



# Does the Low Anterior Resection Syndrome Score Accurately Represent the Impact of Bowel Dysfunction on Health-Related Quality of Life?

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## Abstract

**Background** Bowel dysfunction after rectal cancer surgery is common, but its effect on health-related quality of life (HRQOL) is complex. Objective measures of bowel function may not be a good representation on the actual impact on HRQOL. Therefore, the objective of this study is to determine whether there are differences between patient-reported bowel-related impairment versus a standardized measure of bowel dysfunction on HRQOL.

**Methods** A prospective database starting in September 2018 of adult patients who had undergone sphincter preserving rectal cancer surgery up to October 2021 was queried. Patients were excluded if they had local recurrence, metastasis, persistent stoma, or had less than 1-year follow-up. Patients were administered the study instruments at their standard surveillance visit: patient-reported bowel-related quality of life (BQOL) impairment, HRQOL using the Short Form-36 (SF-36), and bowel dysfunction using the low anterior resection syndrome (LARS) score.

**Results** Overall, 136 patients were included. There were 43% with no LARS, 22% with minor LARS, and 35% with major LARS. For the BQOL, 26% of subjects reported no impairment, 57% minor impairment, and 17% major impairment. There was a high proportion of discordance between BQOL and LARS, with 23% minor or major LARS in patients with no BQOL impairment, and 32% with no or minor LARS with major BQOL impairment. The BQOL was associated with more changes in SF-36 scores compared to the LARS score.

**Conclusions** The patient-reported BQOL is likely to be a more relevant outcome of interest to patients than the objective LARS score. This has important implications for shared decision-making for rectal cancer treatments.

**Keywords** Rectal cancer · Functional outcomes · Low anterior resection syndrome · Quality of life · Patient-reported outcomes

## Introduction

Advances in multimodal treatments, surgical techniques, and surgeon specialization for rectal cancer have increased the proportion of patients that may be eligible for sphincter preservation.<sup>1,2</sup> It has been generally thought that patients would prefer sphincter preservation over abdominoperineal resection and permanent colostomy. However, studies comparing these two procedures have actually shown similar health-related quality of life (HRQOL).<sup>3</sup> Patients that undergo sphincter preservation have a high incidence of bowel dysfunction which may have a negative impact on HRQOL, as many past studies have shown an association between increased bowel dysfunction and poor HRQOL.<sup>4</sup>

However, the impact of bowel dysfunction on each individual's HRQOL is highly specific and is largely affected

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by what each individual patient considers important in their lives.<sup>5,6</sup> The most commonly used instrument to measure bowel dysfunction after rectal cancer treatment is the low anterior resection syndrome (LARS) score, which five symptoms including frequency, urgency, clustering, and gas and fecal incontinence and categorizes patients into no, minor, and major LARS.<sup>7,8</sup> Previous studies have not shown a consistent relationship between increasing LARS categories and worse HRQOL.<sup>4</sup> In order to adequately counsel patients on impact of rectal cancer treatments, it is important to measure the impact of bowel dysfunction on HRQOL based on the patient's own assessment. Therefore, the objective of this study is to determine whether there is a difference between patient-reported bowel-related impairment versus a bowel dysfunction measured using the standardized LARS score on HRQOL scores. We hypothesized that patient-reported bowel-related impairment would be associated with lower HRQOL scores than the LARS categories.

## Material and Methods

### Study Population

A prospectively maintained rectal cancer registry at a single university-affiliated rectal cancer specialist referral center was queried up to October 2021. This registry enrolled patients that were diagnosed with rectal adenocarcinoma and were either treated and/or followed at our colorectal cancer specialist center starting in September 2018. Patients who consented to be included within this registry were administered HRQOL (SF-36) and bowel function (LARS score) instruments at each clinic visit. For this study, adult patients with non-metastatic rectal adenocarcinoma that underwent oncologic proctectomy for curative intent with sphincter preservation (and closure of proximal diversion, if applicable) with at least 1-year follow-up were included. We excluded patients that had developed local recurrence, synchronous or metachronous metastatic disease, stoma (either permanent or temporary diversion) at the most recent follow-up, or had undergone local excision. The local institution research ethics review board approved the study protocol.

### Outcome Measures

Bowel-related HRQOL impairment was measured using the single-item bowel-related quality of life (BQOL) instrument.<sup>9</sup> It asks subjects: "Overall how does your bowel function affect your quality of life?" with a four-level response "not at all", "very little", "somewhat", and "a lot." Respondents are then categorized into no impairment ("not at all"), minor impairment ("very little" or "somewhat"), and major impairment ("a lot"). It has been previously shown to

correlate the LARS score, a measure of bowel dysfunction, and with HRQOL.<sup>10</sup> Bowel function was measured using the LARS score, a 5-item instrument that includes frequency, urgency, clustering, gas incontinence, and incontinence of liquid stools.<sup>11</sup> It is scored from 0 to 42 points, and categorizes patients into no LARS (0–20 points), minor LARS (21–29 points), and major LARS (30–42 points). The LARS score is widely generalizable<sup>12</sup> and validated for many languages, including English and French.<sup>13,14</sup> HRQOL was measured using the SF-36 generic HRQOL instrument.<sup>15</sup> It contains 8 dimensions: physical functioning, general health, vitality, bodily pain, role physical, role emotional, and social functioning, scored from 0 to 100 (higher values = better HRQOL). There are also two summary scores: physical component summary (PCS) and mental component summary (MCS) that are normalized to mean 50 and standard deviation 10. The SF-36 is widely used to measure HRQOL after colorectal surgery.<sup>16</sup> For this study, eligible patients were administered the BQOL at their latest standard rectal cancer surveillance follow-up (LARS and SF-36 routinely administered already), and the most recent measures were used.

### Statistical Analysis

The proportion of patients in each of the BQOL and LARS categories were compared in a 3 × 3 table. Mean SF-36 subscale scores were compared between the BQOL and LARS categories, respectively. Finally, the mean SF-36 subscale scores were compared between patients who reported major LARS versus those that reported significant bowel-related HRQOL impairment. Univariate comparisons were done using Student's *t*, ANOVA, or Kruskal–Wallis tests for continuous variables, and the  $\chi^2$  or Fisher's exact tests for categorical variables. All analyses were performed using STATA 15.1 (StataCorp, College Station, TX). Statistical significance was defined as  $p < 0.05$ .

## Results

A total of 181 patients met inclusion criteria, of which 136 completed all of the relevant study instruments and therefore included in this study. There were 43% of the study cohort that reported no LARS, 22% minor LARS, and 35% major LARS. Patient characteristics according to LARS categories are shown in Table 1. Major LARS was associated with a higher proportion of patients receiving neoadjuvant radiotherapy and diverting loop ileostomy. For the BQOL, 26% of subjects reported no impairment, 57% minor impairment, and 17% major impairment. Table 2 reports the differences in patient characteristics according to the BQOL category. Proximal diversion and surgical

**Table 1** Patient characteristics between LARS categories

	No LARS <i>N</i> =58	Minor LARS <i>N</i> =30	Major LARS <i>N</i> =48	<i>p</i>
Mean age, years (SD)	61.3 (12.0)	62.8 (8.6)	61.5 (10.8)	0.813
Male	45 (77%)	22 (73%)	30 (63%)	0.223
Mean distance from anal verge, cm (SD)	9.5 (4.8)	8.6 (3.5)	8.2 (3.4)	0.219
Tumor height ≤6 cm	15 (26%)	8 (27%)	19 (40%)	0.268
Neoadjuvant radiotherapy	26 (45%)	18 (60%)	36 (70%)	0.017
Diverting loop ileostomy	15 (26%)	15 (50%)	34 (71%)	<0.001
Median time to ileostomy reversal, days [IQR]	160 [87–182]	153 [136–284]	143 [88–223]	0.547
Laparoscopic approach	43 (74%)	25 (83%)	40 (83%)	0.423
Anastomotic creation				0.698
Stapled	50 (86%)	24 (80%)	39 (81%)	
Hand-sewn	8 (14%)	6 (20%)	9 (19%)	
Anastomotic configuration				0.572
End-to-end	9 (16%)	5 (17%)	12 (25%)	
Side-to-end	46 (79%)	24 (80%)	32 (67%)	
Colonic J-pouch	3 (5%)	1 (3%)	4 (8%)	
pT stage				0.492
ypT0-1	17 (29%)	8 (27%)	14 (29%)	
ypT2	19 (33%)	5 (17%)	9 (19%)	
ypT3	21 (36%)	16 (53%)	23 (48%)	
ypT4	1 (2%)	1 (3%)	2 (4%)	
pN positive	12 (21%)	9 (30%)	15 (31%)	0.417
Anastomotic leak	5 (9%)	1 (3%)	8 (17%)	0.179
Adjuvant systemic therapy	15 (34%)	9 (33%)	17 (40%)	0.296
Median follow-up, months [IQR]	21.5 [13.5–62.3]	25.1 [9.3–40.4]	23.6 [17.0–53.8]	0.799

approach was associated with BQOL impairments. The proportion of patients in each LARS category according to their BQOL impairments is shown in Table 3. In patients with no impairment, 23% were categorized as minor or major LARS, and in patients with major impairment, 32% reported no or minor LARS ( $p < 0.001$ ).

Table 4 shows SF-36 subscale scores according to LARS categories. There were significant differences amongst the LARS categories only for bodily pain and the physical component summary, with worse scores in the major LARS categories. Table 5 reports the SF-36 subscale scores according to BQOL categories. There were significant differences between the BQOL categories in the physical functioning, general health, role physical, social functioning, bodily pain, and physical component summary scores, with worse scores in the major impairment category. When comparing SF-36 subscale scores between the major LARS versus major impairment in BQOL categories, there were significant differences in physical functioning ( $p = 0.019$ ), social functioning ( $p = 0.038$ ), and physical component summary scores ( $p = 0.022$ ), with worse scores for the major BQOL impairments across all subscales.

## Discussion

Almost all rectal cancer patients who undergo sphincter-preserving surgeries develop some degree of bowel dysfunction.<sup>17</sup> Although a higher degree of bowel dysfunction has been associated with worsening HRQOL, the relationship between HRQOL and the objective LARS score is not consistent.<sup>4</sup> Furthermore, HRQOL is highly individualized and not all patients will give importance to the same aspects. Therefore, the objective of this study was to assess whether there was a difference in HRQOL impacts based on the patient-reported BQOL compared to the objective LARS score. Our findings show that the BQOL was associated with more changes in HRQOL than the LARS score, and also that there was a high level of discordance between the BQOL and LARS score.

This study confirmed our hypothesis in that the patient-reported BQOL was associated with more changes in HRQOL compared to the objective LARS score. There were more SF-36 subscales that showed significant differences between the BQOL categories compared to the LARS score. Also, the major BQOL impairment category

**Table 2** Patient characteristics between bowel-related QOL impairment categories

	No bowel-related QOL impairment <i>N</i> =36	Minor bowel-related QOL impairment <i>N</i> =78	Major bowel-related QOL impairment <i>N</i> =22	<i>p</i>
Mean age, years (SD)	60.1 (13.2)	61.7 (10.0)	64.9 (7.7)	0.253
Male	23 (64%)	57 (73%)	17 (77%)	0.479
Mean distance from anal verge, cm (SD)	9.2 (4.2)	8.6 (3.4)	8.3 (5.9)	0.679
Tumor height ≤6 cm	10 (28%)	23 (29%)	9 (41%)	0.530
Neoadjuvant radiotherapy	19 (53%)	37 (47%)	16 (73%)	0.110
Diverting loop ileostomy	8 (22%)	39 (50%)	17 (77%)	<0.001
Median time to ileostomy reversal, weeks [IQR]	144 [89–193]	154 [93–279]	136 [107–223]	0.696
Laparoscopic approach	22 (61%)	69 (88%)	17 (77%)	0.003
Anastomotic creation				0.163
Stapled	33 (92%)	64 (82%)	16 (73%)	
Hand-sewn	3 (8%)	14 (18%)	6 (27%)	
Anastomotic configuration				0.319
End-to-end	6 (17%)	14 (18%)	6 (27%)	
Side-to-end	29 (81%)	60 (77%)	13 (59%)	
Colonic J-pouch	1 (3%)	4 (5%)	3 (14%)	
pT stage				0.345
ypT0-1	17 (47%)	16 (21%)	6 (27%)	
ypT2	6 (17%)	23 (29%)	4 (18%)	
ypT3	12 (33%)	37 (47%)	11 (50%)	
ypT4	1 (3%)	2 (3%)	1 (5%)	
pN positive	5 (14%)	22 (25%)	9 (41%)	0.068
Anastomotic leak	2 (6%)	8 (10%)	4 (18%)	0.303
Adjuvant systemic therapy	8 (22%)	26 (33%)	7 (32%)	0.477
Median follow-up, months [IQR]	29.8 [12.3–68.2]	20.8 [13.3–34.2]	29.3 [16.4–60.6]	0.204

**Table 3** Proportion of patients in each LARS category by bowel-related QOL impairment category

	No bowel-related QOL impairment ( <i>n</i> =36)	Minor bowel-related QOL impairment ( <i>n</i> =78)	Major bowel-related QOL impairment ( <i>n</i> =22)
No LARS ( <i>n</i> =58)	28 (78%)	27 (35%)	3 (14%)
Minor LARS ( <i>n</i> =30)	2 (6%)	24 (31%)	4 (18%)
Major LARS ( <i>n</i> =48)	6 (17%)	27 (34%)	15 (68%)

*P*<0.001

was associated with worse HRQOL scores than the major LARS category. This emphasizes that the perception of one's HRQOL is highly specific to each individual. People hold different values, priorities, and thresholds for coping. Thus, not everyone might feel a great impact on their HRQOL despite experiencing changes in bowel dysfunction. These findings are also supported by the available literature. There are many existing studies assessing the correlation between bowel function (commonly via the LARS score) and HRQOL after sphincter-preservation surgery.<sup>4</sup> What is surprising is the magnitude of effect that major LARS has on HRQOL. One would expect that major LARS would be associated with worse HRQOL.

In a recent systematic review, almost all differences in the European Organization for the Treatment of Cancer (EORTC) Quality of Life Questionnaire-30 (QLQ-C30) and SF-36 subscales between major LARS versus the other categories were of small or trivial magnitude of effect.<sup>4</sup> This suggests that the LARS score may be an appropriate measure of bowel function, but it does not always correlate well with HRQOL.

Instead, we found that the BQOL categories had a stronger correlation with HRQOL, in that patients reporting major bowel-related impairments reported worse HRQOL. Furthermore, most of the differences in SF-36 subscales between major BQOL impairment versus no or minor

**Table 4** Differences in SF-36 subscales according to LARS categories. Values represent mean scores (95% confidence intervals)

	No LARS <i>N</i> = 58	Minor LARS <i>N</i> = 30	Major LARS <i>N</i> = 48	<i>p</i>
Physical functioning	92.8 (90.1–95.5)	91.2 (84.7–97.7)	86.2 (80.1–92.4)	0.115
General health	73.1 (67.3–78.8)	76.3 (68.2–84.4)	66.3 (58.9–73.7)	0.110
Vitality	59.7 (55.0–64.5)	64.0 (57.9–70.1)	58.2 (53.5–63.0)	0.274
Mental health	69.1 (65.1–73.0)	71.5 (67.2–75.7)	72.4 (68.4–76.3)	0.550
Role physical	85.5 (77.8–93.3)	80.8 (69.1–92.6)	72.2 (60.9–83.6)	0.426
Role emotional	93.0 (87.3–98.6)	90.0 (81.0–99.0)	91.9 (84.5–99.2)	0.812
Social functioning	87.7 (82.2–93.3)	87.9 (79.8–96.0)	82.5 (75.0–90.0)	0.295
Bodily pain	88.6 (82.9–94.4)	87.8 (81.1–94.6)	74.8 (67.2–82.4)	0.003
Physical component Summary	53.9 (52.0–55.7)	53.3 (50.2–56.4)	48.2 (45.3–51.2)	0.003
Mental component Summary	48.8 (46.6–50.9)	49.9 (47.8–52.0)	50.5 (48.6–52.4)	0.475

**Table 5** Differences in SF-36 subscales according to bowel-related QOL impairment categories. Values represent mean scores (95% confidence intervals)

	No bowel-related QOL impairment ( <i>n</i> = 36)	Minor bowel-related QOL impairment ( <i>n</i> = 78)	Major bowel-related QOL impairment ( <i>n</i> = 22)	<i>p</i>
Physical functioning	94.7 (91.2–98.2)	91.4 (87.7–95.2)	78.9 (70.6–87.1)	0.001
General health	75.7 (69.7–81.8)	73.0 (67.6–78.5)	59.6 (48.7–70.5)	0.027
Vitality	59.0 (53.8–64.1)	62.5 (58.4–66.6)	54.1 (47.1–61.1)	0.168
Mental health	70.8 (66.8–74.5)	71.6 (68.5–74.7)	67.6 (60.3–75.0)	0.579
Role physical	85.3 (74.8–95.8)	83.2 (75.9–90.5)	60.2 (44.4–76.1)	0.011
Role emotional	95.1 (89.4–100.0)	90.4 (84.6–96.1)	92.4 (81.9–100.0)	0.429
Social functioning	92.6 (82.8–98.5)	87.7 (82.8–92.6)	69.9 (58.0–81.8)	0.001
Bodily pain	93.4 (88.2–98.5)	83.4 (78.2–88.6)	70.0 (58.0–81.9)	0.001
Physical component summary	54.7 (52.6–56.9)	52.5 (50.6–54.5)	44.7 (40.5–48.8)	<0.001
Mental component summary	49.6 (47.3–52.0)	49.9 (48.3–51.4)	48.7 (45.2–52.3)	0.817

categories were clinically relevant. Other studies have shown that the minimal clinically important difference for the SF-36 subscales was 10 points,<sup>18,19</sup> and between 5 and 7 points for the physical component summary score.<sup>20,21</sup> In another study, the magnitude of change in in the EORTC-QLQ-C30 subscales between BQOL categories were all moderate to large when comparing major to no impairment, and small

to moderate comparing major to minor impairments<sup>9</sup>. This suggests that the BQOL is more representative of HRQOL impacts. It would be important to know what were the specific factors that influenced bowel-related impairments, especially in those with no or minor LARS. These data are not discernable using generic HRQOL instruments, and future studies should use individualized patient-reported

measures such as the patient generated index to better understand these impacts.<sup>22</sup>

We also reported an important proportion of patients with discordance between their BQOL and LARS categories. We were surprised to find that there were more than 30% of patients that reported major impairments in BQOL were categorized as no or minor LARS. Conversely, more than 20% of patients reporting no BQOL impairment were categorized with major LARS. This reinforces the notion that HRQOL is highly individualized, and that it is important to determine each patient's values and treatment goals. This is especially important with the renewed emphasis on patient-centered care and shared decision-making.<sup>23</sup> In the context of rectal cancer, certain patients may emphasize aspects of their HRQOL that is likely to be more affected by bowel dysfunction and as a consequence have greater impacts even with minor dysfunction.<sup>24</sup> Providing treatment in line with patients' values and preferences is likely to improve their long-term HRQOL.<sup>25</sup> Therefore, the BQOL is likely to be a more relevant outcome of interest to patients than the objective LARS score. There are prediction nomograms for the BQOL that may help inform patients regarding their rectal cancer treatment options.<sup>9</sup> Future studies should investigate the relationship between the patient-reported BQOL and objective LARS score after other rectal cancer treatment options such as organ preservation or local excision. This would greatly enhance the shared decision-making process.

It is also important to note that HRQOL is affected by many other factors, and that it is impossible to completely remove the impact of these other contributing factors. Rectal cancer patients often have other medical comorbidities, undergo different cancer adjuvant therapies, as well as manage other external factors in their personal and work lives, which all play a role in how HRQOL is perceived. We attempted to control for this by excluding patients that developed recurrence or metastatic disease during their surveillance period. Furthermore, we did not account for changes in genitourinary function, which occurs in a significant proportion of patients and may be significantly impact HRQOL after rectal cancer treatments.<sup>26,27</sup> Our study could also have been affected by response shift, as patients may learn to recalibrate and reconceptualize their concept of HRQOL over time.<sup>28</sup> This is pertinent as the median follow-up was over 21 months overall. Postoperative bowel function also changes over time, but usually stabilizes by 18 months,<sup>29</sup> so it is likely that the majority of patients would have had time to adapt by then time of study enrolment. However, it would be interesting to investigate how BQOL itself as well its relationship with objective measures of bowel function changes over time.

The results of our study should be interpreted in light of other limitations. The BQOL assessments were done during the COVID-19 pandemic and the presence of stay-at-home

orders. During this time, many people worked from home, social events were prohibited, and non-essential services/activities were shutdown. This could have been a limitation to our study since bowel dysfunction and the fear of having an accident tends to affect patients in their daily/social activities out in public. Being able to work from the comfort of one's home with a private bathroom nearby, for example, may have reduced impairment of BQOL in certain patients. For example, our study reported a lower proportion of major bowel-related impairment compared to Battersby et al.<sup>10</sup> (17% vs. 41%) despite a higher proportion of patients receiving pelvic radiotherapy. It would be interesting to repeat this study and determine if there are any differences while not under stay-at-home mandates. Volunteer bias is another potential limitation because the patients who chose to participate in the study may not be representative of the population of interest. The LARS score itself may not fully capture the spectrum of bowel dysfunction after rectal cancer treatment, such as constipation and alternating bowel habits, and it is unclear whether these other symptoms would play a role in BQOL impairments.<sup>7,30</sup> We also did not have pre-treatment HRQOL scores for this study, which may affect the interpretation of subsequent scores.<sup>31</sup> However, previous studies have shown that HRQOL scores in rectal cancer patients largely return to pre-treatment levels by 24 months after treatment (although they remained worse than general population norms), suggesting that HRQOL should have stabilized by the time of this study since our median follow-up time was approximately 30 months.<sup>32,33</sup>

## Conclusion

In conclusion, patients' assessment of HRQOL impairment after rectal cancer treatment is complex. The patient-reported BQOL was more sensitive to changes in HRQOL than the objective LARS score, and there was a high level of discordance between BQOL and LARS categories. These findings suggest that it is important to better understand each patients' preferences to determine the specific impact that rectal cancer treatments may have on their HRQOL. This has important implications for shared decision-making in rectal cancer.

**Author Contribution** Conception and design of study: AW, SR, SL, LSF, JFF, LL. Acquisition of data: AW, SR.

Analysis and interpretation of data: AW, SR, SL, LSF, JFF, LL. Drafting of manuscript: AW, SR.

Critical revision: SL, LSF, JFF, LFF. Final approval of version to be submitted: AW, SR, SL, LSF, JFF, LL.

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## Declarations

**Competing Interests** The authors declare no competing interests.

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