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ORIGINAL ARTICLE

Patient-reported outcomes after treatment for rectal cancer—A prospective nationwide study

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Abstract

Aim: While modern treatment has improved rectal cancer (RC) survival, it can cause late side effects that impact health-related quality of life (HRQoL). The aim of this study was to evaluate HRQoL and late effects 1 year after diagnosis in patients who underwent major resection for Stage I–III RC.

Method: All patients with RC registered in the Cancer Registry of Norway between 1 January 2019 and 31 December 2020, aged ≥ 18 years, and a control group without colorectal cancer were invited to participate in the study by answering a questionnaire on HRQoL and late effects. Functional domains and symptoms were compared in different patient groups and between patients and controls.

Results: There were 558 patients and 1693 controls eligible for analysis. Response rates were 41% for patients and 23% for controls. Some differences in HRQoL were observed between treatment modalities. Major low anterior resection syndrome (LARS) was prevalent in 60.8% of patients, and was associated with lower functional and higher symptom scores compared with patients with no/minor LARS. Patients with major chronic pain [$n = 86$ (15.4%)] had significantly lower scores for most of the functional items and higher symptom scores than patients with no/minor chronic pain. Patients had some lower functional scores and several higher symptoms score compared with controls.

Conclusion: Patients who suffered from major LARS or major chronic pain had significantly impaired functions and more symptoms beyond change in bowel function and pain, respectively. Identification and treatment of these patient may hopefully be beneficial for their HRQoL.

KEYWORDS
chronic pain, health related quality of life, late side effects, low anterior resection syndrome, patient reported outcome measures, rectal cancer

INTRODUCTION

The incidence of rectal cancer (RC) has been stable for the last two decades, with a slight decrease in recent years, although an increased incidence among patients below 50 years is observed [1,2]. Around 60% of all RC patients diagnosed in Norway, all stages included, are offered treatment with curative intent [3]. The 5-year relative survival for Stage I–III RC patients operated on with curative intent has improved over the decades and is now about 90%, contributing to an increasing number of RC survivors [4-6].

Surgery is the main curative treatment for RC. In Norway, 30%–40% of RC patients receive preoperative chemoradiotherapy (CRT) or radiotherapy (RT) to reduce the risk of local recurrence. Total neoadjuvant treatment is increasingly used [7], while adjuvant chemotherapy is rarely used [8].

While improving survival, modern treatments may cause late side effects that impact health-related quality of life (HRQoL) [9]. Rectal surgery and RT affect anorectal function [10-12], despite advances in RT techniques that minimize toxicity [13]. Chemotherapy may cause long-term side effects, including fatigue and oxaliplatin-induced neuropathy [14,15]. Other known late effects include impaired urogenital function, pelvic fractures and secondary cancers [16-21].

In addition to outcomes such as survival and relapse, assessment from the patient's perspective using standardized questionnaires on symptoms, functional status and perceived HRQoL, i.e. patient-reported outcomes, is important [22].

The present study aimed to evaluate functional outcomes, late adverse effects and HRQoL in patients who underwent major resection for Stage I–III RC in Norway. Secondary objectives included investigating potential differences in HRQoL across patient characteristics and treatment modalities, and between patients with major versus no/minor low anterior resection syndrome (LARS) or chronic pain. Lastly, the study compared HRQoL between patients and controls.

What does this paper add to the literature?

Patients who underwent major surgery for rectal cancer had impaired quality of life (QoL). One in four patients reported chronic pain and major low anterior resection syndrome was reported by 60.8% of patients who had undergone low anterior resection. The presence of major chronic pain and anorectal dysfunction had a strong impact on QoL.

METHOD

Study design

This prospective nationwide project invited Norwegian patients with colorectal cancer (CRC), and controls to participate by completing of a questionnaire, and thus consenting to participate.

Study population

Eligible patients were registered in the Norwegian Colorectal Cancer Registry with a CRC diagnosis in the period between 1 January 2019 and 31 December 2020, aged ≥18 years, alive and not emigrated 1 year after diagnosis. The present study focuses on patients with Stage I–III RC operated on with abdominoperineal resection (APR), Hartmann's procedure or low anterior resection (LAR), including both total mesorectal excision and partial mesorectal excision. The questionnaire was scheduled to be sent 1 year after diagnosis. However, due to delays, the first invitations were dispatched in early November 2020.

The control group was matched by age group, gender and region of residence, and had no history of CRC recorded in the Cancer Registry of Norway (CRN) between 1953 and the date of invitation. The invitation letter included information and the questionnaire and was sent electronically, or by mail to those who did not use digital services. Patients and controls received identical information ensuring patient confidentiality, although some questions were only relevant for the patients.

Patient-reported outcome measure questionnaires

The generic questionnaire QLQ-C30 and the CRC module QLQ-CR29 from the European Organization for Research and Treatment of Cancer (EORTC) were used for measurement of HRQoL [23,24], and the QLQ-CIPN20 to investigate symptoms and functional limitations related to chemotherapy-induced peripheral neuropathy (CIPN) [25,26]. For EORTC questionnaires, a score is calculated from 0 to 100. A high score on a functional scale indicates a high level of functioning, while a high score on a symptom scale indicates a high level of symptoms. A difference between two groups of ≥10 points was considered clinically relevant [27]. Missing data were handled according to the scoring manual [28].

The LARS score was used to assess bowel function after sphincter-sparing surgery for RC and categorized as no LARS (0–20), minor LARS (21–29) and major LARS (30–42) [29].

The St Mark's incontinence score measures symptoms of anal incontinence over the last 4 weeks. The possible total score ranges from 0 (perfect continence) to 24 (total incontinence) [30].

The Rectal Cancer Female Sexuality score assesses sexual function in women with a total score range of 0–29. A score of 9 or more indicates sexual dysfunction [31].

The Expanded Prostate Cancer Index Composite Short Form (EPIC-26) is validated for prostate cancer patients [32,33]. We considered the section about sexual function to be relevant for male RC patients due to the anatomical proximity. It covers the sexual health

over the last 4 weeks [34]. A score was calculated from 0 (lowest function) to 100 (normal function), according to the manual [35].

Chronic pain (CP) following treatment for RC was assessed by a scoring system developed by Mortensen et al. specifically for this patient group [36]. It consists of seven questions, resulting in a total score ranging from 0 to 45. Patients were categorized to no pain or no significant pain (0–7), minor pain syndrome (8–17), and major pain syndrome (≥18).

The questionnaire also covered marital status, employment, income, highest level of education, weight and height.

Other data sources

The CRN has registered all cancer cases in Norway since 1953. It is mandatory to report all cancer cases to the registry, and the completeness for CRC cases is estimated to be close to 100% [4]. The CRN provided information on patient and tumour characteristics at diagnosis and information on residency, emigration or death.

The Norwegian Colorectal Cancer Registry was established in 1993 for RC as part of the CRN and was expanded to include colon cancer in 2007. This registry provided data on stage, treatment and follow-up. All health regions, except the Northern Norway Regional Health Authority, report date and type of intravenously administered chemotherapy directly from their systems, providing complete data.

The Norwegian Patient Registry provided national information on orally administered chemotherapy, such as capecitabine. For patients treated in Northern Norway, only information on orally administered chemotherapy was used.

The representativeness of patient responders was evaluated by aggregated statistics from the CRN (Table S1) on the distribution of gender, age, stage at diagnosis and treatment for all RC patients with Stage I–III disease who underwent major resection, registered in the CRN in 2018 and 2021 who were alive and not emigrated 1 year after diagnosis.

Treatment

The recommended surgical technique for Stage I–III RC is mesorectal excision, which implies dissection in the proximity of nerves, putting anorectal, bladder and sexual function at risk of damage. Moreover, RT can be harmful to neural tissue. Hartmann's procedure and APR result in a permanent stoma, while LAR aims to preserve bowel emptying without a stoma. For low-risk RC, primary surgery is performed. Possible neoadjuvant treatment strategies for locally advanced RC include short-course RT (SCRT) with 5 × 5 Gy, CRT with (25–27) × 1.8–2 Gy concomitant with capecitabine or 5-fluorouracil, total neoadjuvant treatment with SCRT followed by chemotherapy (CAPOX or FOLFOX) for 3–5 months (RAPIDO regimen) or CRT followed by or preceded by CAPOX or FOLFOX. Surgery is performed 8–12 weeks after RT or CRT, or 2–4 weeks after the last chemotherapy. Adjuvant chemotherapy is only given in selected cases [7,37,38].

Statistical analysis

Standard descriptive statistics are presented. Univariable tests included chi-square tests for categorical variables and independent samples *t*-tests for continuous variables.

Oncological treatment was divided into four groups: 'no radiation therapy or chemotherapy', 'radiation therapy and chemotherapy', 'chemotherapy only' and 'radiation therapy only' to investigate if different treatment strategies had an influence on functional and symptom scores. Moreover, the impact of surgical procedures was assessed by comparing APR/Hartmann's/LAR with stoma versus LAR. Seven patients who were registered with APR/Hartmann's procedure reported not to have a stoma and were excluded from analyses involving those parameters.

Functional and symptom scores of patients were compared with regard to no/minor LARS versus those with major LARS, and no/minor chronic pain versus those with major chronic pain. LARS and St Marks scores were calculated for patients operated with LAR without self-reported stoma. Chronic pain score was calculated for all RC patients. Mean score differences (referred to as 'difference') of ≥10 points were considered clinically relevant and only these results are highlighted to enhance readability.

To assess associations of covariates on the likelihood of reporting a high LARS score, St Marks score, global quality of life (QoL) and chronic pain, multivariable regression models were used. The following covariates were included in the models: age, gender, body mass index, relationship status, education, surgery, oncological treatment and time since surgery. Stratified analyses were performed according to sex. For the CIPN, Cronbach's alpha was below 0.7 for the autonomic subscale analyses and therefore not included.

Standard *p*-values were reported. To account for multiple hypothesis testing, the Benjamini–Hochberg (BH) procedure was applied to control the false discovery rate to 5%. Stata version 18.0 [39] was used for all analyses.

RESULTS

Patient characteristics

Patient characteristics are given in Table 1. A total of 558 Stage I–III RC patients with major resection (65.1% male) and 1693 controls (59.7% male) were eligible for analysis. Response rates in the project were 41% for patients and 23% for controls (Figure 1). Median age was 68 years (range 31–91 years) for patients and 70 years (range 20–88 years) for controls. Among patients, 250 (44.8%) reported having a stoma.

The most frequent surgical procedure was LAR (61.6%), followed by APR (31.4%) and Hartmann's procedure (7.0%). A total of 154 (27.6%) received both RT (≥25 Gy) and chemotherapy as part of their treatment. Thirty seven (6.6%) received only RT and 50 (9.0%) only chemotherapy. Of the 204 patients receiving chemotherapy, 73 (35.8%) had regimens containing oxaliplatin (Table 2).

TABLE 1 Characteristics for Stage I–III rectal cancer patients operated on with major resection and controls.

Patient characteristics	Rectal cancer Stage I–III, major resection ($N = 558$), *n* (%)	Controls ($N = 1693$), *n* (%)	Chi-square *p*-values
Age (years)			0.03
Median (range)	68 (31–91)	70 (20–88)	
18–49	33 (5.9%)	151 (8.9%)	
50–74	380 (68.1%)	1068 (63.1%)	
≥75	145 (26.0%)	474 (28.0%)	
Gender			0.02
Male	363 (65.1%)	1010 (59.7%)	
Female	195 (34.9%)	683 (40.3%)	
Body mass index (BMI) (kg/m^2)			**0.01**
Normal weight/underweight[a] (BMI <25)	253 (45.3%)	653 (38.6%)	
Overweight (BMI 25–29.9)	206 (36.9%)	696 (41.1%)	
Obesity (BMI ≥30)	81 (14.5%)	291 (17.2%)	
Unknown	18 (3.2%)	53 (3.1%)	
Level of education			**0.01**
Elementary school	100 (17.9%)	248 (14.6%)	
High school	227 (40.7%)	602 (35.6%)	
College/university ≤4 years	131 (23.5%)	478 (28.2%)	
College/university >4 years	88 (15.8%)	324 (19.1%)	
Unknown	12 (2.2%)	41 (2.4%)	
Working 1 year ago (controls)/at time of diagnosis (cases)[b]			0.79
Yes	234 (41.9%)	690 (40.8%)	
No	295 (52.9%)	847 (50.0%)	
Unknown	29 (5.2%)	156 (9.2%)	
Working at time of submitted response[b]			0.25
Yes	199 (35.7%)	649 (38.3%)	
No	342 (61.3%)	992 (58.6%)	
Unknown	17 (3.0%)	52 (3.1%)	
Relationship status			0.70
In a relationship[c]	429 (76.9%)	1321 (78.0%)	
Single	113 (20.3%)	332 (19.6%)	
Unknown	16 (2.9%)	40 (2.4%)	
Stoma (self reported)			**<0.01**
Yes	250 (44.8%)	24 (1.4%)	
No	298 (53.4%)	1569 (92.7%)	
Unknown	10 (1.8%)	100 (5.9%)	
Stage			
I	169 (30.3%)		
II	170 (30.5%)		
III	219 (39.2%)		
Time since surgery when answering questionnaire			
<1 year	297 (53.2%)		
≥1 year	261 (46.8%)		

Note: *p*-values that remain significant after adjustment for multiple testing using the Benjamini–Hochberg procedure have been marked in bold.

[a]A total of 18 persons were underweight (ten cases and eight controls).

[b]Full-time, part-time and self-employed.

[c]Includes those in a relationship, regardless of their cohabitation status.

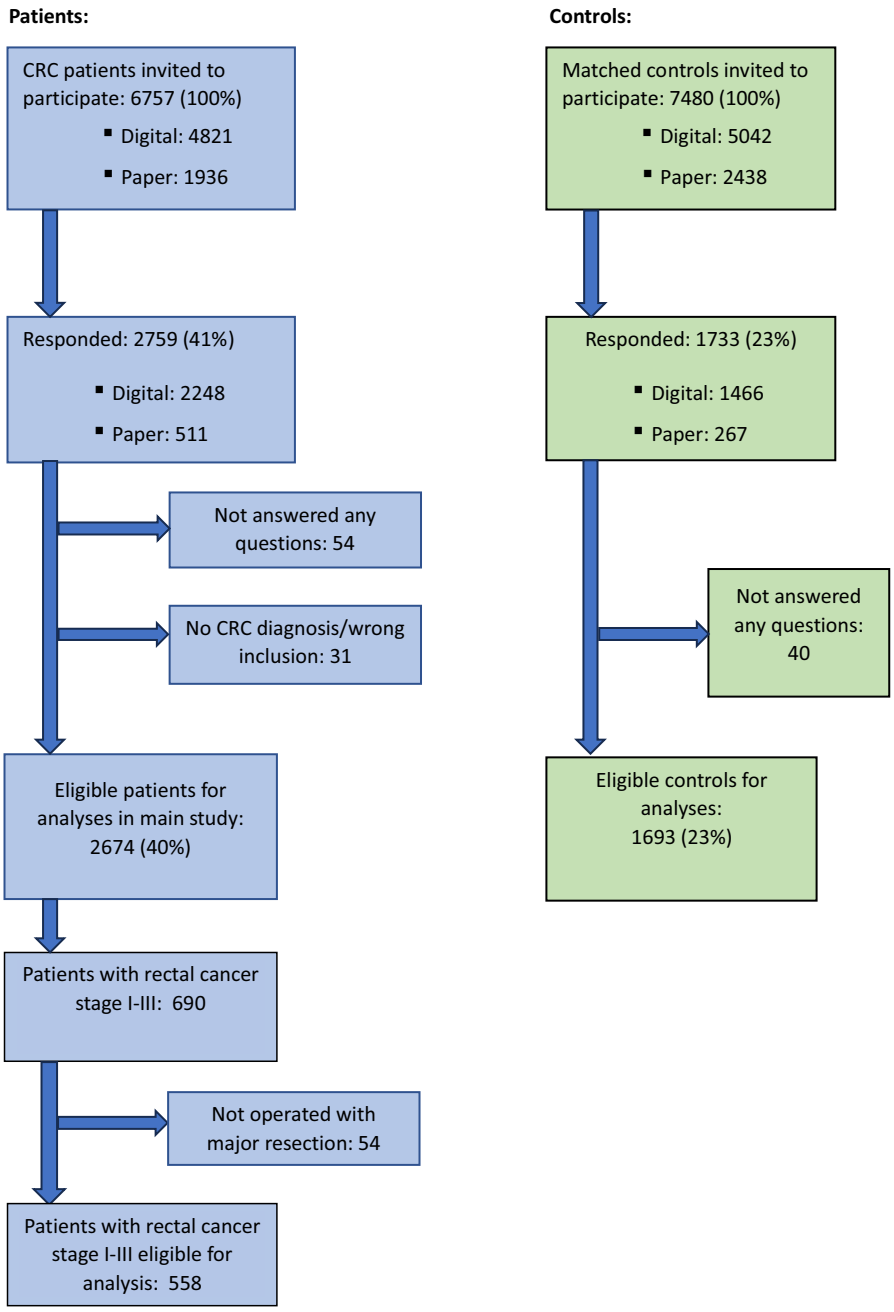


FIGURE 1 Flowchart of included patients and controls. A total of 6757 colorectal cancer (CRC) patients were invited, 41% responded and of them 558 patients met the inclusion criteria for this study.

Functional and symptom scores across treatment regimens

Oncological treatment

Mean scores with 95% CI for QLQ-C30 and QLQ CR-29 are presented in Figure 2 and Table S2. Patients who received both RT and chemotherapy ($n=154$) had a lower functional score for body image (difference −15.4, 95% CI −20.3 to −10.6, $p<0.01$) and weight (difference −10.3, 95% CI −14.7 to −6.0, $p<0.01$) and higher symptom scores for buttock pain (difference 12.1, 95% CI 6.8–17.3, $p<0.01$) and impotence (difference 14.7, 95% CI 5.5–24.0, $p<0.01$) compared with patients who did not receive any oncological treatment ($n=277$).

Clinically relevant differences were also observed between patients who received only RT ($n=37$) or chemotherapy ($n=50$) compared with patients without any oncological treatment. These differences primarily pertained to specific items and were not consistent with the findings for patients who received both RT and chemotherapy.

Surgical procedures

Mean scores with 95% CI for QLQ-C30 and QLQ CR-29 are presented in Figure 3 and Table S3. Overall, only minor differences in functional and symptom scores between patients operated on with the various surgical procedures were seen. However, APR and Hartmann's procedure were associated with lower functional scores for body image (difference −15.8, 95% CI −20.0 to −11.6, $p<0.01$) and impotence (difference 30.3, 95% CI 22.9–37.7, $p<0.01$) compared with LAR. Furthermore, patients who underwent LAR had

TABLE 2 Treatment given to Stage I–III rectal cancer patients operated on with major resection.

Treatment	Rectal cancer stage I–III, major resection ($N = 558$), *n* (%)
Degree of surgery urgency	
Elective	554 (99.3%)
Acute	4 (0.7%)
Type of surgery	
Open surgery	79 (14.2%)
Laparoscopic surgery	479 (85.8%)
Surgical technique	
Low anterior resection	344 (61.6%)
Abdominoperineal resection	175 (31.4%)
Hartmann's procedure	39 (7.0%)
Oncological treatment[a]	
Radiation therapy + chemotherapy	154 (27.6%)
Radiation therapy only	37 (6.6%)
Chemotherapy only	50 (9.0%)
No oncological treatment	277 (49.6%)
Unknown	40 (7.2%)

[a]Seventy three of those receiving chemotherapy received oxaliplatin. Chemotherapy includes oxaliplatin, 5-fluorouracil, capecitabine and irinotecan.

higher symptom scores for constipation (difference −11.0; 95% CI: −15.2 to −6.8; $p < 0.01$) and diarrhoea (difference −13.3; 95% CI −18.2 to −8.5; $p < 0.01$) compared with those who underwent APR or Hartmann's procedure.

Multivariable analyses of global QoL

In multivariable analysis, the global QoL was significantly lower among patients who were single (Coeff −7.8, 95% CI −12.6 to −3.0, $p < 0.01$) compared with those in a relationship (Table 3).

Differences between patients and controls

Mean scores with 95% CI for QLQ-C30 and QLQ CR-29 are presented in Figure 2 and Table S2. Patients had lower scores for four of eleven domains: social function (difference −14.7, 95% CI −17.1 to −12.4, $p < 0.01$), body image (difference −14.5, 95% CI −16.4 to −12.6, $p < 0.01$), anxiety (difference −10.1, 95% CI −12.5 to −7.8, $p < 0.01$) and sexual interest among women (difference −10.3, 95% CI −14.7 to −5.9, $p < 0.01$).

They had higher symptom scores than controls in eight domains, particularly higher for stool frequency (difference 27.7, 95% CI: 25.9–29.5, $p < 0.01$), flatulence (difference 24.2; 95% CI 21.2–27.2, $p < 0.01$) and impotence (difference 24.1, 95% CI 19.4–28.7, $p < 0.01$).

Chemotherapy-induced peripheral neuropathy (EORTC QLQ-CIPN20)

Patients who received oxaliplatin ($n = 73$) reported higher sensory scores (difference 16.2, 95% CI 13.1–19.4, $p < 0.01$) compared with the controls.

LARS score

Major LARS was reported by 60.8% of the 291 patients who underwent LAR and occurred more frequently in women (63.7% vs. 59.0% for men). In the control group, 10.5% experienced major LARS (Table S4).

Patients with major LARS had lower scores for global health status (difference −11.8, 95% CI −16.6 to −6.9, $p < 0.01$), role function (difference −12.4, 95% CI −18.4 to −6.4, $p < 0.01$), social function (difference −20.2, 95% CI −25.9 to −14.5, $p < 0.01$) and body image (difference −11.3, 95% CI −15.9 to −6.7, $p < 0.01$) compared with patients with no/minor LARS.

In addition to all symptoms of anorectal function, patients with major LARS had higher scores for several other symptoms compared with patients with no/minor LARS. The largest difference was observed for flatulence (difference 29.7, 95% CI 23.6–35.8, $p < 0.01$) (Figure 3, Table S3).

There were no significant predictors for major LARS among patients, while multivariable analysis in controls showed that female gender (OR 2.9, 95% CI 2.0–4.1, $p < 0.01$) and obesity (OR 2.0, 95% CI 1.2–3.1, $p < 0.01$) were associated with increased risk for major LARS, but with decreased risk among individuals with a higher level of education (OR 0.6, 95% CI 0.4–0.8, $p < 0.01$) (Table S5).

St Mark's score

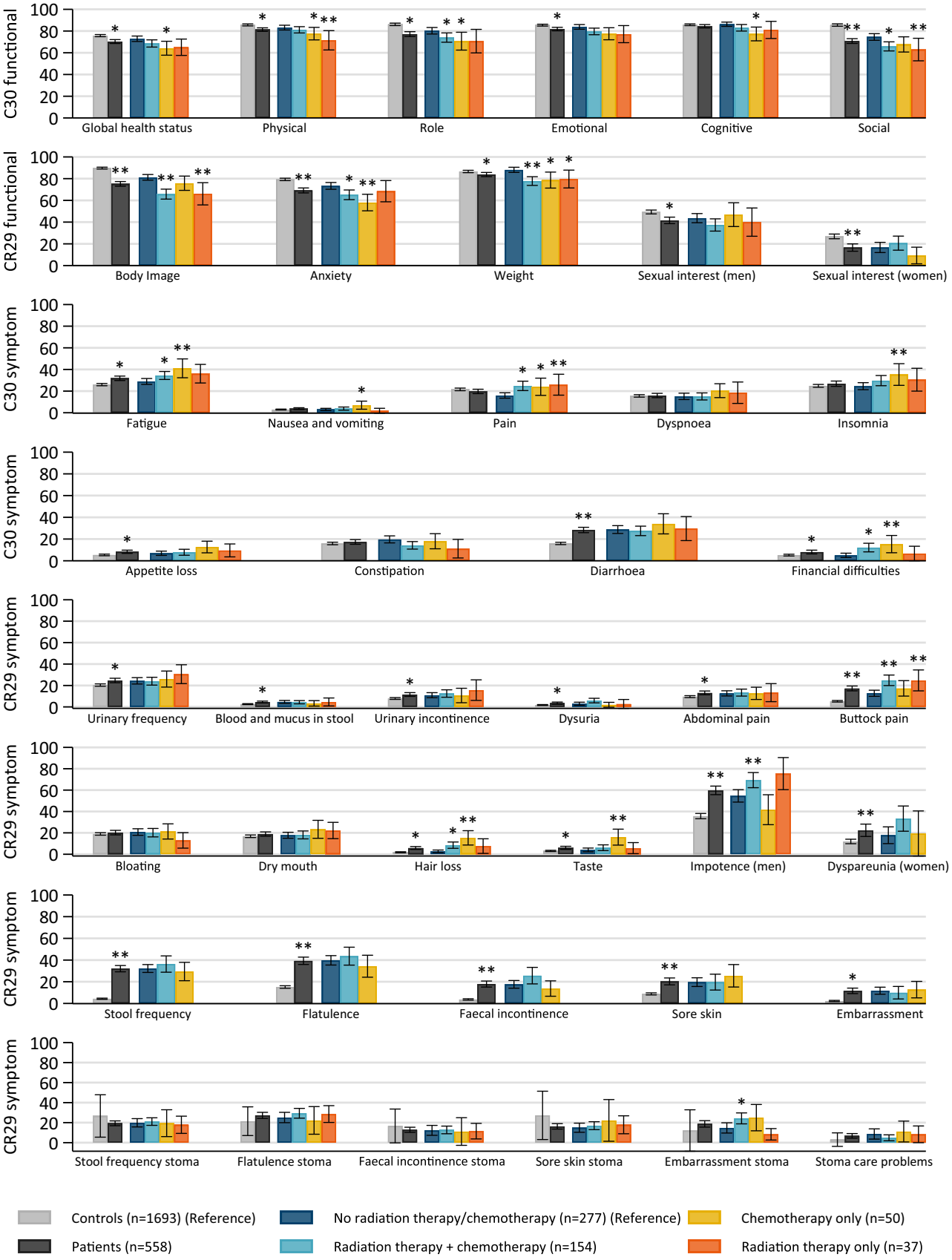
Patients had a significantly higher mean St Marks score than controls (difference 5.3, 95% CI 4.8–5.8, $p < 0.01$). Higher educational level was a predictor for higher incontinence score in multivariable analysis (Coeff 1.9, 95% CI 0.3–3.4, $p = 0.02$).

In the control group, higher education was a predictor for lower St Marks score, whereas age over 75 years, being female and overweight/obesity predicted a higher risk (Table S6).

Sexual function

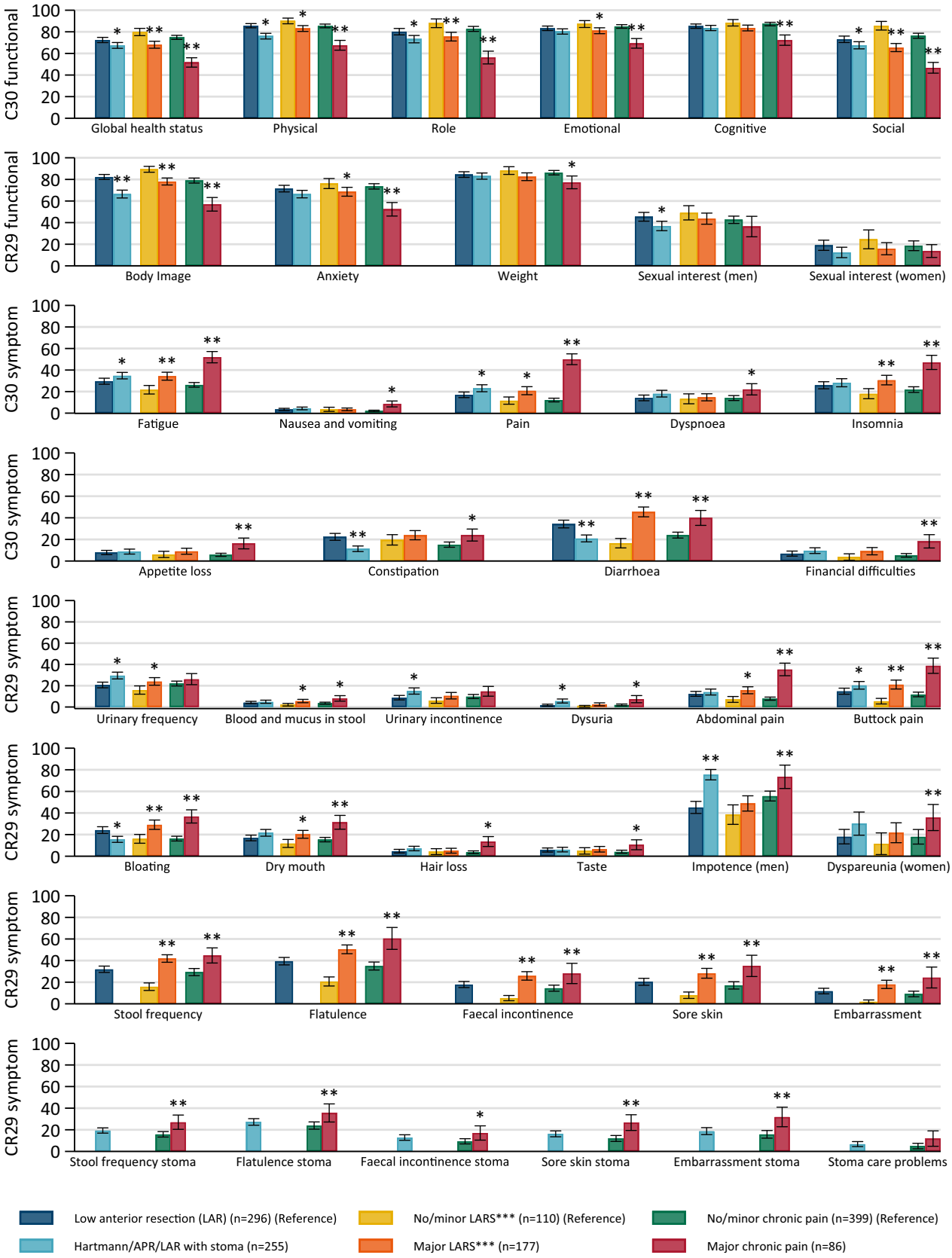
Among male patients, 85 (23.4%) reported being sexually active in contrast to 498 (49.3%) of the controls, and 75 patients (20.7%) reported that they became sexually inactive after diagnosis. The mean sexual score in EPIC 26 was 73.6 (SD 23.7) among patients and 78.7 (SD 18.6) among controls.

Among female patients, 44 (22.6%) reported being sexually active in contrast to 246 (36%) of the controls, and 31 (15.9%)



* Statistically significant after adjusting for multiple testing (Benjamini-Hochberg), t-test against reference group.
** Statistically significant in addition to clinically relevant (≥ 10 points difference)

FIGURE 2 Mean scores with 95% confidence interval of functional and symptom domains from EORTC QLQ-C30 and QLQ CR-29 for patients and controls. Scores are compared between (1) oncological treatment therapies for patients only and (2) patients and controls.



* Statistically significant after adjusting for multiple testing (Benjamini-Hochberg), t-test against reference group.
** Statistically significant in addition to clinically relevant (≥ 10 points difference)
*** Only including patients who underwent low anterior resection and have no stoma (self-reported).

FIGURE 3 Mean scores with 95% confidence interval of functional and symptom domains from EORTC QLQ-C30 and QLQ CR-29 for patients only. Scores are compared by (1) surgical procedures (2) low anterior resection syndrome score and (3) level of chronic pain.

TABLE 3 Linear regression for global quality of life for Stage I–III rectal cancer patients operated on with major resection.

	n	Univariable			Multivariable		
		Coefficient	95% CI	*p*-value	Coefficient	95% CI	p-value
Age (years)							
18–49	29	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
50–74	339	8.2	0.1, 16.3	0.05	6.2	−1.9, 14.3	0.13
≥75	119	7.4	−1.3, 16.1	0.10	5.1	−3.8, 14.0	0.26
Gender							
Male	317	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Female	170	−2.6	−6.6, 1.4	0.20	−2.0	−6.0, 2.0	0.33
Body mass index (kg/m^2) (BMI)							
Normal weight/underweight (BMI <25)	224	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Overweight (BMI 25–29.9)	185	−0.2	−4.4, 3.9	0.91	−0.4	−4.5, 3.7	0.86
Obesity (BMI ≥30)	78	−5.3	−10.8, 0.2	0.06	−4.1	−9.6, 1.4	0.14
Relationship status							
In a relationship	388	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Single	99	−8.6	−13.3, −3.9	**<0.01**	−7.8	−12.6, −3.0	**<0.01**
Level of education							
Elementary school/high school	286	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
College/university	201	−0.8	−4.7, 3.1	0.69	−2.3	−6.1, 1.6	0.25
Oncological treatment							
No oncological treatment	258	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Radiation therapy + chemotherapy	144	−3.8	−8.1, 0.5	0.08	−0.5	−5.6, 4.6	0.85
Radiation therapy only	35	−7.2	−14.7, 0.3	0.06	−1.4	−9.4, 6.7	0.74
Chemotherapy only	50	−8.5	−14.9, −2.1	**0.01**	−7.3	−13.8, −0.8	0.03
Surgery							
Low anterior resection (LAR)	267	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Hartmann's/abdominoperineal resection/LAR with stoma	220	−4.9	−8.7, −1.1	**0.01**	−4.6	−9.0, −0.3	0.04
Time since surgery when answering questionnaire							
<1 year	265	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
≥1 year	222	2.3	−1.5, 6.2	0.23	2.0	−2.1, 6.0	0.35

Note: *p*-values that remain significant after adjustment for multiple testing using the Benjamini–Hochberg procedure have been marked in bold.

of the patients became sexually inactive after diagnosis. As many as 36 (81.8%) of sexually active female patients reported a Rectal Cancer Female Sexuality Score ≥9, compatible with sexual dysfunction.

Chronic pain

Among patients, 142 (25.4%) reported CP. Patients with major CP [*n* = 86 (15.4%)] had lower scores for most of the functional domains and higher scores for symptom items compared with patients with no/minor CP. Especially large differences in functional scores were seen for social functioning (difference −29.6, 95% CI −35.1 to −24.1, $p < 0.01$), role (difference −26.5, 95% CI −32.1 to −20.9, $p < 0.01$) and global health status/QoL (difference −23.2, 95% CI −27.7 to −18.8, $p < 0.01$). Large differences were also observed for several of the symptom scores (Figure 3, Table S3).

Older age (≥75 years) was associated with lower risk for major CP (OR 0.2, 95% CI 0.1–0.6, $p = 0.01$), whereas women (OR 2.2, 95% CI 1.3–3.8, $p < 0.01$) had a higher risk of major CP (Table 4).

Sensitivity analysis

A total of 46 patients (8.2%) developed metastases between diagnosis and the response date. These patients had lower functional scores for role (difference −10.2, 95% CI −18.2 to −2.3, $p = 0.01$), social (difference −11.1, 95% CI −19.0 to −3.1, $p = 0.01$), body image (difference −11.2, 95% CI −19.1 to −3.4, $p = 0.01$) and anxiety (difference −10.6, 95% CI −18.6 to −2.5, $p = 0.01$) and higher symptom

TABLE 4 Logistic regression for presence of major chronic pain for Stage I–III rectal cancer patients operated on with major resection.

	n	Univariable			Multivariable		
		Odds ratio	95% CI	*p*-value	Odds ratio	95% CI	*p*-value
Age (years)							
18–49	29	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
50–74	305	0.5	0.2, 1.1	0.10	0.6	0.3, 1.5	0.27
≥75	92	0.1	0.0, 0.4	**<0.01**	0.2	0.1, 0.6	**0.01**
Gender							
Male	276	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Female	150	1.9	1.2, 3.1	**0.01**	2.2	1.3, 3.8	**<0.01**
Body mass index (BMI)							
Normal weight/underweight (BMI <25)	200	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Overweight (BMI 25–29.9)	160	1.4	0.8, 2.3	0.27	1.3	0.8, 2.4	0.32
Obesity (BMI ≥30)	66	1.9	1.0, 3.7	0.06	1.9	0.9, 3.8	0.09
Relationship status							
In a relationship	342	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Single	84	0.8	0.4, 1.6	0.58	0.8	0.4, 1.6	0.57
Level of education							
Elementary school/high school	246	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
College/university	180	1.1	0.7, 1.8	0.76	1.1	0.7, 1.9	0.67
Oncological treatment							
No oncological treatment	225	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Radiation therapy + chemotherapy	127	2.3	1.3, 3.9	**<0.01**	1.3	0.7, 2.6	0.45
Radiation therapy only	31	1.5	0.6, 4.0	0.41	1.1	0.4, 3.2	0.88
Chemotherapy only	43	1.7	0.7, 3.8	0.23	1.2	0.5, 2.8	0.73
Surgery							
Low anterior resection (LAR)	233	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Hartmann's/abdominoperineal resection/LAR with stoma	193	1.5	0.9, 2.5	0.09	1.6	0.9, 2.8	0.15
Time since surgery when answering questionnaire							
<1 year	233	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
≥1 year	193	0.5	0.3, 0.9	**0.01**	0.7	0.4, 1.2	0.16

Note: *p*-values that remain significant after adjustment for multiple testing using the Benjamini–Hochberg procedure have been marked in bold.

scores for fatigue (difference 13.0, 95% CI 5.7–20.2, $p < 0.01$) and insomnia (difference 14.3, 95% CI 5.5–23.1, $p < 0.01$) compared with patients without metachronous metastases (data not shown).

DISCUSSION

In this study we found that RC patients had impaired HRQoL compared with a control group from the general population, largely related to worse social functioning, body image, anxiety, buttock pain, symptoms related to altered bowel function with faecal incontinence, sexual dysfunction and chronic pain.

Giandomenico et al. [40] reported similar findings in a systematic review of QoL after RC surgery. They commented that a similar global QoL in patients and controls may stem from cancer patients' new perspective on life and adaptation to their situation, altering their QoL reference point. Additionally, they noted impaired anorectal and social functioning among RC patients and the possible correlations between those domains.

A Swedish study on colon cancer and RC patients [9] also found that social functioning, body image, buttock pain and anxiety differed significantly between patients and the general population, but at a much higher degree. They found overall larger differences in all scales compared with the present study, except for an opposite result for anorectal functioning. However, in contrast to our study, they included patients with good QoL in the group of controls, potentially influencing the score of the remaining patients in a worse direction. In addition, they included colon cancer patients, which may explain a lower degree of anorectal dysfunction as the rectum is not involved in the treatment of this group.

In the present study, one in four patients reported chronic pain, often severe, highlighting a largely clinical issue, with scarce literature necessitating further investigation. Feddern et al. [41] found that 31% of RC patients experienced chronic pain, of whom 55% reported moderate to severe pain impacting their QoL, albeit using a different assessment tool than in the present study.

Major LARS was reported by 61% of the present patient cohort operated on with LAR, in line with earlier studies reporting 26%–72% [42-44]. As opposed to many other studies, we did not find RT to be a significant risk factor for major LARS [43-45]. Bohlok et al. [42] did not find major LARS to impact QoL, except for diarrhoea, but with a limited number of patients. Major LARS had a great impact on QoL in the present study, in line with other studies [9,46,47]. Global QoL was comparable between those having major LARS and those with stoma, as described earlier [48].

Interestingly, 10.5% of the control group reported scores consistent with major LARS. This prevalence is in line with four large studies on normative data on LARS score [49-52]. Possible reasons may be benign diagnoses and incontinence after vaginal delivery [51,53,54]. Al-Saidi et al. [49] found only a slightly lower prevalence of LARS among people without comorbidity compared with those with relevant comorbidity. Unfortunately, the current dataset does not contain information on comorbidities.

Despite the high completeness of data from national registries, some limitations apply for this analysis, such as the response rates. Parekh et al. challenge the fact that many oncological studies have low response rates and that there is no consensus on a minimum response rate in medical research, although some journals advocate specific standards [55]. Due to lack of consent to obtain information from nonrespondents, we included aggregated statistics from the CRN for comparison, and responders seemed to be a representative sample of the general patient population. Lie et al. [56] pointed out that it is inadequate to use the response rate to assess the quality of a survey study by not finding evidence for nonresponse bias.

Moreover, this study aimed to assess the HRQoL in patients initially treated with curative intent. Some patients will, however, develop metachronous metastases after the date of diagnosis and before the date of response, which may influence their HRQoL. In our study, we found that about 10% of the patients developed metastases in this period. The sensitivity analysis showed that these patients had lower role and social function scores, and higher scores of symptoms for fatigue and insomnia. This is important information from the perspective of intention to treat a cohort with potentially curable disease.

The high proportion of patients who suffer from impaired HRQoL after treatment for RC highlights the obligation for honest preoperative counselling, better follow-up and management for late effects after treatment.

CONCLUSION

Patients with RC treated with curative intent experienced impaired HRQoL compared with the general population. In particular, those who suffer from major LARS or major chronic pain deserve special attention. Identification and treatment of these patient may hopefully be beneficial for their HRQoL.

AUTHOR CONTRIBUTIONS

Kathinka Schmidt Slørdahl: Writing – original draft; methodology; visualization; writing – review and editing; formal analysis. **Aina Balto:** Methodology; writing – review and editing; visualization; formal analysis; data curation. **Marianne Grønlie Guren:** Conceptualization; funding acquisition; writing – review and editing; project administration; supervision. **Arne Wibe:** Conceptualization; funding acquisition; writing – review and editing; project administration; supervision. **Hartwig Kørner:** Conceptualization; funding acquisition; writing – review and editing; project administration; supervision. **Stig Norderval:** Conceptualization; funding acquisition; writing – review and editing; project administration; supervision. **Ylva Maria Gjelsvik:** Writing – review and editing; methodology; resources; investigation. **Tor Åge Myklebust:** Methodology; writing – review and editing; formal analysis. **Inger Kristin Larsen:** Writing – review and editing; conceptualization; funding acquisition; methodology; project administration; supervision; resources; investigation.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no financial conflicts of interest with regard to the content of this work.

DATA AVAILABILITY STATEMENT

Request for data sharing should be directed to the corresponding author. This project uses data from the CRN, the NCCR, and data collected in a survey with the participants' consent. For all requests for data for research or quality assurance purposes, the recipient of the information must document a legal basis for data processing. If the information is to be used for research, the recipient must also have prior approval from the Regional Committee for Medical and Health Research Ethics. The use of data from the survey must be in accordance with the consent provided by the participants. sharing is not applicable to this article as no new data were created or analyzed in this study.

ETHICS STATEMENT

This study was performed after legal and ethical approvals obtained from the Regional Committee for Medical and Health Research Ethics (2018/1888, South-East D). A Data Protection Impact Assessment (DPIA) was approved by the Data Protection Officer at Oslo University Hospital.

CONSENT

The invitation letter utilized in this study was based on a template provided by the Regional Committee for Medical and Health

Research Ethics. It included information on various aspects such as the aim of the study, how participants were selected, potential benefits and drawbacks of participation, and emphasized the voluntary nature of participation. Participants were informed that by submitting the questionnaire, they gave their consent to participate in the study and agreed to the disclosure and use of their information for cancer research and quality purposes.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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