Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

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DOI: 10.17235/reed.2023.9563/2022
Link: PubMed (Epub ahead of print)

Please cite this article as:
Zabana Yamile, Calvet Xavier. Relevance of patient-reported outcome measures (PROM) and patient-reported experience measures (PREM) to assess disease status and quality of care in patients with inflammatory bowel disease. Rev Esp Enferm Dig 2023. doi: 10.17235/reed.2023.9563/2022.

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Relevance of patient-reported outcome measures (PROM) and patient-reported experience measures (PREM) to assess disease status and quality of care in patients with inflammatory bowel disease

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The 21st century has brough us a paradigm shift regarding patients care: the conventional physician-focused model of care has now changed into a patient-centered mode that puts the patient at the center of his own healthcare. Establishing a non-prescriptive and collaborative therapeutic approach, empowering patients to make major decisions on their management, and strict respect to the patient's autonomy are the major drivers of this patient-centered care. Among other multiple collectives, this change has greatly impacted patients and physicians who deal with inflammatory bowel disease (IBD).

This new model has fuelled the development of tools to capture the patients' perspective regarding their health status and the quality of the care they receive as another critical aspect of this new patient-centered approach. However, capturing the patients' opinion in a reliable and reproductible fashion is a tremendous challenging task in the management of IBD especially when the objective is to measure and monitor disease activity.

PROM (patient-reported outcome measures) and PREM (patient-reported experience measures) are two completely different tools although, by definition, they're both self-

administered. PROM are directed to measure the patients' assessment of their own state of health and overall wellbeing; PROM can assess all relevant health outcomes from quality of life to work disability. However, attention has been recently put on PROM to measure disease activity and response to treatment (1). As a matter of fact, the Food and Drugs Administration (FDA) recommended including PROM as the endpoints of studies to evaluate new drugs against IBD (2). Many different PROM questionnaires have been developed to this date. The most widely used are the PROM-2 and PROM-3 questionnaires derived from the Crohn's disease activity index (CDAI), the IBD disk, developed by Gosh et al. back in 2017 (3), and the IBD control, a set of PROM proposed for the management of IBD by International Consortium for Health Outcomes Measurement (ICHOM) expert consensus (4). However, if self-administered, all tools used to describe clinical activity can be theoretically used as PROM like the SCCAI (simple clinical colitis activity), PUCAI (pediatric ulcerative colitis activity index), Harvey Bradshaw or partial Mayo score.

PROM can evaluate disease activity in every patient. Furthermore, sequential measures may depict the patients' perception on the evolution of their own IBD. They should theoretically capture health aspects that accomplish two major conditions: being considered important and reliably evaluable by patients. It has been suggested that PROM should be a major tool for patient management by guiding IBD therapy in a treat-to-target strategy (5). However, fulfilling all the above-mentioned conditions is still an unsolved challenge. A probable major reason for this is that IBD symptoms extensively overlap with other digestive problems. Specifically, irritable bowel syndrome symptoms are highly prevalent in patients with IBD (6). Even for an expert gastroenterologist, it is often impossible to differentiate between the two entities based on the symptoms reported. Differential diagnosis often requires complementary examinations as radiological or endoscopic procedures. Thus, it should come as a surprise that patient-reported symptoms correlate better compared to clinical assessment with the objective indicators of IBD activity.

In fact, currently, none of the PROM developed for IBD meet the requirements of the FDA guidelines on PROM validation. FDA has recommended a standard validation approach by confirming the construct and criterion validity, reproducibility, and

sensitivity to change (7). In addition, most studies suggest that PROM correlate poorly with objective measures of IBD activity as endoscopy especially in Crohn's disease (CD). For example, Dragasevic et al. found a moderate correlation between PROM-2 and endoscopic activity for ulcerative colitis (UC), but a negative correlation between PROM and endoscopic activity in CD (8).

By contrast, PREM are measurements of the patients' perception of quality of care. Compared to PROM, PREM are not intended to be used individually. Contrarily, they should be used aggregately to provide devoted health-professionals and IBD units with feedback on the patients-perceived quality of care. PREAM are also useful to point the areas suitable for quality improvement. Two major studies had developed quality indicators from the patients' point of view, the Van der Eijk et al. (9) questionnaire for patients with inflammatory bowel disease (QUOTE-IBD) and the IQ CARO project (10). Although PREM have been evaluated much less than PROM, preliminary data using IQCARO quality indicators suggest that specialized IBD care is related to better quality scores (11) while higher IQ CARO scores correlate with better disease outcomes (12).

In conclusion, PROM and PREM —the new players in the IBD arena— have come to stay. Their value and usefulness, however, are still under discussion. Current evidence suggests that PROM are markers of global digestive wellbeing. However, they correlated poorly with the activity of individual diseases and, specifically, with IBD activity. Sequential PROM measurement might be useful to raise concern on new flares. However, there is little evidence supporting its use in this setting. Future research should focus on validating the available tools and testing its usefulness in different settings. By any means, it seems that although PROM will become an additional source of information, it will not significantly change current management. Regarding PREM, evidence on its usefulness is scarce, although they seem very promising tools to measure patients' satisfaction with care and signal areas of care with room for improvement. Furthermore, recording the patient's perspective may help close a 360° evaluation on quality of care.

Globally, PREM and PROM represent a step further into the patient's empowerment for managing IBD. Further developments will set their exact utility and value to improve quality of care and patients' outcomes.

Conflicts of interest: Y. Zabana received support for conference attendance, speaker fees, research support, and consulting fees from AbbVie, Adacyte, Almirall, Amgen, Dr Falk Pharma, FAES Pharma, Ferring, Janssen, MSD, Otsuka, Pfizer, Shire, Takeda, Galapagos, Boehringer Ingelheim, and Tillots. X. Calvet received support for conference attendance, speaker fees, research support, and consulting fees from AbbVie, Janssen, Kern, Takeda, Galapagos, and Ferring.

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