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The impact on health-related quality of a stoma or poor functional outcomes after rectal cancer surgery in Dutch patients: A prospective cohort study

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ABSTRACT

Background: As the survival of patients with rectal cancer has improved in recent decades, more and more patients have to live with the consequences of rectal cancer surgery. An influential factor in long-term Health-related Quality of Life (HRQoL) is the presence of a stoma. This study aimed to better understand the long-term consequences of a stoma and poor functional outcomes.

Methods: Patients who underwent curative surgery for a primary tumor located in the rectosigmoid and rectum between 2013 and 2020 were identified from the nationwide Prospective Dutch Colorectal Cancer (PLCRC) cohort study. Patients received the following questionnaires: EORTC-QLQ-CR29, EORTC-QLQ-C30, and the LARS-score at 12 months, 24 months and 36 months after surgery.

Results: A total of 1,170 patients were included of whom 751 (64.2%) had no stoma, 122 (10.4%) had a stoma at primary surgery, 45 (3.8%) had a stoma at secondary surgery and 252 (21.5%) patients that underwent abdominoperineal resection (APR). Of all patients without a stoma, 41.4% reported major low-anterior resection syndrome (LARS). Patients without a stoma reported significantly better HRQoL. Moreover, patients without a stoma significantly reported an overall better HRQoL.

Conclusion: The presence of a stoma and poor functional outcomes were both associated with reduced HRQoL. Patients with poor functional outcomes, defined as major LARS, reported a similar level of HRQoL compared to patients with a stoma. In addition, the HRQoL after rectal cancer surgery does not change significantly after the first year after surgery.

1. Introduction

In recent decades, the 5-year survival of rectal cancer patients has increased to approximately 80%, leading to more patients having to deal with the consequences of rectal cancer treatment [1]. The cornerstone of rectal cancer treatment is still surgical resection [2]. These consequences of rectal cancer surgery are, for instance, stoma presence, bowel dysfunction, psychological and physical stress [3–5]. Of all the surgically treated rectal cancer patients in the Netherlands, 63.6% receive a (temporary) stoma [6]. The decision on whether or not to make a stoma during rectal surgery can be difficult [7]. This decision between an anastomosis or a stoma is mainly based on two considerations. Firstly, the risk of post-operative complications (e.g., anastomotic leakage) can lead to morbidity and mortality [8,9]. A (temporary) stoma has been shown to reduce the rate of symptomatic anastomotic leakage and re-operations. Secondly, dysfunctional bowel functions, often defined as major low-anterior syndrome (LARS), may have a

Abbreviations: APR, Abdominoperineal Resection; ASA, American Society of Anesthesiologists; EORTC, European Organization for Research and Treatment of Cancer; HRQoL, health-related quality of life; LARS, Low-Anterior Resection Syndrome; NKR, Netherlands Cancer Registry; POLARS, Pre-Operative LARS score; PLCRC, Prospective Dutch Colorectal Cancer; PROFILES, Patient Reported Outcomes Following Initial treatment and Long-term Evaluation of Survivorship.

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detrimental effect on the quality of life and should therefore be taken into account [10–12]. Major LARS is reported in 42% of the patients one year after rectal surgery [13]. Several patient characteristics (e.g., age, gender) and treatment characteristics (e.g., low tumor, neoadjuvant radiotherapy) are prognostic factors for major LARS [14].

The presence of a stoma and poor bowel functions in patients can both affect the quality of life after rectal cancer surgery, therefore the trade-off between the formation of a (temporary) stoma or anastomosis should be explored further [15]. This study aims to determine the influence of a stoma and poor functional outcomes on the health-related quality of life (HRQoL) after rectal cancer surgery in a nationwide population-based study.

2. Methods

2.1. Study population and treatment

Patients who underwent surgical resection for a primary carcinoma in the rectosigmoid and rectum between 2013 and 2020 were retrieved from the ongoing nationwide Prospective Dutch Colorectal Cancer (PLCRC) cohort study [16]. this study collected clinical data and patient-reported outcome measurements (PROMs) from colorectal cancer patients; a total of 59 centers in The Netherlands participated. PROMs were retrieved within the Patient Reported Outcomes Following Initial treatment and Long-term Evaluation of Survivorship (PROFILES) registry [17]. Patients were included at any time during their rectal cancer treatment, therefor a cross-sectional study design was used. Three separate cohorts of 1-, 2- and 3 years after surgery were constructed and analyzed separately. Clinical data were obtained from the Netherlands Cancer Registry (NKR). All patients signed an informed consent form before their medical records were reviewed and questionnaires were sent. Inclusion criteria were: patients with a primary tumor of stage I-III located in the rectosigmoid and rectum treated with surgical resection. Patients who underwent emergency surgery or palliative-intended surgery were excluded.

2.2. Health-related quality of life assessment

The following PROMs were completed by the patients: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core (EORTC) questionnaires: cancer-specific QLQ-C30 and colorectal-cancer-specific QLQ-CR29 and Low-Anterior Resection Syndrome (LARS)-questionnaire at 12 months, 24 months and 36 months after surgery [18–20]. A four-point Likert scale was used in all questionnaires after which all responses were linearly converted to 0–100 scales.

2.3. Statistical analyses

Patients were divided into four groups, patients without a stoma 1 year after surgery, patients with a stoma 1 year after surgery constructed during primary surgery, patients with a stoma 1 year after surgery constructed during secondary surgery and patients who underwent an APR resection. The chi-square test was used for categorical variables, the Mann-Whitney *U* test was used for numeric variables, a post-hoc Bonferroni test was used to correct for multiple testing. For sub-analysis, patients with a stoma were divided into a group of patients with- and without major-LARS. Major LARS was defined as a LARS-score ≥30.

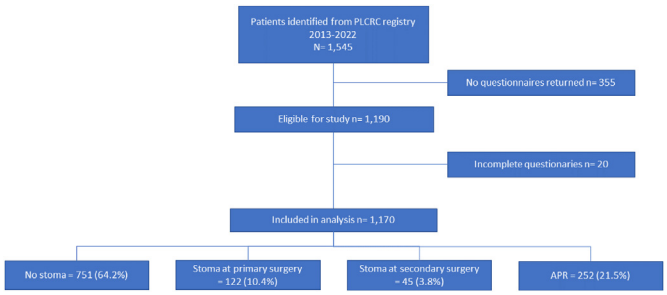

Fig. 1. – Flowchart of patient selection.

3. Results

3.1. Patient characteristics

A total of 1,545 patients were identified from the PLCRC registry of whom 355 (23.0%) were excluded because they had not filled out any questionnaire (Fig. 1). In addition, 20 (1.3%) patients were excluded because essential variables were missing. Patients were divided into four groups; patients without a stoma (64.2%), patients with Low Anterior Resection (LAR) and a stoma constructed at primary surgery (10.4%), patients with a stoma constructed at secondary surgery or a temporary stoma present at 1-year (3.8%) and patients that underwent an APR (21.5%) (Table 1).

Patients with a stoma constructed during primary surgery were older than the other groups, including patients that underwent APR. Furthermore, patients with a stoma and APR had a lower located tumor, compared to patients without a stoma, and received significantly more neo-adjuvant therapy. In addition, patients with a stoma constructed during secondary surgery were significantly more affected by anastomotic leakage.

3.2. Health-related quality of life (12 months)

Patients without a stoma reported an overall better HRQoL compared to patients with a stoma measured by the EORTC qlq-C30 questionnaire (Fig. 2, Table S1). Furthermore, stoma patients who underwent APR reported better HRQoL outcomes than stoma patients after LAR. No significant differences were seen in HRQoL when comparing patients with a stoma constructed during primary or during secondary surgery. Witnessed by the EORTC qlq-CR29 questionnaire, patients with a stoma constructed during secondary surgery reported more problems in stoma care compared to patients with a stoma constructed during primary surgery (Table S2). Another significant finding was that the body image is worse in patients with a stoma compared to patients without a stoma.

3.3. Functional outcome and health-related quality of life

Patients without a stoma were divided into two groups based on their LARS-score, patients with a LARS-score ≥30 (33.1%) were defined as major LARS (Table S3). Major LARS patients had a tumor located lower in the rectum and received more neoadjuvant therapy compared with patients without or with minor LARS. Overall, patients without a stoma reported a better HRQoL (Fig. 3, Table S4). Patients with major LARS did not report a significantly better HRQoL, except for physical functioning, compared to patients with a stoma. Body image was significantly worse in patients with a major LARS than in patients without major LARS, but significantly better compared to stoma patients (Table S5).

Table 1
– Patient characteristics.

		No stoma	Stoma at primary surgery	Stoma at secondary surgery	APR	p-value
		n = 751 (64.2%)	n = 122 (10.4%)	n = 45 (3.8%)	n = 252 (21.5%)	
Age (years)	**Mean**	63.2	69.3	62.7	64.7	<0.01
Gender %	**Male**	484 (64.4%)	85 (69.7%)	32 (71.1%)	167 (66.3%)	0.39
	Female	267 (35.6%)	37 (30.3%)	13 (28.9%)	85 (33.7%)	
BMI	**Mean**	26.1	26.6	28.5	26.3	0.07
ASA	**I-II**	638 (85.0%)	96 (78.7%)	34 (75.6%)	213 (84.5%)	0.20
	III-IV	101 (13.4%)	23 (18.9%)	9 (20.0%)	36 (14.3%)	
	Unknown	12 (1.6%)	3 (2.5%)	2 (4.4%)	3 (1.2%)	
Tumor location	**0-5 cm**	165 (22,0%) [a b c]	69 (56,6%)	17 (37,8%)	223 (88,5%)	<0.01
	5.1–10 cm	277 (36,9%)	36 (29,5%)	20 (44,4%)	18 (7,1%)	
	10.1–15 cm	145 (19,3%)	12 (9,8%)	5 (11,1%)	3 (1,2%)	
	>15 cm	27 (3,6%)	0 (0,0%)	1 (2,2%)	0 0,0%	
	Unknown	137 (18,2%)	5 (4,1%)	2 (4,4%)	8 (3,2%)	
pT-score	**0**	52 (6,9%)	11 (9,0%)	4 (8,9%)	36 (14,3%)	0.64
	I	124 (16,5%)	10 (8,2%)	6 (13,3%)	27 (10,7%)	
	II	239 (31,8%)	42 (34,4%)	9 (20,0%)	88 (34,9%)	
	III	304 (40,5%)	57 (46,7%)	24 (53,3%)	90 (35,7%)	
	IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Unknown	32 (4,3%)	2 (1,6%)	2 (4,4%)	11 (4,4%)	
Neoadjuvant therapy	**Radiotherapy**	170 (22.6%) [a b c]	30 (24.6%)	15 (33.3%)	47 (18.7%)	<0.01
	Chemoradiation	146 (19,4%)	48 (39.3%)	15 (35.6%)	146 (57.9%)	
	None	435 (57.9%)	44 (36.1%)	14 (31.1%)	59 (23.4%)	
Approach	**Open**	15 (2.0%)	6 (4.9%)	0 (0.0%)	22 (8.7%)	0.96
	Laparoscopic	564 (75.1%)	74 (60.7%)	31 (68.9%)	146 (57.9%)	
	Robot-assisted	166 (22.1%)	42 (34.4%)	14 (31.1%)	83 (32.9%)	
	Unknown	6 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	
Anastomotic leakage	**Yes**	44 (5.9%) [a b c]	0 (0.0%)	17 (37.8%)	0 (0.0%)	<0.01

ASA, American Society of Anesthesiologists.
α: statistically different from group no stoma.
[a] Statistically different from group stoma at primary surgery.
[b] Statistically different from group stoma at secondary surgery.
[c] Statistically different from group APR.

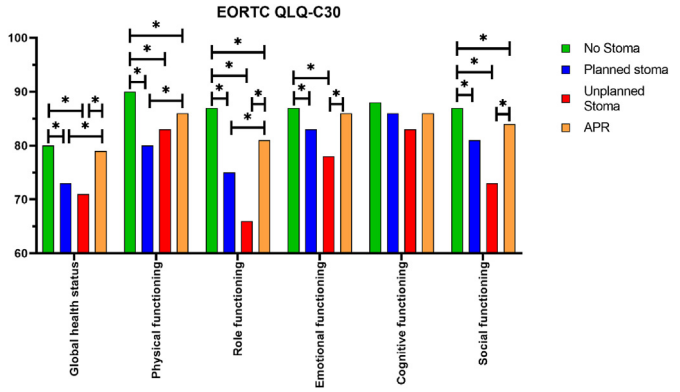

Fig. 2. – Health-related quality of life over time 12 months after surgery, measured using EORTC QLQ-C30 and EORTC QLQ-CR29. Complete overview of data is shown in Table S1 and Table S2.

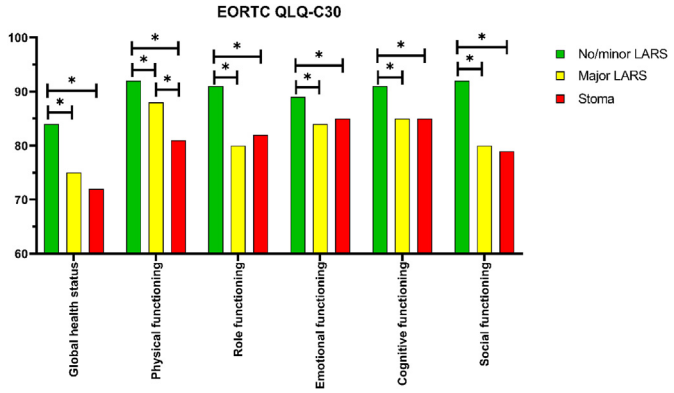

Fig. 3. – Health-Related Quality of Life (HRQoL) 12 months after surgery, using the EORTC QLQ-C30 questionnaire, patients were divided into three groups. Patient characteristics are shown in Table S3 and the complete overview of HRQoL data is shown in Tables S4 and S5.

3.4. Health-related quality of life (HRQoL) over time (12–36 months)

The group of patients (n = 311) who completed all questionnaires, at time points: 12 months, 24 months and 36 months after surgery, were analyzed (Table S6). As shown in Fig. 4, the HRQoL does not change significantly between 12 months and 36 months after surgery.

4. Discussion

This study presents a comparison in the HRQoL between patients with and without a stoma and poor functional outcomes after rectal cancer surgery. The presence of a stoma and poor functional outcomes were both associated with a reduced HRQoL. A primary colostoma can be constructed after APR and after LAR. Reported physical functioning was better in patients with colostoma after APR. HRQoL after rectal cancer surgery did not change significantly after the first year postoperatively over the next two years.

Previous studies have also shown a reduced HRQoL in patients with a stoma or major LARS [15,21]. However, some studies reported ambiguous results for the influence of a stoma on HRQoL. A Cochrane review by Pachler et al. included 26 studies, of which only 10 reported a significantly reduced HRQoL in patients with a

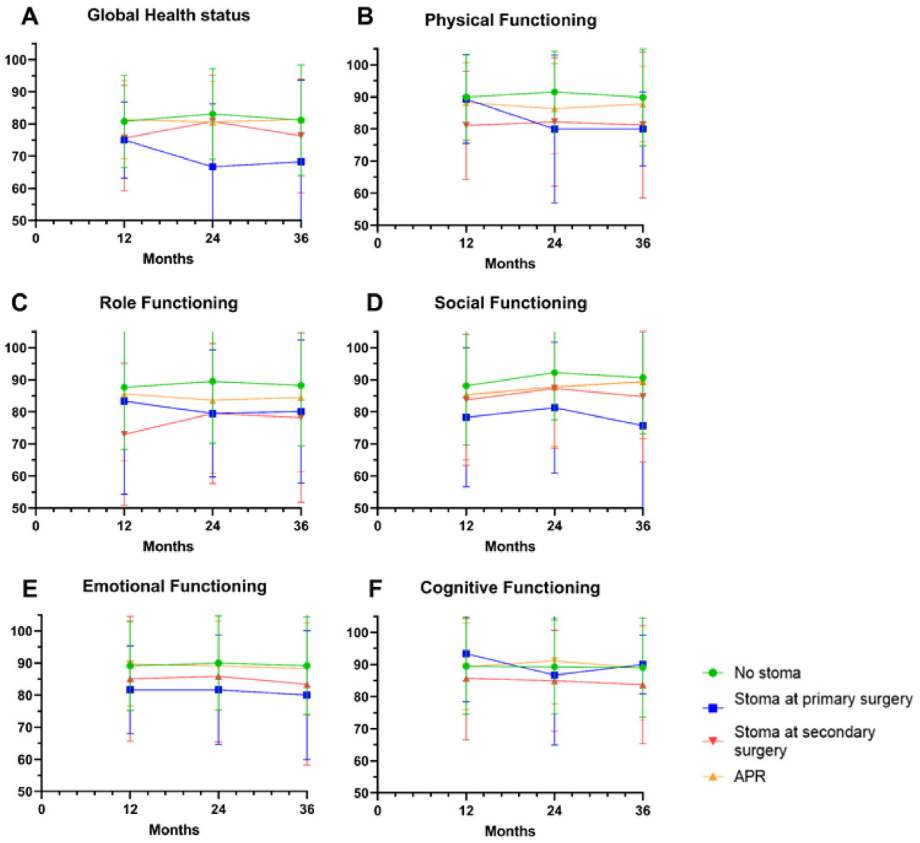

Fig. 4. – Health-related quality of life (HRQoL), using the EORTC-QLQ-C30 questionnaire, over time in the first 36 months after surgery in patients who filled out all three questionnaires (t = 12, t = 24, t = 36), patient characteristics are shown in (Table S6).

permanent colostoma [22]. Moreover, as shown, patients without a stoma can be divided into two groups based on the functional outcomes measured by the LARS score. The outcomes of this study were in line with other studies, as these studies agree that poor bowel function is associated with reduced HRQoL [19,23,24]. The differences between patients with a stoma during primary or secondary surgery stoma have not been widely studied. It has been shown that postoperative complications and anastomotic leakage can affect postoperative HRQoL [25,26]. Additionally, there is a direct independent association between postoperative complications, a permanent stoma and failure to close a (temporary) stoma [27,28]. Additionally, postoperative distant metastasis is associated with failure to close a (temporary) stoma [27,28]. The differences in HRQoL between patients with a LAR and stoma and patients that underwent an APR, might be the result of an APR reducing the risk of pelvic abscesses, persisting mucus production and diversion proctitis and therefore impacting HRQoL, however an APR is associated with increased morbidity and a perineal wound [29,30]. Furthermore, Bakker et al. showed that patients that underwent a LAR with a primary stoma, were significantly older and had more comorbidities, therefore differences in HRQoL might be subjected to worse patient characteristics [31].

Knowledge of postoperative HRQoL after rectal cancer surgery provides essential information regarding treatment options to aid in shared decision-making. Since explicit patient consideration regarding treatment options is positively associated with long-term quality of life and improved acceptance [32]. An important treatment option is whether to construct a stoma, which is usually not a foregone conclusion [7,33]. Two factors are being considered when deciding between anastomosis and a (temporary) stoma in rectal cancer surgery. Firstly, the risk of postoperative complications, especially anastomotic leakage and secondly the expected functional outcomes [8,9,14,34]. The risk of poor functional outcomes can be estimated using the POLARS score, based on prognostic factors, such as age, gender, tumor location, stoma and preoperative radiotherapy [14,35]. In addition, anastomotic leakage can be estimated as well using patient- and treatment characteristics (e.g., comorbidity, gender, tumor location) [9,36,37]. Better information to improve postoperative patient education on stoma care leads to an increased HRQoL and lower healthcare costs [38,39].

4.1. Limitations

Although this study reports valuable results, it has some limitations. First, due to the lack of patients with more than 1 year of follow-up in the database, a cross-sectional approach was used. This hampers an accurate analysis of the development of HRQoL overtime. Second, the data on considerations and subsequent decisions on when to construct a stoma and why a stoma was not reversed were not available. A prospective study might be needed to further investigate the decision towards stoma construction and its consequences. Moreover, the comparison of patients with and without a stoma is subjected to confounding by indication, as the choice to construct a (planned) stoma is based on patient- and treatment characteristics. This effect is apparent in the differences in age, tumor location and neoadjuvant therapy between these groups. These factors may also influence HRQoL and thereby inherently bias comparisons [40]. There is an ongoing debate about the indication to perform an APR as an alternative to a low Hartmann resection, therefore an indication for APR might differ from

other countries [29,30]. Unfortunately, we had no information on whether APRs were intersphincteric or extralevator APRs.

5. Conclusion

This study shows the impact of a stoma and poor functional outcomes on HRQoL after rectal cancer surgery. The presence of a stoma and poor functional bowel outcomes were both associated with a decreased HRQoL. Patients with poor functional bowel outcomes, defined as major LARS, report a similar level of HRQoL compared to patients with a stoma. Additionally, HRQoL after rectal cancer surgery does not change significantly after the first year post-surgery. Information on the effect of treatment decisions and surgical outcomes on the long-term HRQoL of patient undergoing rectal cancer surgery is essential for patient education and shared-decision making.

CRediT authorship contribution statement

Robert T. van Kooten: Study concepts, Study design, Data acquisition, Quality control of data, Data analysis, and interpretation, Statistical analysis, Manuscript preparation, Manuscript editing. **Jelle P.A. Algie:** Study concepts, Study design, Data acquisition, Quality control of data, Data analysis, and interpretation, Statistical analysis, Manuscript preparation, Manuscript editing. **Rob A.E.M. Tollenaar:** Study concepts, Study design, Quality control of data, Data analysis, and interpretation, Manuscript review. **Michel W.J.M. Wouters:** Study concepts, Study design, Quality control of data, Data analysis, and interpretation, Manuscript review. **Hein Putter:** Statistical analysis, Manuscript review. **Koen C.M.J. Peeters:** Study concepts, Study design, Quality control of data, Data analysis, and interpretation, Manuscript review. **Jan Willem T. Dekker:** Study concepts, Study design, Quality control of data, Data analysis, and interpretation, Statistical analysis, Manuscript editing, Manuscript review.

Declaration of competing interest

The authors declare no conflict of interest. There was no grant or financial support for this study.

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Appendix A. Supplementary data

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