

Health-related quality of life in colorectal cancer

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Abstract

Aim As a consequence of the improved survival of patients and of cost-effectiveness requirements for new treatments, health-related quality of life (HRQoL) issues have gained increasing attention in colorectal cancer (CRC). This cross-sectional study assesses HRQoL in several health states of CRC and explores factors influencing HRQoL.

Method Five hundred and eight Finnish CRC patients (aged 26–96 years; colon cancer 56%; women 47%) assessed their HRQoL using generic 15D and EQ-5D and cancer-specific EORTC QLQ-C30 questionnaires. Patients were divided into five groups: primary treatment, rehabilitation, remission, metastatic disease and palliative care. The patients' HRQoL was compared with population reference values. Multivariate modelling was used to find factors associated with HRQoL scores.

Results The HRQoL of CRC patients is fairly good and comparable with that of the standardized general population except for those under palliative care. The mean 15D score of patients in the primary treatment group was 0.889 (95% CI 0.869–0.914), in rehabilitation 0.877 (0.855–0.907), in remission 0.886 (0.875–0.903), in metastatic disease 0.860 (0.844–0.878) and in palliative care 0.758 (0.716–0.808). The respective

EQ-5D scores were 0.760 (0.699–0.823), 0.835 (0.777–0.881), 0.850 (0.828–0.882), 0.820 (0.783–0.858) and 0.643 (0.546–0.747). Multivariate analysis showed that fatigue, pain, age and financial difficulties had a marked negative impact on HRQoL.

Conclusion The mean HRQoL scores of CRC patients varied considerably depending on the HRQoL instrument used, but remained surprisingly good up to the palliative stage. In addition to age- and cancer-related symptoms, financial difficulties also had a clear negative impact on HRQoL, which needs to be taken into consideration when supporting patient HRQoL.

Keywords Health-related quality of life (HRQoL), colorectal cancer, disease states, EORTC QLQ-C30, EQ-5D, 15D

What is new in this paper?

The health-related quality of life of colorectal cancer patients seems to be surprisingly good compared with a general population including all disease states excepting palliative patients. The three standardized instruments used provided very different scores. Pain, fatigue and financial difficulties were the main drivers for poor health.

Introduction

The incidence of colorectal cancer (CRC) has increased in Western countries [1]. In Finland 2736 new cases were diagnosed in 2010, making it the third most common cancer after breast and prostate cancer [2]. During the last 40 years, CRC has increased threefold. At the same time, 5-year survival

has improved, and is currently 61% for colon and 63% for rectal carcinoma [2]. When treatment choices are under consideration, improved survival underlines the importance of health-related quality of life (HRQoL). Although many new treatment options have become available, the need for optimal therapy remains unmet [3]. To evaluate whether future interventions should be implemented, what is crucial is a proper understanding of patients' HRQoL and cost of the treatment in real life.

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This study assesses HRQoL among various disease states of CRC in a real-world setting using three standard instruments and compares it with the HRQoL of the general population. It also explores clinical and demographic factors determining HRQoL in CRC.

Method

This cross-sectional observational survey of the HRQoL of CRC patients was carried out over 17 months between October 2009 and February 2011 in the Helsinki and Uusimaa Hospital District, which is responsible for the secondary care of nearly 1.5 million inhabitants of southern Finland representing nearly 30% of the whole Finnish population. The study was approved by the Ethics Committee of Helsinki University Central Hospital, and patients provided their written informed consent before inclusion. Their treatment followed normal routines and was not affected by the study. The trial has been registered in the Helsinki and Uusimaa Hospital District Register (www.hus.fi) with the unique trial number 233895.

Patients

All patients diagnosed with CRC were eligible and were identified from hospital records by date of diagnosis; each received a questionnaire by mail. Recently diagnosed patients or those receiving only palliative care were recruited on their visit to the hospital. All patients fulfilling the inclusion criteria received an invitation to participate. Those patients not responding to the original invitation to participate received one reminder.

Respondents' clinical background information regarding disease stage, treatment strategy and therapies in the previous 3 months came from hospital records. The data were validated by the hospital accounting database, which includes precise information about patient visits and diagnoses. Patients were divided into five mutually exclusive health states based on tumour stage, treatment and time from diagnosis. For patients with local disease, health states were primary treatment (0–6 months after diagnosis), rehabilitation (6–18 months after diagnosis) and remission (more than 18 months after diagnosis). Division of patients with metastatic disease was by two health states: metastatic disease, in which patients received oncological treatment, and palliative care.

The questionnaires

We used two generic HRQoL questionnaires, the 15D and the EuroQoL (EQ-5D). The latter also includes a visual-analogue scale (VAS) and the cancer-specific Euro-

pean Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire, (EORTC QLQ-C30). Generic, preference-based instruments, the EQ-5D and the 15D, produce a single index score for health status (HRQoL score), which makes it possible to compare commensurably HRQoL within a wide range of health conditions. This is essential for health economic analysis. With a generic profile instrument like the SF-36, these comparisons are impossible. The cancer-specific EORTC QLQ-C30 has been designed to capture cancer-related symptoms and functionality restrictions. It does not produce a comparable single-index HRQoL score. All instruments are validated, standardized and self-administered. The population reference values for these instruments are available from the Finnish Health 2000 Health Examination Survey [4].

The 15D consists of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental functioning, discomfort and symptoms, depression, distress, vitality and sexual activity [5]. Each dimension has five levels from 1 (no problems) to 5 (extreme problems). In addition to providing a single-index HRQoL score (ranging from 0 to 1), the 15D can also serve as a profile instrument depicting patients' assessment of their HRQoL on each of the 15 dimensions of health. For the 15D we used the Finnish valuation algorithm for HRQoL scores and profiles. 15D responses with more than three values missing must be excluded from analysis; otherwise, the missing values can be imputed by linear regression. The minimal important difference (MID) of the 15D has been estimated to be 0.03 [6].

The EQ-5D is a five-dimensional (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) instrument. Each dimension has three levels. The index score cannot be calculated if any answer is missing. The maximum score of 1 represents full health with no problems on any dimension. The minimum score depends on the valuation algorithm used. To calculate the HRQoL scores, we used the UK time-trade-off (TTO) tariff which produces a minimum score of -0.594 [7]. The minimal clinically important difference (MID) for the EQ-5D TTO is estimated to be 0.08 [8]. The EQ-VAS expresses the patient's self-perceived evaluation of his/her health state on a 100-point vertical scale with its end-points being the best/worst imaginable health state. For the VAS, the MID has been estimated to range between 7 and 12 [8].

The EORTC QLQ-C30 is a 30-item cancer-specific HRQoL instrument producing a global health status, five functioning scales (physical, role, social, emotional and cognitive functions), three symptom scales (fatigue, nausea/vomiting and pain) and six single-symptom

items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties), but no single-index values [9]. We calculated the items according to the EORTC scoring manual [10].

Furthermore, patients answered background questions regarding marital status, education level, occupational status, treatments received outside the hospital and informal care.

Statistical analysis

We performed three types of analysis. First, we calculated proportions for the key demographic characteristics and unadjusted means, standard errors and confidence intervals for HRQoL in each disease state.

Second, we compared the EQ-5D and 15D scores and the 15D profiles with those of the general population by means of Student's independent samples *t*-test. The age, gender and education distributions of the population samples were weighted to correspond to those of the patients in each state.

Thirdly, we built a multiple regression model using ordinary least square (OLS) to assess the determinants of HRQoL measured by the EQ-5D, VAS and 15D. In the multivariate analysis we pooled the patients into one group in order to explore all factors irrespective of any predefined disease state. The model was built in two steps. In the first we included, as potential predictors, gender, age, education, marital/cohabiting status, working status, presence of a stoma, tumour site, symptoms, disease stage, time since diagnosis, presence of extrahepatic metastasis, time from surgery, treatments

given within the previous 3 months, palliative care status and, from the EORTC QLQ-C30, financial difficulties. The analysis was run by stepwise selection. In the second, we added EORTC QLQ-C30 symptom variables (fatigue, nausea/vomiting and pain, dyspnoea, insomnia, appetite loss, constipation and diarrhoea). A risk level of 5% was used for Type I error in all analyses. Analyses were performed with spss 20 (SPSS Inc., Chicago, Illinois, USA).

Results

Study population

Of the 845 CRC patients approached, 519 (61%) responded, of whom 11 were excluded for failing to meet inclusion criteria (Fig. 1). Of the patients included, 357 had local and 151 metastatic disease. The patients were further divided into five groups as follows: primary treatment (< 6 months from diagnosis; 61), rehabilitation (6–18 months; 79), remission (> 18 months; 217), metastatic (110) and palliative (41).

Patient age ranged from 26 to 96 years with a mean of 68 (Table 1); 57% had colon cancer, 47% were women and 15% had stomas (ranging from 10 to 18% based on disease state). In the primary treatment group, 46% answered the questionnaire before their primary surgery. The majority of the patients were married/cohabiting and had higher education, defined as at least having completed high school. Working status differed among the groups: 57% in the primary treatment group were retired compared with 72–90% in the other

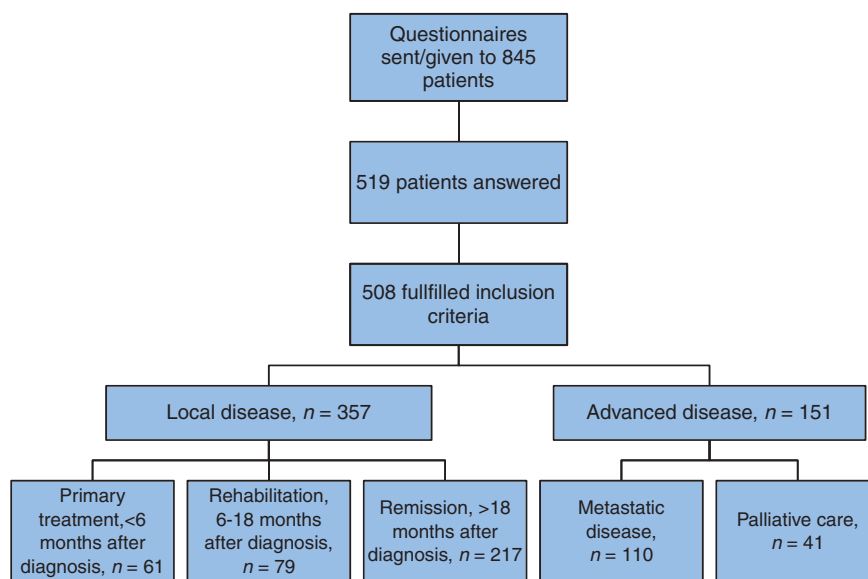


Figure 1 Colorectal patient flow chart.

Table 1 Patient characteristics.

	Primary treatment	Rehabilitation	Remission	Metastatic disease	Palliative care	All patients
Responders	61 (12)	79 (16)	217 (43)	110 (22)	41 (8)	508 (100)
Demographic factors						
Age, mean (SD) (years)	64.8 (10.8)	72.4 (11.1)	67.9 (11.7)	64.8 (10.2)	69 (9.1)	67.7 (11.3)
Female (%)	28 (46)	43 (54)	101 (47)	53 (48)	13 (32)	238 (47)
Higher education (%)	39 (64)	41 (53)	117 (54)	62 (56)	20 (51)	279 (55)
Work status (%)						
Employed	20 (33)	12 (15)	53 (25)	26 (24)	4 (10)	115 (23)
Retired	35 (57)	62 (79)	155 (72)	78 (72)	35 (90)	365 (73)
Unemployed/not working	6 (10)	4 (5)	8 (4)	5 (5)	0 (0)	23 (5)
White collar employment (%)	30 (49)	36 (46)	113 (53)	51 (46)	21 (54)	251 (50)
Married/cohabiting (%)	36 (59)	50 (64)	139 (64)	84 (76)	25 (64)	334 (66)
Tumour factors						
Months from diagnosis (SD)	1.8 (1.6)	14.4 (2.6)	34.2 (14.2)	31.0 (23.9)	37.7 (31.5)	26.8 (20.6)
Months from metastases (SD)	–	–	–	18.8 (16.1)	17.6 (15.9)	–
Tumour site (%)						
Colon	31 (51)	48 (61)	114 (53)	69 (63)	26 (63)	288 (57)
Rectum	30 (49)	31 (39)	103 (47)	41 (37)	15 (37)	220 (43)
Extrahepatic metastases (%)	–	–	–	74 (67)	31 (76)	–
Treatment factors, within the previous 3 months						
Radiotherapy (%)	11 (18)	1 (1)	0 (0)	2 (2)	2 (5)	16 (0.031)
Chemotherapy (%)	7 (11)	3 (4)	1 (0)	60 (55)	24 (59)	95 (19)
Targeted therapy (%)	0 (0)	0 (0)	1 (0)	37 (34)	20 (49)	58 (11)
Stoma (%)	6 (10)	11 (14)	39 (18)	14 (13)	6 (15)	76 (15)

groups. Age and sex distribution showed no significant difference between respondents and nonrespondents.

HRQoL scores by disease states

The 15D provided the highest scores, ranging from 0.423 to 1 with a mean for the whole group of 0.869. HRQoL scores with EQ-5D ranged from –0.429 to 1, mean 0.813. VAS scores, representing patients' subjective assessment of health status, ranged from 1 to 100, mean 74.6 (Table 2, Fig. 2). In the palliative care state, HRQoL fell and differed significantly from other states, regardless of the instrument used. The EQ-5D score

and VAS were highest in the remission state, unlike the 15D which was highest in the primary treatment state. The ceiling effect (patients reporting perfect health) was most pronounced with the EQ-5D: 41% of responders reported full health compared with 9% with the 15D and 5% with the VAS.

Comparison with a control population

Compared with the general population standardized for age, gender and education, the patients' HRQoL values, measured by 15D and EQ-5D, were good in relation to those of the general population (Table 3).

Table 2 Mean health-related quality of life scores among colorectal cancer disease states.

	15D				EQ-5D				VAS			
	Mean	n	SD	95% CI	Mean	n	SD	95% CI	Mean	n	SD	95% CI
Primary treatment	0.889	60	0.090	0.869; 0.914	0.760	60	0.233	0.699; 0.823	68.1	59	22.2	62.0; 73.7
Rehabilitation	0.877	77	0.103	0.855; 0.907	0.835	74	0.207	0.777; 0.881	77.0	73	18.7	72.4; 81.7
Remission	0.886	216	0.106	0.875; 0.903	0.850	208	0.207	0.828; 0.882	78.9	213	18.0	77.1; 81.8
Metastatic disease	0.860	110	0.090	0.844; 0.878	0.820	108	0.198	0.783; 0.858	73.9	110	17.7	70.5; 77.3
Palliative care	0.758	41	0.143	0.716; 0.808	0.643	41	0.311	0.546; 0.747	58.8	40	22.2	51.6; 65.9
All patients	0.869	504	0.109	0.862; 0.881	0.813	491	0.225	0.795; 0.835	74.6	495	19.8	73.0; 76.5

VAS, visual-analogue scale; SD, standard deviation; CI, confidence interval.

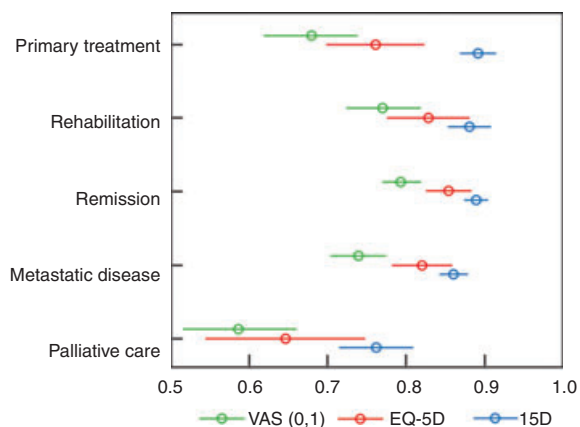


Figure 2 Mean health-related quality of life scores in colorectal cancer.

The mean 15D score was significantly worse than that of the general population only in the palliative care state, in which most of the domains were impaired. The mean EQ-5D score of CRC survivors was even higher in rehabilitation and remission states than was that of the general population.

Differences in 15D dimensions between disease states and compared with the general population were relatively minor, except in the palliative care state (Fig. 3). Mobil-

ity, sexual activity, vitality, excretion and usual activity in particular showed the largest impairment. In the metastatic disease state, no significant difference emerged in 15D score, but depression, distress, vitality, sexual activity and excretion were significantly impaired compared with the general population. Among patients with localized disease, only excretion was significantly impaired in primary treatment and remission states when compared with the general population. The discomfort and symptoms dimension was even higher in the rehabilitation and remission states than it was for the general population, as were scores for eating in the rehabilitation and mental functioning in the remission state.

EORTC QLQ symptoms and functionality scales

The cancer-specific EORTC QLQ-C30 highlighted the fact that patients in the palliative state (Fig. 4) reported more symptoms than did patients in other states. Patients in the primary treatment state were the second most symptomatic. In the total sample, 24% of patients reported at least some financial difficulties due to their cancer, problems most pronounced in the palliative care state (44%). The global health score was lowest in the palliative care state, and likewise in the functional domains of physical, social and role functioning.

Table 3 Health-related quality of life of colorectal cancer patients compared with that of the standardized general population.

	Primary treatment Δ	Rehabilitation Δ	Remission Δ	Metastatic disease Δ	Palliative care Δ
EQ-5D score	-0.033	0.064*	0.046***	-0.005	-0.119*
15D score	-0.008	0.015	0.008	-0.016	-0.107***
Mobility	0.013	0.036	0.012	0.014	-0.136***
Vision	0.007	0.009	0.020*	0.006	-0.051
Hearing	-0.012	0.002	0.014	-0.003	-0.058
Breathing	0.029	0.035	0.014	0.004	-0.120**
Sleeping	-0.005	-0.014	-0.005	-0.020	-0.093*
Eating	-0.016	0.018***	0.006	0.009	-0.069**
Speech	0.005	0.014	0.010	0.002	-0.074**
Excretion	-0.100***	-0.029	-0.074***	-0.076***	-0.141***
Usual activities	-0.018	0.022	0.008	-0.037	-0.202***
Mental function	0.029	0.027	0.043***	0.008	-0.041
Discomfort and symptoms	-0.009	0.055*	0.049**	0.009	-0.057
Depression	0.009	0.004	0.006	-0.043***	-0.074***
Distress	-0.027	-0.019	0.002	-0.063***	-0.053
Vitality	-0.027	0.015	0.002	-0.044**	-0.167***
Sexual activity	-0.062	0.010	-0.010	-0.111***	-0.254***

Δ, Difference from general population. A negative/positive number indicates that the patients are on average worse off/better off than the general population.

*P < 0.05.

**P < 0.01.

***P < 0.005.

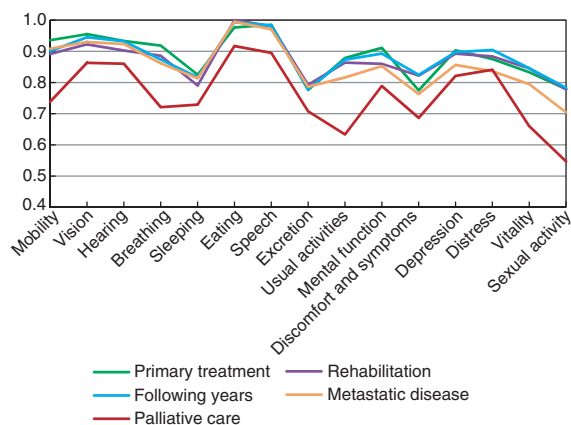


Figure 3 15D profile in colorectal cancer disease states.

Factors influencing HRQoL

First-phase multivariate analysis showed that demographic and clinical factors can explain 22–32% of the variance in HRQoL. Financial difficulties, age and palliative care status were associated with lower HRQoL with all instruments. Within EQ-5D and VAS, marriage/cohabiting improved HRQoL. Whether patients answered before or after the primary surgery had no effect on their HRQoL scores. Neither did stoma, gender nor tumour site (colon/rectal) explain changes in HRQoL.

In the second phase, symptom scales and items from the EORTC QLQ-C30 were included in the regression models, which as expected improved predictive accuracy (52–66%). The models revealed that, in addition to age and financial difficulties, fatigue and pain were the main drivers for poor HRQoL (Table 4).

Discussion

In this observational cross-sectional study examining the HRQoL in different states of CRC with three different instruments, HRQoL was lowest among patients receiving only palliative care, as could be expected. However, the differences between the other states were relatively small, despite the instrument used. HRQoL improved after primary treatment when measured by EQ-5D and VAS, and by EQ-5D it was even higher than in a general population. Compared with figures for the general population, the HRQoL was significantly impaired only in the palliative care state. Diagnosis of CRC as such does not therefore seem to impair HRQoL (Table 3).

At present, only a limited number of studies have examined the HRQoL of CRC patients by using generic measures. In a Finnish national-level health survey, the mean score for cancer patients was 0.855 measured by the 15D and 0.741 by the EQ-5D, compared with our 0.869 and 0.813 [11]. In a Japanese study investigating the HRQoL score of long-term survivors,

Table 4 Factors associated with health-related quality of life scores.

Variable	15D		EQ-5D		VAS	
	Std coefficient	P-value	Std coefficient	P-value	Std coefficient	P-value
Phase 1 model	$R^2 = 0.321$		$R^2 = 0.250$		$R^2 = 0.215$	
Age	-0.302	<0.001	-0.135	0.001	-0.191	<0.001
Financial difficulties	-0.408	<0.001	-0.381	<0.001	-0.332	<0.001
Married/cohabiting	-	-	0.159	<0.001	0.092	0.031
Metastatic disease	-0.103	0.015	-	-	-	-
Palliative care	-0.188	<0.001	-0.173	<0.001	-0.184	<0.001
Radiotherapy	-	-	-	-	-0.099	0.015
Phase 2 model	$R^2 = 0.660$		$R^2 = 0.593$		$R^2 = 0.515$	
Age	-0.225	<0.001	-0.097	0.002	-0.129	<0.001
Appetite loss	-	-	-	-	-0.085	0.032
Diarrhoea	-	-	-0.106	0.001	-	-
Dyspnoea	-0.148	<0.001	-	-	-	-
Fatigue	-0.391	<0.001	-0.304	<0.001	-0.418	<0.001
Financial difficulties	-0.165	<0.001	-0.128	<0.001	-0.093	0.010
Insomnia	-0.168	<0.001	-	-	-	-
Married/cohabiting	-	-	0.079	0.011	-	-
Metastatic disease	-0.074	0.008	-	-	-	-
Pain	-0.155	<0.001	-0.410	<0.001	-0.252	<0.001

VAS, visual analogue scale; Std coefficient, standardized coefficient.

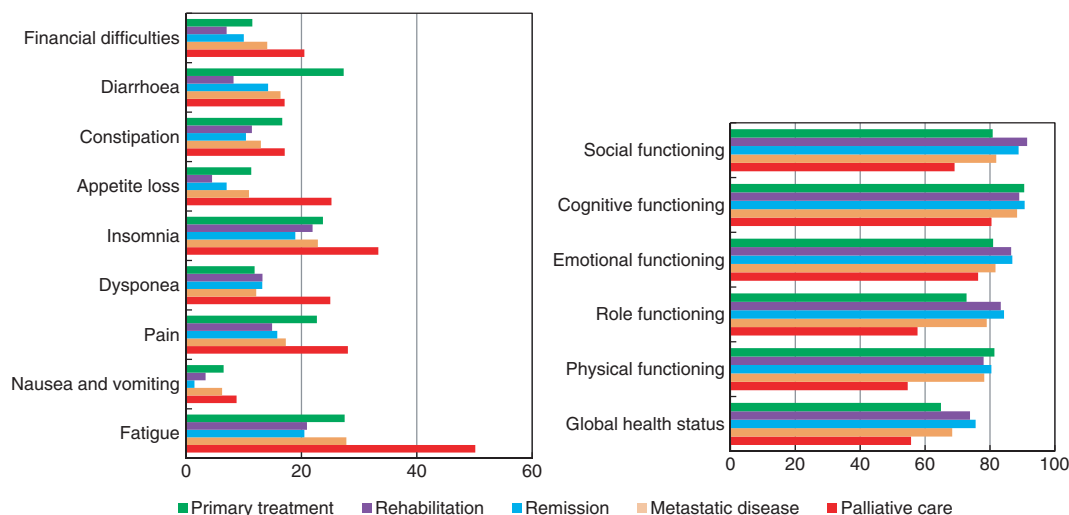


Figure 4 EORTC QLQ-C30 functionality and symptoms in colorectal cancer.

the EQ-5D was 0.865 in nonstoma patients and 0.842 in patients with a stoma [12]. Both studies used the same EQ-5D valuation algorithm (UK TTO) as in this study. The EORTC QLQ-C30 is the most frequent HRQoL instrument for CRC [13]. In a German study assessing HRQoL of 3-year CRC survivors with the EORTC QLQ-C30, those patients reported lower functional ability and more symptoms than did ours [14].

The study revealed that the instruments used are applicable in this patient population. However, different HRQoL instruments provide very different estimates for the HRQoL. Choice of HRQoL instrument thus has a marked effect on HRQoL scores: the 15D provided the highest mean values and patients' self-rating on the VAS the lowest. 15D scores were higher than the EQ-5D scores, possibly because the EQ-5D does not produce values between 1 and 0.88, and very low negative values are possible. The ceiling effect was most prominent with the EQ-5D. This is associated with poor sensitivity in terms of discriminatory power. Based on our results, what appears essential is that the same instruments and valuation methods are involved when HRQoL results are compared or combined, for instance in health economic modelling. When HRQoL scores based on the same instrument are unavailable, mapping methods are one alternative.

Multivariate analysis showed a clear association with fatigue and pain and poor HRQoL. Focusing more on the symptoms may help clinicians identify patients possibly at risk for poor HRQoL. The clinical and demographic background factors did not explain the HRQoL as well as the symptoms did. The analysis showed no difference in HRQoL between patients with colon or rectal cancer, and interestingly nor did

the treatments given or stoma have any significant effect in this analysis. However, financial difficulties related to a cancer diagnosis and treatment, although not very common, are clearly associated with impaired HRQoL.

Some limitations of our study require consideration. The response rate was rather modest, even though there was no difference in gender or age distribution between nonrespondents and respondents. We had no access to the patient files of the nonrespondents to know their disease severity. Multivariate analysis of HRQoL scores, especially when one uses the EQ-5D, is problematic, as distributions are highly skewed, discontinuous and triple-peaked.

Understanding patients' HRQoL and factors associated with it is essential in evaluating future health technologies. To our knowledge this is the first study to use the 15D in CRC patients and to compare several HRQoL instruments in an observational real-world setting covering all disease states in one study.

This study provides valuable information on the HRQoL of CRC patients as it occurs in real life. In the less advanced states of the disease, patients' HRQoL appears to be relatively good, comparable to that of a general population. However, HRQoL varies considerably, depending on choice of HRQoL instrument. When new health technologies and treatment options for CRC are assessed in terms of HRQoL, it is important to select sensitive tools which enable one to react to changes between different disease states.

HRQoL is an important factor to be taken into account when treating patients – especially those with metastatic disease for whom there may be no cure. In that stage it may be wiser to allocate resources to

improving patients' HRQoL rather than investing in expensive oncological treatments. The results also emphasize that a variety of factors need to be taken into account when trying to maintain patients' QoL. Fatigue and pain are self-evident factors affecting HRQoL, but the fact, for instance, that financial difficulties can be an important determinant of HRQoL is an important finding for the clinician.

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Author contributions

All authors have contributed to study conception and design, acquisition of data, analysis and interpretation of data and writing the manuscript.

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