

## REVIEW ARTICLE

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# Quality of life aspects in patients operated for low rectal cancer

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## Summary

Neoplasms of the rectum represent a common therapeutic problem, with plenty of different possible operative decisions for low-situated tumor cases. Some unfavorable consequences of these surgical approaches seriously affect the patient's life. From the surgical point of view, sparing the sphincter can be considered as achievement of the desired result. This seldom matches what the operated people expect before and experience after the treatment.

The necessity of critical assessment of the used operative techniques arises with the rectal cancer surgery development. Despite their undeniable attractiveness, sphincter-sparing operations (SSO) are not accompanied with the

awaited result in every case. A need of feedback mechanism arises to control vacillation from saving sphincter by all means to the tremendous number of abdominoperineal excisions (APE).

With the introduction of the integral psychometric term "Quality of Life" (QoL) a possibility for a dynamic control over the obtained results was created. This control is realized by a set of instruments. These tools help measure objectively the results taken, as well as their practical use aiming to optimize our treatment policy. Recognition of their modifications and principles could be a step forward for the best interpretation.

**Key words:** carcinoma, incontinence, quality of life, rectum

## Introduction

Due to better therapeutic results after total mesorectal excision (TME), in recent years the distal rectal resections have extended down to the anus. The advances of combined chemoradiation have resulted in less APE interventions. But most of these sphincter-spared patients suffer mainly from functional disturbances and sometimes they chose an elective stoma [1]. There are plenty of technical innovations with the aim to improve the bowel function [2-5]. The debate over the optimal solution of the problem is still going on.

Sexual and urogenital disorders are well known after these operations and they depend on the volume of resection. These patients are in an impressively distorted social and emotional status. The presence of fecal incontinence (FI) is an important factor, dramatically influencing their QoL. FI measurement is a basic element for the evaluation of the holistic postoperative result.

In recent years some additional instruments have been introduced for the optimization of the obtained results. The complex conception of QoL has been introduced and a variety of objective parameters have been tailored, enabling a comparison of the applied surgical methods. In some north European countries the increased knowledge for failures after low rectal resections and, following bad QoL, has led to increased numbers of APE [6]. There are prospective randomized studies assessing different functional results and QoL in cases with or without stoma [7]. The present evidence suggests that a SSO is not absolute indication in cases of low rectal cancers [8,9].

## Quality of life

Unlike other social standards, QoL is a broad conception, integrating various criteria of physical, psycho-

logical and social nature. QoL includes the degree of dynamics of individual or group well-being. Its value is in close relation with measuring health, i.e. health-related QoL (HRQoL). In the narrow sense of the word the problem was defined in the 1980's in relation with the control over clinical trials and with the goal to set a patient's perspective [10]. The relevant leading institution in Europe is EORTC QLG (European Organization for Research and Treatment of Cancer-Quality of life Group) [11]. This group coordinates teams and specialists working on this topic in different countries [12]. Their working tools assess highly subjective and indirect variables so that QoL is objectively presented. Three basic types of measurement have been used in QoL assessment: 1) generic QoL scales, helping in rough estimation of gross change and comparison between target and other populations; 2) specialized scales, which are more useful in trying to isolate effects of specific variables, such as depression; and 3) condition-specific QoL scales, which measure the relationship between a specific medical condition, and treatment and QoL outcomes.

### Generic scales assessing QoL

The usage of these instruments has some advantages when measuring QoL in specific populations. One of them is GIQLI (Gastrointestinal Quality of Life Index), used in patients with gastrointestinal pathology [13], whereas the EORTC instrument QLQ-C30 is applicable to all cancer cases [11,14]. GIQLI was introduced by Eypasch et al. [13] and includes 36 points valued from 0 to 4. All of them cover symptoms connected with physical, emotional or social dysfunction, as a result of the disease or the applied treatment. The whole index is calculated via accumulation of all values. Zero suggests lowest QoL station contrary to 144 which represents the best one. In addition, every single element of the scale could be analyzed towards the others as a different matter.

The questionnaire suggested by EORTC QLQ-C30 is a 30-item scale, including 5 functional scales: physical, role, emotional, cognitive and social functioning. Another 3 symptom scales and 6 single items (fatigue, nausea and vomiting, pain, dyspnoea, insomnia appetite loss, constipation, diarrhea and financial difficulties) frame the structure of C30 [14] which is usefully tested on heterogeneous groups of cancer patients with different disease localizations [15,16].

A new advance is one of the most used generic tools – the questionnaire SF-36 (Short Form 36 General Quality of Life Assessment) [17]. It was introduced by a Community for measuring health outcome and ensures

a better possibility in correlation analysis of different populations, for instance patients with fecal incontinence to these with urinary incontinence, or with myocardial infarct, or even with healthy people [15,18]. SF-36 includes two basic criteria (physical and mental health) consisting of 36 questions and 8 multidimensional scales: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. In addition there is one-dimensional self-rating of change in the individual health status.

Responsiveness of any scale used is the ability to detect change. Responsiveness is viewed in the context of two main questions: 1) how much change is meaningful (in a particular area, such as clinical or personal change); and 2) how much change must occur before the instrument is capable of assessing the change? Generic instruments are usually adequate for detecting gross changes in a specific population, but they often lack the specific content (questions) to detect subtle changes. Some centers rely on their traditional and verified tools, which often cover the most used ones. For example, RAND-36 and SF-36 have different scoring number for sensation of general health, but essentially their items are identical and the coverage approximates 99% [19].

### Specialized scales assessing QoL

QLQ-CR38 of EORTC is a specialized tool for colorectal pathology. It comprises 38 questions which include a total of 4 functional scales/items: body image, sexual functioning, sexual enjoyment and future perspective. Like QLQ-C30 each functional scale has a range between 0 and 100 and higher value reflects better QoL. Furthermore, it includes a number of multi-item scales and single items and assesses a variety of symptoms associated with colorectal cancer: radiotherapy side-effects on micturition, chemotherapy side-effects, general symptoms in the gastrointestinal area, sexual dysfunction in men, sexual dysfunction in women, problem with defecation, stoma-related problems and weight loss [16,20].

Specialized instruments have some distinct advantages over general QoL tools [18]. They are developed around a specific condition, not a specific population. As such, they are similar to Condition-Specific QoL instruments. Their first great advantage is the lower probability that the floor effect will emerge, and the instrument will therefore be more responsive to change. Second, as with general QoL measures, specialized scales allow comparison of the construct across different populations (for instance, comparing the presence of depression in fecal incontinence vs. depres-

sion in multiple sclerosis). Their disadvantage is that, when assessing specific variables, they comply with a single score and they lack sense of gestalt of the problem, whereas scales such as GIQLI and SF-36 perform summary evaluation and the impression left is that they cover a larger part of overall QoL partitions.

### **Fecal incontinence and condition-specific QoL instruments**

FI is one of the most serious after-effects of low rectal resections [4]. Its higher frequency is a result of descending the level of anastomosis, related to loss of perception, distal volume and compliance of neorectum wall [1,21]. The patients' inability of controlling the passage of stool and gases creates serious fear of social communication. It can dramatically change their life rhythm, up to total restriction of their activities [18,22].

The American Society of Colon and Rectal Surgeons defines FI as the impaired ability to control gas or stool, ranging in severity from mild difficulty with gas control to complete loss over liquid and formed stools regulation [23]. The possibility of its measuring is a challenge, because it has an apparently subjective nature with an individual perception of its severity. Two basic aspects are available. The first one is assessing FI via frequency and quantity of the released faeces. The second aspect is measuring the influence of FI over the mechanism of its overcoming by changing the rhythm of life [18]. The problem is more complicated, because setting criteria of validity and reliability for these instruments is very difficult. Despite this, there are 3 main categories: descriptive weights (without summary score); quantity weights (they assess type and grade of incontinence); and weights, estimating the influence of FI over QoL. Some objective methods available, like anal tonometry, defecography, electromyography, endoanal ultrasonography, stimulation of sacral nerves etc, are auxiliary tools in the diagnostic process. They can help measure FI severity and follow-up the response of the treatment applied.

A great variety of strategies, all with advantages or shortcomings, are used for the FI quantity measuring. A subjective score is defined by practical questionnaires connected to corresponding symptoms. Three types of measures have been primarily used in rating FI: no weights, self-determined weights, and externally developed weights. Basically, they are related to stool consistency (type - solid, liquid, gas, mucus); wearing a pad or diapers as a coping mechanism; the change of daily routine (diet, enemas), defined by non exact formulated quantifiers. Some newly introduced tools have

as main goal to minimize the subjectivism. For instance in the Fecal Incontinence Severity Index (FISI) patients determine the weights not only into the groups, but between different groups [6,18]. It reflects the final score. The surgeon's opinion is an additional criterion, which corrects the value, like in FISI, and this gives the best opportunity for correlation analysis [24].

How FI influences the QoL is still a matter of investigation. The next important point focuses on the necessity of further development of these tools, like integrating the adapting mechanisms of operated patients and including of urgency into the whole sum. For this group of patients further development in learning QoL is the usage of Condition-Specific QoL scale. Rockwood et al. from Minnesota worked out their instrument FIQL (Fecal Incontinence Quality of Life) and published it in 2000 [25]. There are some adapted versions of the scale in different languages [12,26,27], without any principal differences. The authors' desire is to create a valid and reliable questionnaire for FI patients, with maximum QoL psychometric quantity reading and the ability of application and control over the treatment process.

FIQL comprises 4 scales formulated by 29 separated questions. Ten of them are joined to lifestyle; 9 are connected with coping and behavior mechanisms; depression/self-perception - 7 items; and embarrassment - 3 items [28]. A panel of experts, including colon and rectal surgeons and health service researchers, convened to identify QoL-related domains adversely affected by FI. A 41-item questionnaire was originally tested in 6 panels with a control group of gastrointestinal patients without FI. Its reliability in psychometric analysis was checked by test/retest for reproducibility that shows stability over time. For internal FIQL reliability the Cronbach's alpha test was used.

The instrument assessment was made by two types of validity: discriminative validity was taken via a selected control group, with affirmative factor analysis. Two scales and some of the questions dropped from the final variant of the instrument. Convergent validity was tested with the SF-36 comparable measures. A dozen of statistical significant coincidences supported the main aim of creating a condition-specific sensibility [25]. Such examples are depression (FIQL) to Mental Health, as well as Embarrassment to Role Physical (SF36).

Rockwood and coworkers' conclusion was that FIQL matches the psychometric requirements for measuring QoL in patients with FI. The questionnaire is reliable and sensitive, and stays dynamically stable, overlooking the effect of treatment. Receiving an assembling score from all 4 scales could be a next step in generalizing the results at population level, but according to the

inventors, the instrument specificity could be restricted. Each scale's separated weight has to be measured in order to improve FIQL instrument in the future.

### Does the presence of stoma impair QoL?

One of the main paradigms during the last years is the hypothesis of lower QoL of patients having stoma. Increased knowledge over carcinogenesis and some recent technical advances have led to a considerable increase of SSO in some Centers [29-32]. In a recent survey a Japanese group noticed a worse QoL in patients operated with low resection with temporary ileostomy, compared to others with upper anterior resection [33]. Role physical and role functioning scales are decreased in similar studies, which results in reduced overall QoL score [34]. An interesting fact is the lack of a condition-specific instrument in the study. Not including such a kind of scale the authors did not detect unfavorable functional results of low anastomoses. The main problem is the proper time for measuring QoL, along with the necessity of a new operation and all the related risks and possible complications.

Performing Miles operation we found reduced sexuality of patients. First, the presence of stoma is psychologically affecting the patient. The next important point is related to the volume of resection: the more the operative difficulties, the greater the chance of autonomous nerves' injury. A significant difference was reported by Schmidt et al. using the EORTC C30 [7]. They reported functional disturbances after SSO, such as diarrhea and FI, which were missing in stomated people. The final score provided evidence that the presence of stoma is a non-aggravating QoL factor, confirmed by the non-oncological SF-36 instrument. Another German team emphasizes the fact that patients offered SSO had better future confidence [8]. They gradually lost it waiting normal continence and the final QoL score was worse. Surprisingly, APE patients showed an easy and without sense of a problem adaptation, guaranteed by contemporary stoma appliances. The result was a better QoL. This is an example that the approach to the patient should be individualized, discussing all the possibilities and reaching the best decision.

The problem of measuring and comparing QoL in patients with SSO and APE remains still unsolved. Many reports over this topic, some of which randomized, continue to be published. A recent Danish review of 25 papers with over 620 participants matching the criteria reported that at this moment there is not enough evidence for better QoL for patients operated with a modification of low rectal resection compared to those having APE [35].

### QoL and transanal endoscopic microsurgery (TEM)

A micro-invasive approach in small distal tumors is an up-to-date strategy. TEM demands transanal access, and the sphincter's dilatation that follows leads to continence-related problems. Retrosopes of 4-cm diameter are used. In a study, the functional disturbances were more apparent during the first and second months after the procedure, especially for lesions nearer to the anal verge (less than 7 cm) [36]. There were no significant difference in the lifestyle and future perspective domains, while for embarrassment, coping and behavior differences were significant ( $\leq 0.05$ ). On a background of a worse functional result derived by FISI, a better QoL score by the generic instrument and FIQL was noted. Fenech et al. conclude an analogous result by conventional transanal approach for removing initial rectal tumors and polyps [37].

### Conclusion

The necessity of understanding sphincter-sparing related problems has become obvious in recent years. Clinicians need critical assessment of the final outcome so that they could dynamically control their operative tactics. Measuring QoL should be a supporting element for feedback of this specialized surgery.

The variety of QoL examination tools reflects the evolution in the contemporary comprehension of this important issue. Considering its subjective nature, its significance in the social sphere and the necessity of precise interpretation in clinical practice, it is very difficult to recommend any particular scale. Their future usage is justifiable and wanted for the improvement of this topic's knowledge, as well as for the achievement of a better QoL of patients operated with rectal cancer.

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