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Registry-based study comparing health-related quality of life between patients with primary rectal cancer and locally recurrent rectal cancer

Niamh McKigney [a,*], Amy Downing [b,c], Galina Velikova [b,d], Julia M. Brown [a], Deena P. Harji [a,e]

[a] Clinical Trials Research Unit, Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK
[b] Leeds Institute of Medical Research at St. James's, University of Leeds, Leeds, UK
[c] Cancer Epidemiology Group, University of Leeds, Leeds, UK
[d] Leeds Cancer Centre, St. James's University Hospital, Leeds, UK
[e] Department of Colorectal Surgery, Manchester University NHS Foundation Trust, Manchester, UK

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ABSTRACT

Aim: National clinical registries offer the benefits of a comprehensive dataset, particularly when linked with patient-reported outcome (PRO) data. This aim of this study was to utilise UK registry data to assess cross-sectional differences in health-related quality of life (HrQoL) in patients with primary rectal (PRC) and locally recurrent rectal cancer (LRRC).

Materials and methods: Data were extracted from the COloRECTal cancer Repository (CORECT-R) and the Locally Recurrent Rectal Cancer – Quality of Life (LRRC-QoL) datasets. Propensity score matching was undertaken in a 1:1 ratio using two covariates: age and sex. The primary outcome was the FACT-C Colorectal Cancer Subscale (CCS). Statistical significance was determined using $p < 0.05$ and clinical significance using effect size (ES) and minimally important clinical difference (MCID).

Results: A matched cohort with 72 patients in each group was identified. Overall FACT-C CCS scores were worse in patients with LRRC from a statistical (11.80 vs 18.03, $p < 0.001$) and clinically meaningful perspective (ES 1.63, MCID 6.23). Patients with PRC reported better digestion ($p < 0.001$, ES 0.85), better control over their bowels ($p < 0.001$, ES 1.03) and increased appetite ($p < 0.001$, ES 1.74, MCID 2.08). Patients with LRRC reported worse stomach swelling ($p < 0,001$, ES 0.97) and more diarrhoea ($p < 0.001$, ES 0.92), however they reported better body image ($p < 0.001$, ES 0.80).

Conclusion: Patients with LRRC reported significantly worse overall scores in the FACT-C CCS from both a statistical and clinical perspective, demonstrating the ability of the FACT-C to distinguish between these patient groups and the benefits of the inclusion of PROs within colorectal cancer registries, specifically including patients with advanced/recurrent disease.

1. Introduction

National clinical registries of routinely collected healthcare data and linkage of such datasets, present several benefits and potential applications. These include providing information regarding the incidence of specific conditions and their clinical characteristics, identifying variation both in healthcare delivery and clinical outcomes, and utilising this data to inform interventions and improve patient care [1]. Integrating patient-reported outcomes (PROs) within national clinical registries conveys additional benefits, enabling the evaluation of interventions at a national level from a patient-centred perspective, comparison of PROs within specific sub-groups of patients, and across national populations. These benefits have been observed through the NHS patient-reported outcome measures (PROMs) programme and data-linkage with the

Abbreviations: PROs, Patient-reported outcomes; PROMs, patient-reported outcome measures; NBOCA, National Bowel Cancer Audit; CORECT-R, COloRECTal cancer data Repository; HrQoL, health-related quality of life; PRC, primary rectal cancer; LRRC, locally recurrent rectal cancer; R0, complete surgical resection margin; R1, microscopically positive surgical resection margin; EORTC QLQ-C30, the European Organisation for Research and Treatment of Cancer core measure; EORTC QLQ-CR29, the European Organisation for Research and Treatment of Cancer colorectal cancer measure; FACT-C, Functional Assessment of Cancer Therapy - Colorectal measure; CCS, FACT-C Colorectal Cancer Subscale; PPI, patient and public involvement; ES, effect size; MCID, minimally important clinical difference.

* Corresponding author. Clinical Trials Research Unit, Worsley Building, Clarendon Way, University of Leeds, Leeds, LS2 9NL, UK.
E-mail address: N.McKigney@leeds.ac.uk (N. McKigney).

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National Joint Registry in the UK [2–8].

There are several national colorectal cancer clinical registries [9], including the National Bowel Cancer Audit (NBOCA) and the COloRECTal cancer data repository (CORECT-R) in the UK. NBOCA is a mandatory national audit of all patients diagnosed with colorectal cancer in England and Wales, it aims to assess quality of care and clinical outcomes [10]. The introduction of NBOCA has had a number of benefits, from mapping variation in care delivery and outcomes at a regional level [11–13], and in relation to specific patient characteristics [14–18], through to documenting the impact of the COVID-19 pandemic on colorectal cancer care [10,19–21]. CORECT-R was created to facilitate access to curated colorectal cancer linked datasets for researchers undertaking projects to improve outcomes in this disease setting [22], and includes access to PRO data from the Cancer Survivors in England 2013 PROMs survey [23,24]. CORECT-R has led to several research outputs with a particular focus on supporting earlier diagnosis [25–27] and tackling inequalities in treatment and outcomes [28–33]. Data from the 2013 PROMs survey has also previously been linked to NBOCA [34]. In the context of cancer care, capturing PROs is particularly important given the potential impact of treatments such as surgery and oncological treatments on health-related quality of life (HrQoL), and is highly valued by patients [35]. The inclusion of PROs within cancer registries enables evaluation of patient-centred outcome data on a large scale.

Primary rectal cancer (PRC) and locally recurrent rectal cancer (LRRC) differ considerably both in their natural history and treatment. There were 7486 new cases of PRC reported in England and Wales from April 2020 to March 2021, with an estimated incidence of 732,210 cases worldwide in 2020 [36]. There are a range of curative treatment strategies for PRC, including oncological treatments such as radiotherapy with or without chemotherapy, and surgery, including both major resection and local excision. In relation to patients undergoing major resection for PRC, complete circumferential resection margin rates are reported to be greater than 90 % [10,37–42], with 5-year survival rates of over 70 % following surgical resection [43–45]. Conversely, LRRC occurs in less than 10 % of cases following PRC resection [46–50] and curative treatment approaches in this setting are largely limited to radical surgical resection in the form of pelvic exenteration. The PelvEx collaborative data from 27 international centres reports a R0 resection rate of 55.4 % with associated 5-year survival rates of 28.2 % [51].

Although the clinical differences between PRC and LRRC are evident, both are known to have a significant impact on HrQoL [52–59], however, the differences in the degree of impact on HrQoL are less clearly documented. Current evidence suggests that patients with LRRC experience a greater depreciation in their HrQoL when compared to patients with PRC [60], particularly during the initial months following surgery [61]. This is unsurprising given that treatment, particularly curative surgical resection, is more complex due to its re-operative and radical nature, with high levels of post-operative morbidity [62–66]. Registries including HrQoL data offer an efficient means to assess potential differences in both clinical outcomes and PROs between these patient groups at a population-level. One of the key difficulties in comparing PROs is the availability of data collected using the same measures and the utilisation of measures which have been validated for use in specific contexts. The European Organisation for Research and Treatment of Cancer core (EORTC C30) and colorectal (EORTC QLQ-CR29) modules and Functional Assessment of Cancer Therapy - Colorectal (FACT-C) measure, have been developed for use in the PRC setting, however, are the most commonly used PROMs in LRRC [67,68]. This is primarily due to the lack of validated disease-specific measures for LRRC [67]. The availability of PRO data, utilising measures which can be directly compared between these patient groups, could offer clinically valuable insights.

There have been no recent studies comparing patients with PRC and LRRC in the UK. Additionally, the CORECT-R PROMs data has not been used to compare outcomes between these two groups of patients. This aim of this study was to assess cross-sectional differences in HrQoL in patients with PRC and LRRC; utilising the FACT-C to quantify HrQoL differences in these two patient groups in the context of a UK registry-based study utilising data from CORECT-R and the Locally Recurrent Rectal Cancer – Quality of Life (LRRC-QoL) study.

2. Materials and Methods

A propensity score matched cohort analysis was undertaken utilising cross-linked data from CORECT-R and LRRC-QoL datasets, to compare cross-sectional HrQoL outcomes in patients with PRC and LRRC.

2.1. Data extraction

2.1.1. The LRRC-QoL dataset

The LRRC-QoL dataset consists of data on 117 UK and Australian patients with LRRC, who participated in this study to develop a disease-specific PROM in this cohort [69]. The LRRC-QoL study was approved by the Yorkshire and the Humber Research Ethics Committee (reference: 12/YH/0518). Participants were recruited between January 2015 and December 2019 from three centres in the UK and two Australian centres. The eligibility criteria for inclusion in the LRRC-QoL study were age $\geq$18 years, with an existing resectable LRRC either currently receiving neo-adjuvant treatment or having undergone surgical treatment or non-surgical palliative treatment within the last two years, in addition to being able provide written, informed consent. Patients who had declined treatment or who were considered too frail to pursue surgical and/or oncological treatment were excluded. Data were extracted from the UK cohort alone for the purposes of this cross-sectional study.

2.1.2. The CORECT-R dataset

The CORECT-R research database was approved by the South West - Central Bristol Research Ethics Committee (reference: 18/SW/0134). The CORECT-R database includes data collected during the Cancer Survivors in England 2013 PROMs survey, including self-reported clinical and demographic characteristics [23]. Previous data-linkage enabled extraction specifically of patients with a history of primary rectal cancer, however further clinical data-linkage has not been undertaken. The eligibility criteria for inclusion in this survey were patients age >16 having survived 12–36 months after a diagnosis of colorectal cancer in 2010 or 2011 and treated in the NHS. The survey was administered by NHS England.

2.2. Outcome assessment

The primary outcome was the FACT-C Colorectal Cancer Subscale (CCS). The FACT-C is a disease-specific PROM measuring QoL in patients with primary colorectal cancer, demonstrating robust psychometric properties [70]. The FACT-C CCS is a scale within the FACT-C which consists of 7 heterogenous items measuring cancer-specific concerns unique to colorectal cancer patients (see supplementary material) [70]. Scoring was undertaken as per the FACT-C guidelines, scores range from 0 to 28, with a higher score indicating lower burden and better QoL [71]. The full FACT-C was not included in the Cancer Survivors in England 2013 PROMs survey and therefore was not compared.

2.3. Statistical analysis

Propensity score matching was undertaken using nearest neighbour replacement to match a cohort of patients with PRC to the cohort of 80 LRRC patients in a 1:1 ratio, this ratio was selected due to its low risk of bias [72]. Two covariates were used for propensity matching: age and sex, these covariates were chosen to ensure similar demographic groups of patients for comparison. Most of the clinical data extracted from CORECT-R from the 2013 PROMs survey was self-reported, for this reason, it was not possible to match clinical data categories as they were reported differently in each group. Other demographic characteristics

Table 1
Clinical and demographic characteristics.

	Primary Rectal Cancer (%)		Locally Recurrent Rectal Cancer (%)	
Gender	(Self-reported)		(Self-reported)	
	Male	54 (75.0)	Male	54 (75.0)
	Female	18 (25.0)	Female	18 (25.0)
Mean Age (SD)	65.26 (9.26)		65.26 (9.26)	
Employment status	**(Self-reported)**		**(Self-reported)**	
	Full time or part time employment	16 (22.2)	Full time or part time employment	5 (6.9)
	Unemployed – seeking work	0 (0.0)	Unemployed	1 (1.4)
	Unemployed – unable to work	6 (8.3)	Sick Leave	8 (11.1)
	Retired	41 (56.9)	Retired	42 (58.3)
	Other	5 (6.9)	N/A	
	N/A		Self-employed	12 (16.7)
	Unknown	4 (5.6)	Unknown	4 (5.6)
Length of time since completion of initial treatment for primary colorectal cancer	**(Self-reported)**		**N/A**	
	Less than 12 months	15 (20.8)		
	More than 12 months	57 (79.2)		
Treatment for primary rectal cancer	**(Self-reported)**		**(Clinician-reported)**	
	Surgery only	15 (20.8)	Surgery only	14 (19.4)
	Surgery and radiotherapy	11 (15.3)	Surgery and radiotherapy	0 (0.0)
	Surgery and chemotherapy	12 (16.7)	Surgery and chemotherapy	15 (20.8)
	Surgery, radiotherapy, and chemotherapy	30 (41.7)	Surgery, radiotherapy, and chemotherapy	2 (2.8)
			Surgery and chemoradiotherapy	9 (12.5)
			Surgery, chemoradiotherapy, and chemotherapy	13 (18.1)
	Chemotherapy and/or radiotherapy	4 (5.6)	N/A	
	N/A		Unknown	19 (26.4)
Presence of a stoma	**(Self-reported)**		**(Self-reported)**	
	Stoma present	45 (62.5)	Stoma present	32 (44.4)
	Stoma reversed	20 (27.8)		
	No stoma	4 (5.6)	No stoma	40 (55.6)
	Unknown	3 (4.2)		
Mode of detection of LRRC	**N/A**		**(Clinician-reported)**	
			Surveillance	42 (58.3)
			Symptomatic	12 (16.7)
			Unknown	18 (25.0)
Pattern of LRRC	**N/A**		**(Clinician-reported)**	
			Anterior	5 (6.9)
			Central	21 (29.2)
			Lateral	17 (23.6)
			Posterior	11 (15.3)
			Unknown	18 (25.0)
Presence of metastases in LRRC	**N/A**		**(Clinician-reported)**	
			Yes	10 (13.9)
			No	44 (61.1)
			Unknown	18 (25.0)
Treatment intent for LRRC	**N/A**		**(Clinician-reported)**	
			Curative	34 (47.2)

(*continued on next page*)

Table 1 (*continued*)

	Primary Rectal Cancer (%)		Locally Recurrent Rectal Cancer (%)	
Gender	(Self-reported)		(Self-reported)	
	Male	54 (75.0)	Male	54 (75.0)
	Female	18 (25.0)	Female	18 (25.0)
			Palliative	20 (27.8)
			Unknown	18 (25.0)
Margin status following surgery for LRRC (n = 34)	**N/A**		**(Clinician-reported)**	
			R0	21 (61.8)
			R1	11 (32.4)
			Unknown	2 (5.9)
Disease status at time of participation	**(Self-reported)**		**(Clinician-reported)**	
	Responded fully	54 (75.0)	Disease free	21 (29.2)
	Cancer treated but still present or has come back	7 (9.7)	Distant disease recurrence	3 (4.2)
			Local disease recurrence	10 (13.9)
	Not certain what is happening	9 (12.5)	N/A	
	Unknown 2 (2.78 %)	2 (2.8)	Unknown	38 (53.8)

were also recorded in different categories which prevented further matching. A descriptive analysis of all clinical and demographic data was reported for both groups. Data completeness for the FACT-C CCS data was assessed and missing data were handled with half-mean imputation [73,74].

The scores for the FACT-C CCS were compared between patients with PRC and LRRC using independent t-tests, with p values of <0.05 considered statistically significant; higher FACT-C scores denote better QoL. Cohen effect sizes (ES) were calculated to allow for comparison of the magnitude of differences in scores, ES of 0.2 are considered small, 0.5 moderate and >0.8 large [75]. Minimal clinically important differences (MCID) have been reported for the FACT-C CCS as 2–3 points [76] and were used to inform interpretation of the results from a clinical perspective. Further subgroup analyses were not planned due to the small sample size following propensity score matching.

2.4. Patient and public involvement

Patient and public involvement (PPI) work was undertaken during the development of this study, a PPI focus group meeting was held in May 2022 with two patients with a history of LRRC who reviewed the study protocol and contributed to the development of a lay summary. The study results were presented to the CORECT-R Patient-Public Group in October 2022 and their comments informed the writing of this manuscript.

3. Results

Patients who had undergone surgical resection for PRC were identified from the CORECT-R database and were matched in a 1:1 ratio to the 80 patients in the LRRC-QoL dataset, resulting in 72 patients in each group. Eight patients in the LRRC group had missing age data and could not be matched.

3.1. Clinical and demographic characteristics

Table 1 details the clinical and demographic characteristics for matched cohorts, there were 54 (75.0 %) male patients with a median age of 65.26 in both cohorts following matching. Most patients with PRC reported having completed treatment between 1 and 5 years ago at the time of participation (n = 56, 77.8 %). The UK patients with LRRC had all been diagnosed between 3 and 24 months of participating. The majority of patients (>90 %) included in both cohorts were of white ethnicity (data not shown due to small numbers). Participants were most commonly retired, (41 (56.9 %) in PRC and 42 (58.3 %) in LRRC). Most of the patients with PRC had undergone surgery, (n = 68, 94.4 %), with the majority of these receiving neoadjuvant or adjuvant treatments (n = 53, 77.9 %). Thirty-four (47.2 %) patients with LRRC had undergone surgery. At the time of participation, 62.5 % (n = 45) of patients with PRC reported having a stoma, compared with 44.4 % (n = 32) of the patients with LRRC, data regarding form of stoma (ileostomy vs colostomy, temporary vs permanent) were not collected. In terms of disease status at the time of participation, the majority of patients with PRC

Table 2
Data completeness and comparison of FACT-C colorectal cancer Subscale in the propensity matched cohorts.

Scale/Item	Primary Rectal Cancer				Locally Recurrent Rectal Cancer				p Value	ES	MCID [2,3]
	N	Missing (%)	Mean	Std Dev	N	Missing (%)	Mean	Std Dev			
Total Colorectal Cancer Subscale	72	16 **(22.2)**	18.03	4.77	72	3 **(4.2)**	11.80	2.55	**<0.001**	**1.63**	**YES (6.23)**
1. I have swelling or cramps in my stomach area	72	2 **(2.8)**	0.70	1.05	72	0 **(0.0)**	2.03	1.61	**<0.001**	**0.97**	NO (1.33)
2. I am losing weight	72	4 **(5.6)**	0.23	0.56	72	0 **(0.0)**	0.46	1.32	0.177	0.23	NO (0.23)
3. I have control of my bowels	72	11 **(15.3)**	1.47	1.49	72	0 **(0.0)**	0.28	0.65	**<0.001**	**1.03**	NO (1.19)
4. I can digest my food well	72	2 **(2.8)**	2.51	1.53	72	1 **(1.4)**	1.23	1.48	**<0.001**	**0.85**	NO (1.28)
5. I have diarrhoea (diarrhoea)	72	3 **(4.2)**	0.91	1.22	72	0 **(0.0)**	2.22	1.60	**<0.001**	**0.92**	NO (1.31)
6. I have a good appetite	72	1 **(1.4)**	2.70	1.36	72	2 **(2.8)**	0.62	0.99	**<0.001**	**1.74**	**YES (2.08)**
7. I like the appearance of my body	72	2 **(2.8)**	1.19	1.20	72	0 **(0.0)**	2.38	1.60	**<0.001**	**0.80**	NO (1.19)

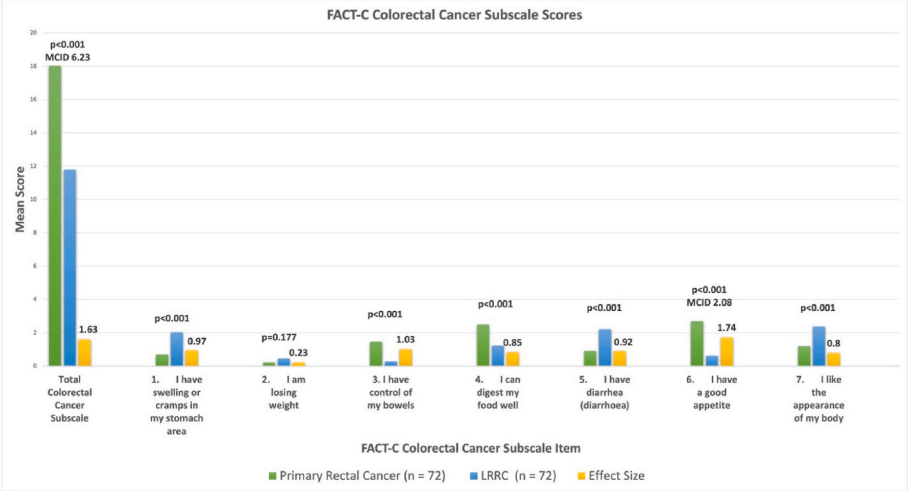

Fig. 1. FACT-C colorectal cancer Subscale scores.

reported that their disease had responded fully to treatment (n = 54, 75.0 %), whereas 29.2 % (n = 21) of patients with LRRC were disease free at the time of participation.

3.2. Data completeness

Table 2 demonstrates the data completeness for the items within the FACT-C Colorectal Cancer Subscale for the propensity-matched cohorts each containing 72 patients, missing data for the other items were handled with half-mean imputation. Item 3, "I have control of my bowels" had a higher level of missing data (15.3 %) in patients with PRC. Patients with a stoma, of which there were 45 (62.5 %) with PRC, may not have felt this item was relevant to them, though this was not reflected in the LRRC cohort.

3.3. FACT-C Colorectal Cancer Subscales

The mean scores for the overall FACT-C CCS and its constituent items can be found in Table 2 and Fig. 1. Overall, the FACT-C CCS scores were significantly higher, denoting better QoL, in patients with PRC when compared with LRRC, from both a statistical ($p < 0.001$, ES 1.63) and clinically meaningful standpoint with an MCID of 6.23. At an item level, patients with LRRC reported statistically significant worse levels of swelling or cramps in the stomach area (item 1, $p < 0.001$, ES 0.97), worse ability to digest their food well (item 4, $p < 0.001$, ES 0.85) and poor control over their bowels ($p < 0.001$, ES 1.03), though not clinically significant. Patients with LRRC reported experiencing more diarrhoea (item 5, $p < 0.001$, ES 0.92) and worse appetite from a both a statistical and clinical standpoint with a MCID of 2.08 points (item 6, $p < 0.001$, ES 1.74). There were no significant differences in weight loss from a statistical or clinically meaningful perspective (item 2, $p = 0.177$, ES 0.23). Finally, patients with LRRC reported statistically significant greater satisfaction with the appearance of their body (item 7, $p < 0.001$, ES 0.80).

In relation to the scores for the overall FACT-C CCS, items 3, 4, 6, and 7, a higher raw score indicates better HrQoL. In terms of items 1, 2, and 5, a higher raw score indicates worse HrQoL.

4. Discussion and conclusions

The results of this study demonstrate that patients with LRRC reported significantly worse overall scores in the FACT-C CCS from both a statistical and clinical standpoint, denoting worse colorectal-cancer specific QoL when compared to patients with PRC in the context of a UK registry-based study. The responses to the individual items in the CCS also indicate that patients with LRRC experience worse abdominal swelling or cramps, worse digestion and appetite, and higher levels of diarrhoea. Conversely, patients with LRRC reported greater satisfaction with their appearance. The study demonstrates the ability to utilise existing data from registries to demonstrate HrQoL differences between patients with PRC and LRRC.

This study highlights several benefits to accessing national PROMs survey data via CORECT-R. The ability to access this data for research purposes offers an efficient means to further interrogate the impact of colorectal cancer on HrQoL. It also facilitates comparison with other subgroups of patients, as reported in this study, through combining with LRRC-QoL study data. One of the key limitations of the CORECT-R dataset is the paucity of clinical data contained in the PROMs survey data. This limits the ability to examine these HrQoL outcomes in relation to clinical characteristics and outcomes, in addition to limiting the ability to restrict the inclusion criteria for the PRC patient group. There are several challenges related to data-linkage across registries, including regulatory requirements, personal data protection and privacy preservation, and methodological challenges related to linkage, such as the availability of a common identifier across different datasets ([1,77]). The availability of detailed outcome data is another challenge; cancer progression/recurrence, including LRRC, is not currently routinely captured in UK registries. However, this is changing with an increasing focus on this group of patients in NBOCA, pelvic exenteration surgery being reported from 2019 for patients with locally advanced PRC, alongside the inclusion of advanced and recurrent disease management within the annual organisational survey [78]. Ultimately, prospective HrQoL outcome reporting in patients with PRC, including those who go on to develop LRRC, would offer much greater insight into the impact of these conditions. Integrating prospective PRO data collection within existing colorectal cancer registries such as NBOCA or CORECT-R would further enhance their utility, particularly in facilitating research on HrQoL. However, the realities of collecting data in this way and maintaining high response rates present many challenges and are unlikely to be feasible until routine PRO data collection is mandated and fully integrated into existing clinical care pathways [2,79].

From a clinical standpoint, the findings of this study confirm those of previous studies in the context of a UK cohort, demonstrating reduced HrQoL in patients with LRRC compared with PRC. In relation to outcome measures, the FACT-C is commonly used to report HrQoL in both PRC and LRRC. The FACT-C has not been validated for use specifically in patients with LRRC, though does contain a proportion of the HrQoL issues that have been identified as relevant to this patient group [67]. The ability of the FACT-C CCS to discriminate between these two groups of patients also suggests that it is sufficiently sensitive to detect a

higher burden of symptoms in patients with LRRC. The FACT-C CCS relates predominately to gastrointestinal symptoms, including abdominal swelling or cramps, control over the bowels, digestion, appetite, and diarrhoea. The results suggest that patients with LRRC can anticipate a greater frequency of gastrointestinal symptoms when compared with experiences during and after treatment for PRC. Radical surgery in the form of pelvic exenteration for patients with pelvic malignancy, including rectal and gynaecological malignancy, has been shown to lead to an initial deterioration in gastrointestinal symptoms, as measured by the EORTC QLQ-C30 and FACT-C, followed by improvement and return to baseline by 6–24 months [80]. The majority of patients with LRRC recruited to the study were either receiving treatment or had recently undergone surgery, which is reflected in their worse CCS scores. Curative treatment strategies for LRRC are predominately surgical, frequently extensive and by their nature re-operative; often involving further resection of the gastrointestinal tract in addition to resection of the pelvic disease. The longer-term impact demonstrated here in patients with LRRC may be a result of chronic gastrointestinal dysfunction following these procedures. Other treatments for LRRC, such as radiotherapy and chemotherapy can also cause significant short-term gastrointestinal symptoms and longer term issues such as radiation enteritis which can have a significant impact on function [81]. Regarding reported greater satisfaction with appearance in the LRRC group, this could reflect adaptive survivorship in this patient group, wherein they adapt to accommodate the symptoms and psychological distress experienced as a result of their diagnosis and treatment [82], meaning issues such as body image may be less important to them when compared to patients with PRC. Overall, we hope that these findings can be used to guide discussions with patients regarding different potential treatments and their impact from both a functional and HrQoL perspective.

This study has several strengths, including the use of national-level data and propensity score matching to control for potential confounding. The utilisation of MCIDs offers a clinical interpretation of the study results in addition to a traditional statistical approach and are likely to be more meaningful to patients. The cross-sectional nature of this study means it is impossible to offer direct comparison at specific time points, however, it gives a snapshot comparison of QoL outcomes, indicating that patients with LRRC experience a greater degree of colorectal-cancer specific symptoms. There are some limitations to this study, including the high rates of missing data and lack of clinical data cross-linkage to the PROMs survey within CORECT-R, as described. It is also very challenging to compare or match for clinical variables as they are not directly comparable between PRC and LRRC; TNM staging is established for PRC whereas there is no similar system for LRRC. Surgical management of LRRC is comparably more heterogenous and complex in relation to PRC and accompanied with higher levels of post-operative morbidity. Utilising the full FACT-C measure would have offered a better measure of overall QoL, however this was not possible as it was not included in full in the Cancer Survivors in England 2013 PROMs survey [23]. The study compares data collected in 2013 from cancer survivors with PRC to data collected in 2015–2016 from UK patients with LRRC a median of 14 months following their diagnosis. The different timing of recruitment in relation to treatment phase may be a factor in the worse outcomes observed in the LRRC cohort. However, in relation to the timeframe of the two studies, treatment approaches for both PRC and LRRC in the UK did not change significantly between 2013 and 2016.

The findings of this study confirm that UK patients with LRRC also experience reduced HrQoL when compared with patients with PRC. This is a significant addition to the current literature as outcomes reported from individual countries may not be internationally generalisable, given the geographical variation in treatment pathways and guidelines, and associated variation in outcomes reported across high-income countries for patients with rectal cancer [83]. Though the FACT-C has not been validated for use in patients with LRRC [67], this study demonstrates its ability to quantify clinically meaningful differences in HrQoL in patients with PRC and LRRC. Further work to establish the content validity of this measure in patients with LRRC would support its ongoing use. This study also highlights the benefits and areas for future work in the inclusion of PROMs data within national colorectal cancer clinical registries, particularly if collected prospectively from diagnosis with primary disease. This would enable interrogation of the impact on HrQoL of PRC and LRRC, in addition to comparing the impact of specific treatments on HrQoL. Overall, these registries represent an important area of work within this field and will hopefully facilitate both clinical and PRO research in patients with advanced and recurrent colorectal cancer in the future.

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Declarations of interest

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Ethical approval

Ethical approval was granted for all components of the study, REC references: 12/YH/0518 and 18/SW/0134. All patients included in the study provided written consent.

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Appendix A. Supplementary data

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