



## Surgical perspectives

## Patient-Reported Outcome Measures (PROMs) in colorectal cancer surgery

## Patient-Reported Outcome Measures (PROMs) en cirugía del cáncer colorrectal

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In recent years, there has been a paradigm shift in the evaluation of colorectal cancer surgery outcomes. Refinement of surgical techniques, implementation of prehabilitation and intensive postoperative recovery protocols (RICA or ERAS), among other measures, have led to a decrease in morbidity together with an increase in life expectancy. According to value-based clinical practice with the patient at the centre of the process, it is important to know not only the clinical results of an intervention, but also the impact on the quality of life of patients and the results they anticipate. Patient-Reported Outcomes (PROs) reflect the patient's point of view, recorded by Patient-Reported Outcome Measures (PROMs), generally in the form of questionnaires available online in multiple languages.

Since their introduction in 2006, PROMs, described by Michael E. Porter and Elizabeth Olmsted, have focused medical attention on the aspects that provide the most value.<sup>1</sup> In colorectal cancer surgery, in addition to survival, it is imperative to assess functional outcome and side effects over time. Despite gaining relevance, PROMs in this area lack standardisation and consistent implementation in clinical practice.

## Selection

PROMs cover different domains of physical and mental health. Although they can be used as an objective in themselves, they

appear as secondary objectives in most studies. Among the most commonly used instruments are:

- 1 Generic: EuroQoL-5 Dimension and the Short Form 36. They question mobility, self-care, emotional well-being and anxiety/depression, among other items.
- 2 Specific to cancer: Functional Assessment of Chronic Illness Therapy (FACIT) organisation's Functional Assessment of Cancer Therapy (FACT-G) and the European Organization for Research and Treatment of Cancer's Quality of Life Questionnaire, Cancer (EORTC-QLQ-C30). They examine overall health status, function, and symptoms.
- 3 Specific to colorectal cancer: EORTC-QLQ-CR38 (or its new version, EORTC-QLQ-CR29) and FACT-Colorectal (FACT-C), which analyse appetite, weight loss, gastrointestinal symptoms, and stoma-related problems.
- 4 Related to the after-effects of colorectal cancer surgery: LARS score for low anterior resection syndrome (LARS) and Wexner score for faecal incontinence, among others.<sup>2,3</sup>

The range and complexity of available PROMs are obstacles to summarising the evidence. A systematic review carried out by the CONSENSUS-CRC (Core Outcomes and Information-Set in Surgical Studies – Colorectal Cancer) Working group identified 58 different PROMs in 104 studies, 69% of them used in a single study.<sup>4</sup> The most commonly used questionnaire was the EORTC-QLQ-C30, present in less than half of

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them. Since there are multiple ways of questioning the same symptom, the use of a core outcome set or minimum group of variables to be investigated in all studies on colorectal cancer surgery is proposed, to facilitate the interpretation and comparison of results. Sutton et al.<sup>5</sup> managed to group these variables into four areas: physical symptoms, emotional response, provision of information and coping mechanisms.

Although the Colorectal Cancer Working Group of the International Consortium for Health Outcomes Measurement (ICHOM) recommended the use of the EORTC-QLQ30 and EORTC-QLQ-C29 for patients undergoing colorectal surgery,<sup>6</sup> currently no single instrument or set of variables is universally recommended, rather only the suggestion to consistently use validated tools.

## Limitations

A general limitation of these instruments is the narrow range of response options for assessing symptom severity (from zero to four or five points per item), which restricts the extrapolation of results. It is also important to consider the time involved in completing them, especially if they are offered during a medical visit. The advantages and disadvantages of the questionnaires mentioned above are summarised in Table 1.

## Application

Although PROMs have historically been applied in the form of interviews or printed questionnaires today more efficient options exist. The introduction of technology has led to an increase in the rate of response and use of questionnaires by medical professionals. In today's immersive digital era the first publications with promising results already exist.<sup>7</sup>

The literature addresses the use of these tools at each point in the care process of the patient undergoing colorectal cancer surgery, from screening and preoperative processes, through immediate recovery, to the evaluation of short- and long-term sequelae.

Regarding sequelae, the effect of a stoma on quality of life is obvious, but, beyond the clinical implications, the impact on self-esteem, social interactions, discomfort in the workplace, dependence on care, among others, must be evaluated. A review of 14 studies focusing on specific questionnaires for ostomy patients concluded that the problems reported by them change over time and that their quality of life is worse than that of other groups of patients.<sup>8</sup> The three scales used were the EORTC-QLQ-C30, the Stoma Quality of Life Questionnaire and the Modified City of Hope Colorectal Cancer Quality of Life Questionnaire - Ostomy.

**Table 1 – Practical summary of PROMs used in colorectal cancer surgery research.**

Type	Tool	Parameters assessed	Advantages	Limitations
Generic	EQ-5D-3L	Mobility, self-care, daily activities, pain/discomfort, anxiety and depression in three levels of intensity.	Available in >150 languages; Requires <5 min.	Low correlation with other PROMs.
	EQ-5D-5L	Five levels of intensity	Available in >150 languages; Requires <5 min.	Scarce sensitivity for certain population groups.
	SF-36	36 items on various domains (physical, pain, general health, mental health, vitality, social, emotional functioning)	Strong validity.	Requires up to 15 min.
Specific	FACT-C (including FACT-G)	36 items on physical, social/family, emotional and functional well-being. Attaches greater importance to the emotional domain than the EORTC. The -C version includes questions on digestive symptoms and stoma.	Available in 22 languages; Short questionnaire.	Requires 20–30 min. Not very informative in neo/adjuvant treatment.
	EORTC-QLQ-CR38 (including QLQ-C30)	Questions functionalism (body image, concern for the future, sexual function) and symptoms (problems with defecation, sexual dysfunction in men and women, side effects of chemo and radiotherapy). More sensitive in radiotherapy; more focused on symptoms than FACT-C.	Available in 16 languages.	Long questionnaire (68 items); Requires >11 min.
	EORTC-QLQ-CR29 (including QLQ-C30)	Adds specific items for symptoms associated with a stoma (feeling of shame, local irritation, disc leak) or, alternatively, anal incontinence (gas, faeces, daytime/night-time bowel habits). Sensitive in palliative chemotherapy; more symptom-focused than FACT-C.	Available in 17 languages.	Long questionnaire (59 items); Requires >11 min.

Abbreviations: PROMs, Patient-Reported Outcome Measures; EQ-5D-3 L, European Quality of Life, 5 Dimensions, 3 Levels; FACT, Functional Assessment of Chronic Illness Therapy (FACIT) organization's Functional Assessment of Cancer Therapy, Colorectal (-C) y General (-G); SF-36, Short Form-36; EORTC-QLQ, European Organization for Research and Treatment of Cancer's Quality of Life Questionnaire, Cancer.

PROMs have also been used to monitor new surgical techniques and audit their results. An example is transanal total mesorectal excision (TaTME). Koedam et al.,<sup>9</sup> concluded that the deterioration in quality of life was most evident during the first month, and recovered six months after surgery. They reported a LARS score higher than 30 in 33% of cases after ileostomy closure. The patient understands the oncological advantages of TaTME, but is unaware of the details of the possible impact on defecation, sexual and urinary function. PROMs in this field could help the patient decide on the type of intervention (e.g., with or without anastomosis, laparoscopic or combined approach) and avoid authority bias.<sup>10</sup> It is precisely when the effects of an intervention on quality of life are questioned that the opportunity arises to propose alternative strategies, such as Watch and Wait, which offers a better functional outcome than TaTME according to Quezada-Díaz et al.<sup>11</sup>

## Conclusion

Although their use has not been systematic and is diluted in the plethora of questionnaires and items, PROMs represent the future of designing a treatment centred on data provided by the patient, for the patient. The key also lies in the correct choice and consistent application of these tools in our clinical practice.

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## Declaration of competing interest

The authors have no conflict of interests to declare.

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