to support and empower patients to take a more active role in the management of their condition, increasing and fostering treatment adherence, and ultimately improving health outcomes.

Conclusion

Our findings underscore the utility of patient activation and engagement in IBD. To better understand the exact parameters that play a role in improving quality of life and health parameters, a large-scale prospective interventional study should be performed. One strategy can be to perform specific screening for patients with low activation levels and then introduce patient-tailored interventions aimed at increasing the activation level. This could improve care and ultimately improve outcomes among these patients.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Sheba Medical Center. All participants provided informed consent for using the application and the data privacy policy of the app by marking 'I have read the app usage conditions and privacy policy and agree to install the app'.

Consent for publication

Not applicable.

Author contribution(s)

Ola Haj: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing.

Miri Lipkin: Conceptualization, Data curation.

Uri Kopylov: Conceptualization, Resources, Supervision, Writing – original draft, Writing – review & editing.

Sigal Sina: Formal analysis, Methodology.

Racheli Magnezi: Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing.

ORCID iDs

Ola Haj 🔘 https://orcid.org/0000-0002-8411-056X

Uri Kopylov 🔘 https://orcid.org/0000-0002-7156-0588

Supplemental material

Supplemental material for this article is available online.

References

1. Coughlan A, Wylde R, Lafferty L, *et al.* A rising incidence and poorer male outcomes characterise early onset paediatric inflammatory bowel disease. *Aliment Pharmacol Ther* 2017; 45: 1534–1541.

2. Stulman MY, Asayag N, Focht G, *et al.* Epidemiology of inflammatory bowel diseases in Israel: a nationwide epi-Israeli IBD research nucleus study. *Inflamm Bowel Dis* 2021; 27: 1784–1794.

3. Colombel J-F, Panaccione R, Bossuyt P, *et al.* Effect of tight control management on Crohn's disease (CALM): a multicentre, randomised, controlled phase 3 trial. *Lancet* 2017; 390: 2779–2789.

4. Grady PA and Gough LL. Self-management: a comprehensive approach to management of chronic conditions. *Am J Public Health* 2014; 104: e25–e31.

5. Magnezi R, Glasser S, Shalev H, *et al.* Patient activation, depression and quality of life. *Patient Educ Couns* 2014; 94: 432–437.

6. Magnezi R and Glasser S. Psychometric properties of the Hebrew translation of the patient activation measure (PAM-13). *PLoS One* 2014; 9: e113391.

7. Barnes EL, Long MD, Kappelman MD, *et al.* High patient activation is associated with remission in patients with inflammatory bowel disease. *Inflamm Bowel Dis* 2019; 25: 1248–1254.

8. Hibbard JH, Mahoney ER, Stockard J, *et al.* Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005 ; 40: 1918–1930.

9. Lightfoot CJ, Wilkinson TJ, Memory KE, *et al.* Reliability and validity of the patient activation measure in kidney disease: results of rasch analysis. *Clin J Am Soc Nephrol* 2021; 16: 880–888.

10. Zimbudzi E, Lo C, Ranasinha S, *et al.* The association between patient activation and self-care practices: a cross-sectional study of an Australian population with comorbid diabetes and chronic kidney disease. *Health Expect* 2017; 20: 1375–1384.

11. Shah SL and Siegel CA. Increasing patient activation could improve outcomes for patients with inflammatory bowel disease. *Inflamm Bowel Dis* 2015; 21: 2975–2978.

12. Hibbard JH and Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood)* 2013; 32: 207–214.

13. Hibbard JH, Stockard J, Mahoney ER, *et al.* Development of the patient activation measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004; 39: 1005–1026.

14. Greene J, Hibbard JH, Sacks R, *et al.* When patient activation levels change, health outcomes and costs change, too. *Health Aff (Millwood)* 2015; 34: 431–437.

15. Satsangi J, Silverberg MS, Vermeire S, *et al.* The Montreal classification of inflammatory bowel disease: controversies, consensus, and implications. *Gut* 2006; 55: 749–753.

16. Irvine EJ, Zhou Q and Thompson AK. The short inflammatory bowel disease questionnaire: a quality of life instrument for community physicians managing inflammatory bowel disease. CCRPT investigators. Canadian Crohn's relapse prevention trial. *Am J Gastroenterol* 1996; 91: 1571–1578.

17. Jowett SL, Seal CJ, Barton JR, *et al.* The short inflammatory bowel disease questionnaire is reliable and responsive to clinically important change in ulcerative colitis. *Am J Gastroenterol* 2001; 96: 2921–2928.

18. Kochar B, Martin CF, Kappelman MD, *et al.* Evaluation of gastrointestinal patient reported outcomes measurement information system (GI-PROMIS) symptom scales in subjects with inflammatory bowel diseases. *Am J Gastroenterol* 2018; 113: 72–79.

19. Walmsley RS, Ayres RC, Pounder RE, *et al.* A simple clinical colitis activity index. *Gut* 1998; 43: 29–32.

20. U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. *Health Qual Life Outcomes* 2009; 4: 79.

21. IBD Control Collaborative, Bodger K, Ormerod C, Shackcloth D, *et al.* Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-control questionnaire. *Gut* 2014; 63: 1092–1102.

22. Dawson J, Doll H, Fitzpatrick R, *et al.* The routine use of patient reported outcome measures in healthcare settings. *BMJ* 2010; 340: c186.

23. STROBE Initiative, von Elm E, Altman DG, Egger M, *et al.* The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med* 2007; 147: 573–577.

24. Munson GW, Wallston KA, Dittus RS, *et al.* Activation and perceived expectancies: correlations with health outcomes among veterans with inflammatory bowel disease. *J Gen Intern Med* 2009; 24: 809–815.

25. Magadi W, Lightfoot CJ, Memory KE, *et al.* Patient activation and its association with symptom burden and quality of life across the spectrum of chronic kidney disease stages in England. *BMC Nephrol* 2022; 23: 45.

Visit SAGE journals online
journals.sagepub.com/home/tag

$SAGE journals