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Patient Reported Outcome Assessments Used in the Evaluation of Patients after Ileal Pouch-Anal Anastomosis: A Systematic Review

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Abstract

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Authors' Contributions:

Edward L. Barnes was responsible for the conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, writing of the original draft and review and editing. Marcella H. Boynton was responsible for the conceptualization of the study, investigation, methodology and provided review and editing of the manuscript. Darren A. DeWalt was responsible for the investigation, methodology, supervision, validation and provided review and editing of the manuscript. Hans H. Herfarth was responsible for data curation, formal analysis, investigation, project administration, resources, supervision, validation and provided review and editing of the manuscript. Michael D. Kappelman was responsible for the conceptualization, investigation, methodology, project administration, supervision, and provided review and editing of the manuscript.

Conflicts of Interest:

These authors disclose the following: Edward L. Barnes has served as a consultant for AbbVie, Bristol-Meyers Squibb, Lilly, and Target RWE. Hans H. Herfarth has served as a consultant for Alivio, AMAG, BMS, Boehringer, ExeGi Pharma, Finch, Gilead, Janssen, Lycera, Merck, Otsuka, Pfizer, PureTech, Seres and research support from Allakos, Artizan, NovoNordisk, Pfizer. Michael D. Kappelman has served as a consultant for Abbvie, Takeda, Janssen, Pfizer, and Eli Lilly and has received research support from Abbvie and Janssen. The remaining authors disclose no conflicts.

Ethical Statement:

The corresponding author, on behalf of all authors, jointly and severally, certifies that their institution has approved the protocol for any investigation involving humans or animals and that all experimentation was conducted in conformity with ethical and humane principles of research.

Reporting Guidelines:

MOOSE.

Supplementary Materials

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BACKGROUND AND AIMS: There is a paucity of validated measures to evaluate how patients feel and function after restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) for ulcerative colitis. We performed a systematic review to evaluate all published patient reported outcomes (PROs) to assess symptom burden, functional status, and quality of life (QoL) after IPAA.

METHODS: An electronic literature search on PubMed, Embase, and Web of Science was performed from inception through October 12, 2021. Eligible full texts were further characterized by the type of assessment as well as the individual domains assessed by questions in the PRO measure.

RESULTS: Among the 129 full texts analyzed, 51 specific PRO measures were utilized. In the evaluation of all PRO measures, 46% included an assessment of disease-specific QoL with 27% evaluating more general QoL, and 15% assessing symptoms related to pouch function. Among the studies using disease-specific instruments, the Cleveland Clinic Global Quality of Life (42%) and the Inflammatory Bowel Disease Questionnaire (21%) were the most commonly used PRO measures. PRO questions were mapped to individual domains using binning methodology, with the greatest number of questions from individual PRO measures mapped to the bowel function domain (122).

CONCLUSION: In our assessment of PRO measures among patients after IPAA, the studies and individual measures varied widely in both the patient populations being evaluated as well as outcomes and specific domains being assessed. A valid measure that assesses the range of outcomes after IPAA could standardize assessment and advance the study of patients after IPAA.

Keywords

Patient Reported Outcome Measures; Pouchitis; J-Pouch; Quality of Life

Introduction

Although proctocolectomy with ileal pouch-anal anastomosis (IPAA) remains the predominant restorative surgery for patients with medically refractory ulcerative colitis (UC) and UC-related dysplasia,[1] there is a paucity of measures that evaluate how patients feel and function after IPAA. In particular, patient-reported outcome (PRO) assessments to gauge the lived experience specific to both normal pouch function and inflammatory conditions of the pouch are lacking. As a result, IPAA researchers have used multiple different and nonspecific measures, leading to inadequate outcome assessment and difficulty pooling or comparing results across studies.

A recent statement generated by a Delphi consensus of the Crohn's & Colitis Foundation Surgery Research Network described a new condition termed the ileoanal pouch syndrome (IPS), an overarching patient-centered concept defining the functional symptoms that patients consider most important after an IPAA surgery.[2] This consensus statement and definition of the IPS was an important initial step in defining the symptoms and consequences that impact the functional status and quality of life (QoL) of individual patients after pouch surgery. Although a variety of methods have been utilized to evaluate patient-related outcomes after IPAA, standardized PROs specific to pouchitis and other

inflammatory conditions of the pouch are lacking. This represents a critical need in clinical care and research settings, given that the symptoms of pouchitis and their impact on a patient's quality of life represent a unique presentation compared to more general assessments of life with an IPAA. Additionally, the Food and Drug Administration (FDA) provides specific guidance for the development of PROs, including the need to develop and/or validate PROs in the specific condition where they will be studied or utilized and to include input from the target population in this process.[3]

To better understand the currently available PROs to assess symptom burden, functional status, and QoL after IPAA, and specifically, those that are appropriate for use in studying pouchitis and other inflammatory conditions of the pouch, we performed a systematic review of all previously published data using PROs to assess patients after IPAA for UC.

Methods

This study was conducted according to the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines.[4]

Selection Criteria

All studies that examined PROs among patients after IPAA for UC were eligible for inclusion in this systematic review. Eligible studies included retrospective and prospective studies, provided that a PRO was used in the assessment of patients with an IPAA. Rather than using a traditional population, intervention, control, and outcomes framework, we sought to perform a scoping assessment, identifying all studies utilizing PROs in the evaluation of patients after IPAA. The individual PRO utilized in a study could be an assessment of overall QoL, health-related QoL, specific QoL domains, pouch-related symptoms, or pouch function. There were no exclusion criteria based on the clinical condition being evaluated, as long as the included patients had an IPAA. Any study where the author identified the use of a PRO was eligible for inclusion, and the use of a validated or pouch-specific PRO was not required. Because no meta-analysis was planned to accompany this systematic review, if multiple studies from the same center met the above inclusion criteria, each eligible study was included. We excluded any study that included patients with a preoperative diagnosis of Crohn's disease (CD) or familial adenomatous polyposis.

Search Strategy

We performed an electronic literature search on PubMed, Embase, and Web of Science using the following combination of keywords: IPAA, PROs measures, pouch, pouchitis, as well as corresponding medical subject heading (MeSH) terminology (See Table A1 for individual search strings). Searches were conducted including all studies from inception to October 12, 2021. In addition, we hand-searched references to the original articles and reviews to identify other potential studies for inclusion in the systematic review. All initial searches had no language restrictions; however, for final abstraction, the full manuscript was required to be in English. Duplicate references were identified and removed with the assistance of Covidence Systematic Review Software (Veritas Health Innovation, Melbourne, Australia).

One author (E.L.B.) performed initial screening of abstracts for inclusion and then those articles felt to be relevant were obtained in full text. Any questions regarding the potential for inclusion, in the final systematic review were discussed and mediated with a second author (H.H.H.).

Data Abstraction

During full-text review, relevant data from included manuscripts was abstracted and collected on a standardized form. Data elements included in the initial abstraction process included the first author and year of the study, pouch-related diagnosis being studied, PRO measure utilized in the study, and type of assessment or domain being studied.

Eligible full texts were further characterized by the type of assessment as well as the individual domains assessed by questions in the PRO measure. Individual questions from PRO measures containing more than one scale item were assigned to domains via a systematic process of binning, where items are grouped according to their meaning and the specific construct that they were intended to assess.[5] The development process of individual PROs and the validity of measures to assess patients after IPAA were also evaluated based on criteria previously outlined by the FDA.[3] Finally, we analyzed the primary center where each study was performed to evaluate a potential preference for PRO assessments by individual centers.

Statistical Analysis

Descriptive statistics were used to summarize the findings across studies. Continuous variables are described using means and standard deviations (SD) while categorical variables are reported as raw count values with accompanying percentages. All analyses were performed using SAS version 9.4 (SAS Institute, Cary NC, USA).

Results

From inception, a total of 1299 potential studies were identified (Figure 1). Using the predefined selection process for potential inclusion, 129 full texts were selected for inclusion.

Patient-reported Outcome Measures Utilized

Among the 129 full texts analyzed, 51 specific PRO measures were utilized (Table A2, Figure A1) which could be grouped into 8 types of assessments (Figure 2). Additionally, 8 measures were developed by authors and used for individual studies. In the evaluation of all PRO measures, 46% included an assessment of disease-specific QoL with 27% evaluating more general QoL, and 15% assessing symptoms related to pouch function. Among studies using disease-specific instruments, the Cleveland Clinic Global Quality of Life scale (42%) and the Inflammatory Bowel Disease Questionnaire (21%) were the most commonly used PRO measures. The Cleveland Clinic Global Quality of Life scale asks the patient to rate their current QoL, current quality of health, and current energy level using a 1–10 rating (where 10 is best). The score on each of these 3 components is added, and the final Cleveland Clinic Global Quality of Life utility score can be obtained by dividing this result

by 30.[6] Although developed for use in patients after IPAA, the questions are not specific to pouch symptoms or pouch-related QoL. The validity of the Cleveland Clinic Global Quality of Life scale was initially demonstrated by correlating, it with a general measure of QoL, the Rand 36-item short form health survey (SF-36).[7] Among studies assessing general QoL, a majority of studies used the SF-36[7] (58%) with an additional 5% of studies using the SF-12 or SF-8.

In assessments of pouch symptoms, the Cleveland Clinic Pelvic Pouch Questionnaire (22%), Oresland Score (19%), and Wexner Continence Grading Scale (14%) were the 3 most commonly used PRO measures. The Cleveland Clinic Pelvic Pouch Questionnaire is a self-administered, structured assessment that assesses several symptoms and experiences related to pouch function including bowel frequency, urgency, fecal incontinence, and stool seepage, as well as dietary, social, work, and sexual restrictions.[8] The Oresland Score is similar, as it was designed in 1989 to assess functional outcomes after IPAA, including symptoms of frequency, urgency, pad use, and perianal soreness.[9] The Wexner Continence Grading Scale specifically evaluates fecal continence, assessing degree of incontinence, lifestyle alterations, and the need to wear a pad to create a score of 0 (perfect continence) to 20 (complete incontinence).[10]

We also analyzed the use of PRO measures by the primary center where each study was performed, limiting this analysis to those studies where PRO measures were used in 5 or more studies. In this analysis, a preference for some measures was demonstrated by center, with 60% of all studies utilizing the Cleveland Clinic Global Quality of Life scale and 75% of studies using the Cleveland Clinic Pelvic Pouch Questionnaire being performed at Cleveland Clinic sites (Table A3).

Disease States Analyzed

The majority of studies utilizing PROs evaluated patients with an IPAA in general, without defining any specific pathology or disease state (Table A4). In assessing the specific PRO measures used, the 4 studies evaluating patients with chronic inflammatory conditions of the pouch (CD of the pouch and chronic pouchitis) used the Cleveland Clinic Global Quality of Life scale.[11–14] The Inflammatory Bowel Disease Questionnaire or Short Inflammatory Bowel Disease Questionnaire was used in 3 studies evaluating patients with specific pouch-related conditions,[11,15,16] and the Irritable Bowel Syndrome-Quality of Life Scale was used in 2 studies assessing patients with CD of the pouch.[11,12]

Validity of Questionnaires and Assessments

Given the number of assessments identified and the heterogeneity in disease states analyzed, we also assessed the validity testing of the questionnaires used to study patients with an IPAA. The validity of the measures was first assessed using criteria previously reported by the FDA, as summarized for the 5 most commonly used assessments in Table A5. In our evaluation, validity was judged as related to the assessment of patients after IPAA, noting that this may not have been the original population where many measures were developed. In the validation of the Cleveland Clinic Global Quality of Life scale, global questions of QoL and health were correlated to specific symptoms among patients after

IPAA such as bowel frequency and incontinence.[6] Additionally, construct validity was assessed by determining the effects of fecal incontinence of restriction in activities on a reduction in global QoL. The Cleveland Clinic Foundation Pelvic Pouch Questionnaire is a self-administered assessment measuring several symptoms that may be key in the evaluation of patients with inflammatory conditions of the pouch, such as bowel frequency, urgency, and incontinence.[8] However, the validation of this measure lacks detail, making it hard to assess.[8] Other measures, such as the Inflammatory Bowel Disease Questionnaire[17] and Short Inflammatory Bowel Disease Questionnaire[18] demonstrate robust development processes; however, their content validity for the assessment of patients after IPAA, and specifically patients with inflammatory conditions of the pouch, has not been definitively demonstrated.

Domain Assessments

In an attempt to identify major domains assessed by PRO measures, we mapped individual items from each PRO measure using the binning method previously described.[5] A total of 15 domains were identified, with the number of items per domain varying considerably. In these assessments, the greatest number of questions from individual PRO measures mapped to the bowel function domain (122), while the least number of questions mapped to the medical care domain ([2], Figure 3). Given that the bowel function domain represented the largest proportion of individual questions in PRO measures identified, we explored themes within this domain. Many of the individual measures contained questions surrounding symptoms of incontinence and leakage and the subsequent impact on patient's QoL.[9,10,17–23]

Discussion

In this systematic review of published studies evaluating PRO measures and assessments of patients after IPAA, we identified 129 studies utilizing 51 specific PRO measures. The studies and individual measures varied widely in both the patient populations being evaluated as well as outcomes and specific domains being assessed by the PRO measures. Furthermore, existing measures that were developed for patients who have undergone colectomy and IPAA are focused on post-operative outcomes and do not include items related to pouchitis symptoms. These findings confirm heterogeneity in assessment of the lived experience of having an IPAA and potential pouch-related complications. A valid set of measures that assess the range of outcomes after IPAA could standardize assessment and advance the study of patients after IPAA.

The need for better descriptions of the patient experience and evaluation after IPAA has been well recognized, and recent efforts to standardize the assessment of patient symptoms and pouch function after surgery have been launched. In a Delphi sonsensus study, Cavallaro et al.sought to create a patient-centered core outcome set that could be utilized in the reporting of pouch function.[2] Importantly, this study involved patients as key stakeholders, ultimately identifying 7 symptoms and 7 consequences from which a diagnosis of having IPS could be made. Many of the symptoms of IPS are reflected by questionnaire items in the bowel domain identified in our study, including incontinence, soiling, urgency, frequency, and nocturnal symptoms. These symptoms were then related to consequences that may

be evaluated specifically by patients including the need to wear pads, dietary or medical adjustments, and alterations in social roles.[2]

The FDA has indicated the need to develop and/or validate PROs in the specific condition where they will be studied/utilized.[3] This guidance has important implications when considering patients with pouchitis and other inflammatory conditions of the pouch, as these patients may require specific symptom-related PROs that are different from the global experience of having an IPAA. In our assessment of the validity of the most common PROs used in the evaluation of patients after IPAA, gaps existed in the validation of these measures, particularly in relation to the study of patients with pouchitis or pouch-related symptoms and the involvement of patients in the validation process.

Future work should evaluate the need for PROs specific to patients with pouchitis (and potentially other pouch-related disorders) as a defined population. Given the breadth of PRO measures that have been utilized in the assessment of patients after IPAA, critical discussions should surround both the goals of any assessment and the potential need for evaluation of a targeted patient population. For example, although broad assessments of all patients after IPAA may be useful, when considering the assessment of patients in clinical practice or in research settings, more dedicated assessments of specific pouch-related conditions such as pouchitis or Crohn's-like disease of the pouch are needed for longitudinal assessment and to evaluate response to therapy.

With these goals in mind, the ideal PRO for the assessment of patients with inflammatory conditions of the pouch in particular must offer objective assessments of both pouch symptoms as well as the potential impacts on QoL. To date, the most widely used PROs among patients after IPAA have not specifically assessed pouch symptoms[6,7], or in the case of the SF-36, have not been responsive to changes after IPAA.[2] Defining the domains or symptoms that patients find most problematic will be critical in the development of new, rigorously developed, and validated PRO measures and detecting their responsiveness to pouchitis-specific treatments. One of the most common indices used in the assessment of patients on therapy for inflammatory conditions of the pouch is the clinical portion of the pouchitis disease activity index.[24] Given that this measure is not a standalone PRO (but is a portion of a disease activity index), this was not included in our systematic review, further illustrating the significant opportunity for patient-centric assessments of symptoms and QoL as a dedicated measure of responsiveness to therapy.

We performed a thorough systematic review, evaluating all available studies that utilized PRO measures between 1995 and 2021. However, our study does have limitations. Traditionally, many of the fundamental studies in the pouch-related literature have been generated by single centers of inflammatory bowel disease excellence, which tended to repeatedly use the same measures. There is heterogeneity present, given multiple disease states (including normal pouches, functional pouch disorders, and inflammatory conditions of the pouch) present in the population analyzed and the numerous measurements utilized, which is a reflection of the literature to date. We attempted to evaluate the validity of existing PROs in the assessment of patients after IPAA; however, we recognize that many measures were created prior to current FDA guidance on the development of PROs. None

of these limitations hampers our ability to demonstrate the variety of PRO measures that have been used in the assessment of patients after IPAA or the need for more standardized assessments in this population.

In conclusion, among the 129 studies of patients after IPAA, we identified 51 specific PRO measures. As in many assessments, each of these measures has its own limitations. When evaluated in a systematic review; however, these results serve to highlight the critical need for standardized assessments in this population, driven by rigorous development and validation. Future work involving patients as key stakeholders will be key to continuing to advance our understanding of the lived experience after IPAA and opportunities for intervention, particularly among those patients with inflammatory conditions of the pouch.

Conclusion

In conclusion, among the 129 studies of patients after IPAA, we identified 51 specific PRO measures. As in many assessments, each of these measures has its own limitations. When evaluated in a systematic review; however, these results serve to highlight the critical need for standardized assessments in this population, driven by rigorous development and validation. Future work involving patients as key stakeholders will be key to continuing to advance our understanding of the lived experience after IPAA and opportunities for intervention, particularly among those patients with inflammatory conditions of the pouch.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Transparency Statement:

Raw data tables from systematic review are available upon request from the corresponding author (edward_barnes@med.unc.edu)

Abbreviations used in this paper:

CD	Crohn’s disease
FDA	Food and Drug Administration
IBD	inflammatory bowel disease
IPAA	ileal pouch-anal anastomosis
MeSH	Medical Subject Heading
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis

PROs	patient reported outcomes
QoL	quality of life
SF-36	Rand 36-Item Short Form Health Survey
UC	ulcerative colitis
US	United States

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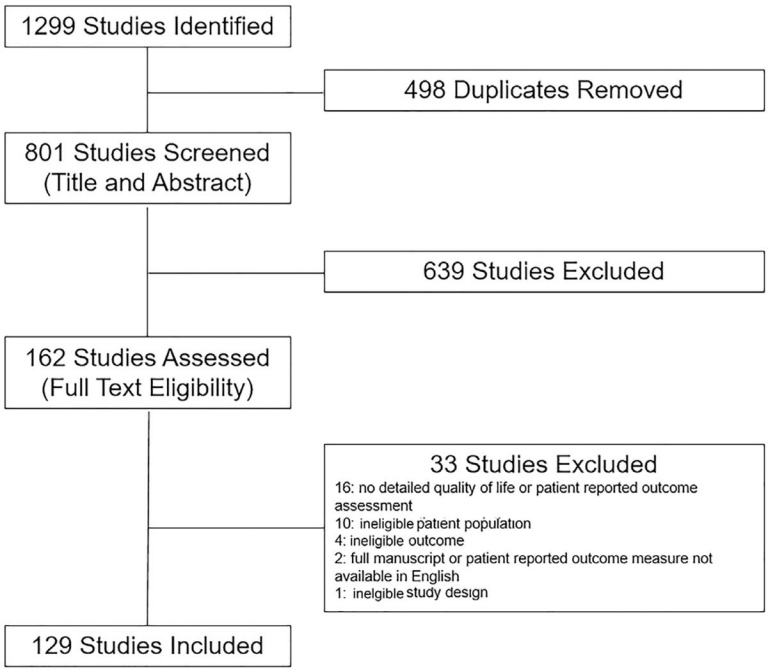

Figure 1.
Study flow diagram.

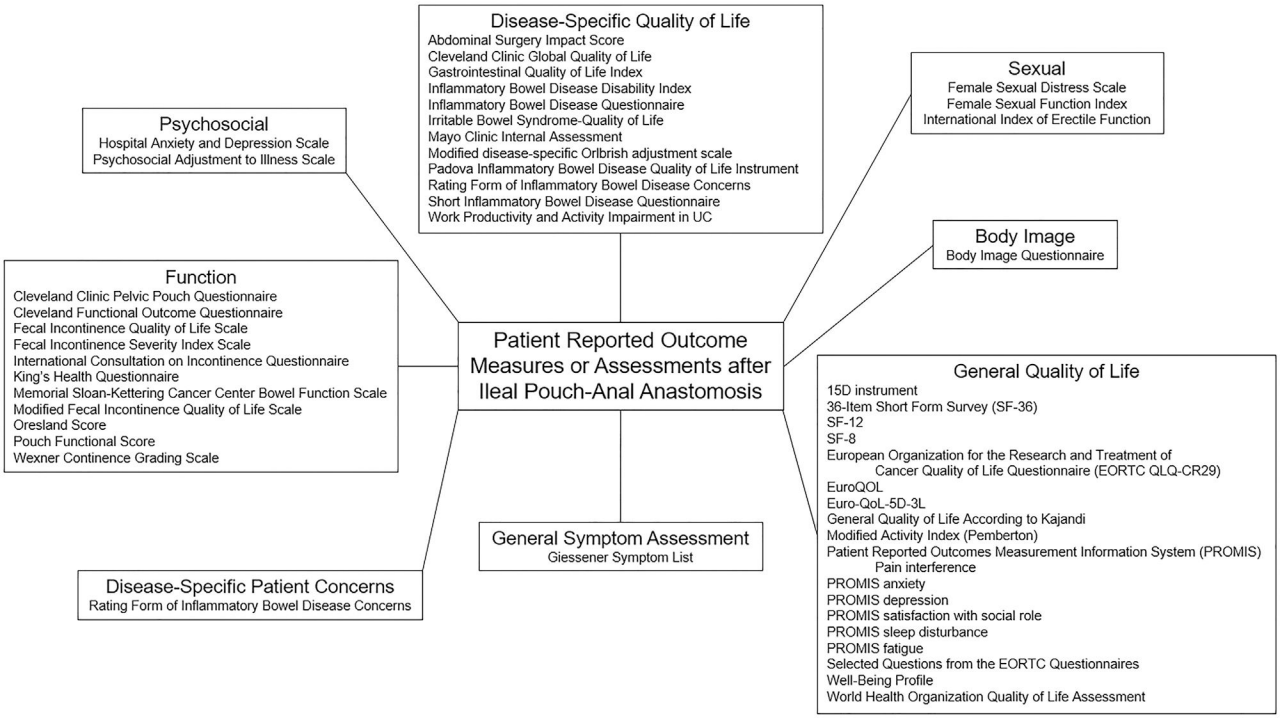

Figure 2.

PROs measures or assessments used in the evaluation of patients after IPAA, grouped by type of assessment.

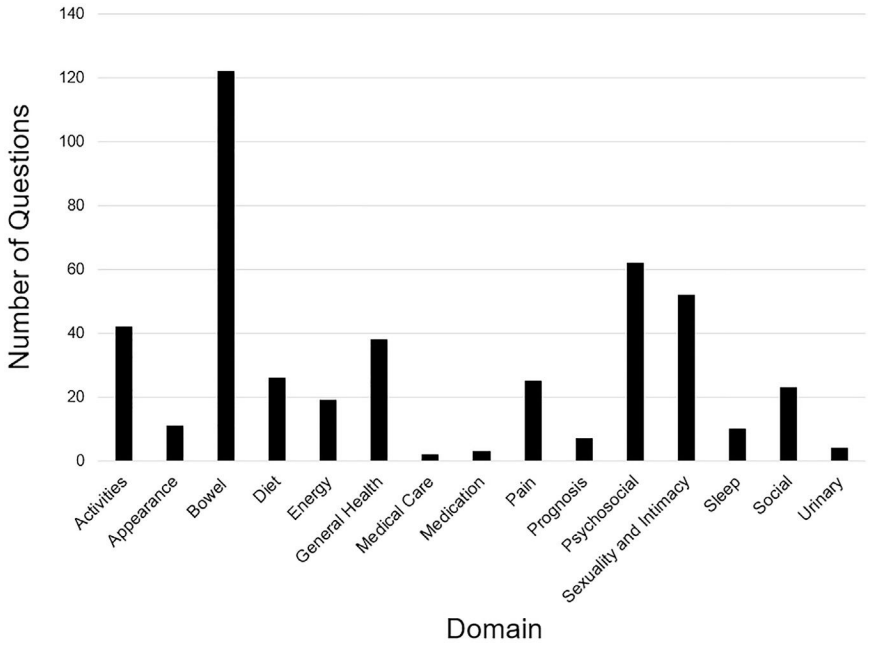

Figure 3.
Number of questions per domain assessed in PRO measures among patients after IPAA.