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ORIGINAL ARTICLE

Is evaluation by questionnaires sufficient to cover all aspects of bowel symptoms in rectal cancer patients after low anterior resection?

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Abstract

Aim: The aim of the study was to investigate whether bowel symptoms related to low anterior resection for rectal cancer can be sufficiently well evaluated by the Low Anterior Resection Syndrome (LARS) questionnaire score or the ColoRectal Functional Outcome (COREFO) questionnaire compared with a stool diary.

Method: All patients underwent low anterior resection for rectal cancer. They were asked to fill out a stool diary, the LARS questionnaire and the COREFO questionnaire, at 1, 4, 6 and 12 months after low anterior resection or stoma closure. The main outcome measure was the amount of association (calculated by means of canonical correlation analysis) between items on anal incontinence for faeces, frequency of bowel movements, clustering of bowel movements, urgency and soiling.

Results: Ninety-five patients were included. Items on anal incontinence for faeces and frequency of bowel movements were significantly correlated between the LARS questionnaire or the COREFO questionnaire, versus the stool diary, respectively. Items on soiling were significantly correlated between the COREFO questionnaire and the stool diary.

Conclusion: Although the LARS questionnaire and the COREFO questionnaire are reliable and valid for measuring low anterior resection syndrome after rectal cancer, our results show that there are no strong associations with the stool diary. Therefore, we can conclude that there is additional clinical information to be obtained from the stool diary. In order to evaluate all aspects of low anterior resection syndrome, we suggest the addition of a stool diary or a combination of different measurement methods during patient follow-up.

KEYWORDS
bowel symptoms, low anterior resection, questionnaires, rectal neoplasms, stool diary

Trial registration: this trial has been registered at the Netherlands Trial Register (NTR6383).

INTRODUCTION

Colorectal cancer is highly prevalent in both women and men, and almost 40% of colorectal tumours originate in the rectum [1]. A low anterior resection (LAR) – more specifically a nerve-sparing, total mesorectal excision (TME) – remains the standard of surgical care in treating these rectal cancers (RCs), but unfortunately is not without debilitating functional consequences [2]. Between 60% and 90% of RC survivors experience a range of bowel symptoms, commonly known as 'low anterior resection syndrome' (LARS) [3–5]. Recently, a consensus definition of LARS was formulated, which incorporates symptoms as well as consequences [6]. LARS was defined as the presence of at least one of the following symptoms: variable and unpredictable bowel function, altered stool consistency, increased stool frequency, repeated painful stools, emptying difficulties, urgency, incontinence or soiling. In order to classify these bowel symptoms as LARS, the presence of these symptoms should lead to an impact on predefined consequences, such as toilet dependence or dissatisfaction with the bowels [6].

To assess bowel symptoms in the context of LARS, a real-life prospective stool diary could be considered as a reference method, since it records every bowel movement and stool leakage as it occurs in detail [7,8]. However, a 7-day stool diary is time-consuming for the patient and labour-intensive for the clinician to analyse in depth. A recent study showed that the use of an electronic application instead of a paper form can facilitate diary keeping [9]. Nevertheless, it would be easier if the stool diary could be replaced by more time-efficient, bowel-specific questionnaires if comparable clinical information could be gathered.

In patients with LARS after treatment for RC, the LARS questionnaire was proven to be a reliable and valid questionnaire [10]. This questionnaire was specifically designed to clinically evaluate the severity of LARS through five short items that were deemed to be the most bothersome by patients [11]. The ColoRectal Functional Outcome (COREFO) questionnaire is a broader questionnaire to evaluate symptoms related to LARS [12]. However, associations between these questionnaires and a stool diary as measurement methods for evaluating bowel symptoms have not yet been examined in RC patients after LAR. The aim of the present study was to investigate whether different LARS symptoms can be sufficiently well evaluated by the LARS questionnaire or the COREFO questionnaire compared with the stool diary in RC patients after LAR.

What does this paper add to the literature?

This is the first study to investigate the association between questionnaires and the stool diary for evaluating bowel symptoms after low anterior resection for rectal cancer. To grasp all aspects of bowel function during patient follow-up, the stool diary should be added or different measurement methods should be combined.

METHOD

This study was conducted from January 2017 to March 2020 and was part of a larger randomized controlled trial investigating the effect of pelvic floor muscle training on bowel symptoms after RC [13]. Participants were recruited in Belgium, in the following centres: University Hospitals Leuven, OLV Hospital Aalst or General Hospital Groeninge Kortrijk. Approval for this trial was granted by the local ethical committee of the University Hospitals Leuven (main ethical committee, s59761) and additionally positive advice from the other centres was obtained. The trial was registered with the Netherlands Trial Register (NTR6383).

Patients were included if they underwent a LAR (TME) for RC. Patients were excluded if they: (1) had another type of surgery for colorectal cancer (a Hartmann procedure, abdominoperineal excision, transanal endoscopic microsurgical resection or sigmoid resection), (2) were incontinent for faeces before surgery, (3) had a neurological disease or (4) already had previous pelvic surgery, previous pelvic radiation or LAR for reasons other than cancer.

After signing the informed consent form, participants were asked to fill out the three measurement tools mentioned below at 1, 4, 6 and 12 months after LAR or, in case of a temporary ileostomy, after stoma closure.

Stool diary

A stool diary represents objective, real-time occurrences for 7 days in succession, which results in multiple parameters that can be derived, in accordance with LARS symptoms. The comprehensive stool diary used in this study (Table 1) was based on the input of a small group of Dutch RC patients with bowel symptoms after LAR, physiotherapists specialized in treating bowel symptoms and colorectal surgeons at our institution [14]. This diary was checked against current guidelines [7,15]. Additionally, most items of the LARS questionnaire (except incontinence for flatus, as indicated in the limitations) were integrated in the stool diary. Participants were asked to keep track of the frequency of the following items (during 24 h for seven consecutive days): (1) frequency of bowel movements, (2) frequency of anal incontinence for faeces, (3) frequency of urgency (whether or not related to a bowel movement, indicated on a scale of 0–4; 0 = no urge and 4 = severe urge with stool leakage), (4) clustering (number of times having to open bowels again within 1 h) and (5) frequency of soiling. For the bowel movements and stool leakage, patients were asked to indicate the consistency on the Bristol Stool Chart (classification of type of stools) [16]. An instruction sheet with information regarding the stool diary was provided for each patient. The stool diary used in this study did not include any items on anal incontinence for flatus.

TABLE 1 Overview of items for each evaluation tool

LARS	COREFO	Stool diary
1. Do you ever have occasions when you cannot control your flatus (wind)? 2. Do you ever have any accidental leakage of liquid stool? 3. How often do you open your bowels? 4. Do you ever have to open your bowels again within one hour of the last bowel opening? 5. Do you ever have such a strong urge to open your bowels that you have to rush to the toilet?	1. How many bowel movements have you had during the day? 2. How many bowel movements have you had during the night? 3. If you needed to go urgently, did you have trouble stopping your bowel movement for longer than 15 min? 4. Have you had a false alarm? (i.e. a need to go without a bowel movement)? 5. Have you had pain during your bowel movements? 6. Have you experienced blood loss during your bowel movements? 7. Have you unintentionally passed wind? 8. Have you unintentionally passed liquid stools during the day? 9. Have you unintentionally passed liquid stools during the night? 10. Have you unintentionally passed solid stools during the day? 11. Have you unintentionally passed solid stools during the night? 12. Have you had a smear of faeces in your underwear during the day? 13. Have you had a smear of faeces in your underwear, pyjamas or night-gown at the end of the night? 14. Was it difficult to distinguish between passing wind and a bowel movement? 15. When you went to the toilet, did your bowel movement require more than 15 min? 16. Did you feel that your bowels were not empty after your bowel movement? 17. After you had a bowel movement, did you have to return to the toilet within 1 h for a bowel movement? 18. Have you used medicines to thicken your stools? 19. Have you used medicines to make your stools thinner? 20. Have you eaten certain foods on purpose to make your stools thicker or thinner? 21. Have you purposely avoided certain foods to prevent your stools becoming loose or hard? 22. Have you had irritated skin around your anus? 23. Have you used something to protect your underwear, such as sanitary towels, panty liners or nappies? 24. Did you adjust your activities to the availability of a toilet? 25. Were you limited in your daily activities (e.g. work or house work) due to problems with your bowel movements? 26. Were you limited in your social activities (e.g. family visits, visits to the theatre, or eating out) due to problems with your bowel movements? 27. Were you limited in your sexual activities (with or without sexual intercourse) due to problems with your bowel movements?	DAY (date/month/year) Hour | Stool (1–7) | Urgency (0–4) | Soiling (Y/N) | Loss (1–7) | Clustering (no./hour) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 TOTAL (number of bowel movements during 24 hours): Stool (1–7): Bristol Stool Scale for stool Urgency (0–4): 0 = no urgency; 1 = slight urgency; 2 = moderate urgency; 3 = strong urgency; 4 = strong urgency with leakage Soiling (Y/N): yes/no Loss (1–7): Bristol Stool Scale for leakage Clustering (no./hour): number of times per hour

LARS questionnaire

The LARS questionnaire was developed as a quick and easy tool to be used in daily clinical practice to assess bowel dysfunction after treatment for RC [11]. This questionnaire was specifically designed to clinically evaluate the severity of LARS through items that were deemed to be the most bothersome by patients. An expert panel was also involved [11]. It consists of five questions (Table 1), each to be scored with its own weighted score value, resulting in a score of 0 to 42. The items used in this questionnaire are as follows: incontinence for flatus, incontinence for liquid stools, frequency of bowel movements, clustering of stools and urgency. Adding item score values results in classification of LARS severity into three groups: 'no LARS' (0–20), 'minor LARS' (21–29) and 'major LARS' (30–42). This questionnaire has been validated to evaluate LARS after RC surgery and translated into different languages and normative data have been published [17]. Emmertsen et al. [11] did not specify a recall period for the LARS questionnaire, but in this study a recall period of 4 weeks was implemented to avoid overlap between different measuring points.

COREFO questionnaire

The COREFO questionnaire evaluates bowel dysfunction after colorectal surgery over a 2-week period, by means of 27 questions (Table 1) related to the following items: incontinence, social impact, frequency, stool-related aspects and medication. During the development of this questionnaire, input from colorectal surgeons as well as patients was used [12]. The questions are scored on a five-point Likert scale. The total score can be calculated in a range from 0 to 100, with higher scores representing a worse bowel function. The COREFO questionnaire is validated to evaluate bowel symptoms after RC surgery and is available in Dutch, English and Greek [12,18].

Statistical analysis

The LARS questionnaire, the COREFO questionnaire and the stool diary use different scoring methods, include a different number of questions concerning the same construct and apply different values to responses regarding the same construct. Therefore, the use of canonical correlation analysis was necessary to evaluate associations between the measurement methods in this study.

In canonical correlation analysis, the magnitude of the relationship between a linear combination of variables between two sets of variables is assessed. As such, a canonical correlation analysis can be seen as a multivariate analysis of association between sets of variables to identify the amount of shared information between the different constructs through correlation coefficients and the proportion of explained variance, and to capture whether the information quantified by the stool diary can also be captured by the questionnaires.

In this study, the constructs that were assessed were as follows: (1) anal incontinence for faeces, (2) frequency of bowel movements, (3) clustering of bowel movements, (4) urgency and (5) soiling. In Table 2, an overview of the corresponding items used per construct is provided for each evaluation tool. For the stool diary, more items were available for analysis, but not all of them could be included due to singularity, i.e. some of the derived parameters of the stool diary contained too much similar information, which prevented them from being included.

The data available for each timepoint were used as a stacked dataset in order to provide a more stable estimation of the canonical correlation between the variables. Since canonical correlation analysis allowed us to compare multiple variables from each evaluation tool, more than one pair of canonical variates was sometimes found to be significantly correlated. If that was the case, a range was displayed concerning the correlation coefficient. The correlation coefficients were interpreted as weak (below 0.40), moderate (0.40–0.74), strong (0.75–0.90) and very strong (above 0.90) [19]. Statistical analyses were performed using the Statistical Package for Social Sciences software for Windows, version 27 (SPSS, Inc. Chicago, IL). A level of significance of 0.05 was applied.

RESULTS

This study included 95 patients (65 men, 30 women) with a mean age (SD) of 57.2 (±11.8) years. After LAR, 64% of patients received a straight coloanal anastomosis, 21% a side-to-end coloanal anastomosis and 15% a J-pouch. Other patient characteristics concerning surgical and (neo)adjuvant treatment are presented in Table 3. The descriptive data in Table 4 on bowel symptoms reflect the variation between proportions of patients experiencing a specific type of bowel complaint, according to the measurement method used. In particular, the representation of complaints concerning clustering of bowel movements and urgency seems to vary greatly between the questionnaires and the diary. An overview of the associations between the measurement methods is provided in Table 5.

For anal incontinence, the items from the LARS (r = 0.434) and COREFO (r = 0.283–0.724) questionnaires were significantly correlated with those of the stool diary. The fraction of information found in the LARS questionnaire that could be explained by the stool diary items was 18.8%. For the COREFO questionnaire, this fraction was 37.1%.

The items on frequency of bowel movements were also significantly correlated with those of the stool diary for both questionnaires [r = 0.596 (LARS), r = 0.595–0.722 (COREFO)]. For the LARS questionnaire, 35.5% of the information could be explained by the stool diary and for the COREFO questionnaire the figure was 45.0%.

Regarding the items on clustering of bowel movements, no significant association was found between either the LARS or the COREFO questionnaire and the information provided by the stool diary. More specifically, no association could be found since there was no overlapping information to interpret regarding these

TABLE 2 Items used in the canonical correlation analyses

		LARS[a]	COREFO[b]	Stool diary
DOMAIN	Anal incontinence for flatus	1: Do you ever have occasions when you cannot control your flatus (wind)?	7: Have you unintentionally passed wind?	–
	Anal incontinence for faeces	2: Do you ever have any accidental leakage of liquid stool?	8: Have you unintentionally passed liquid stools during the day? 9: Have you unintentionally passed liquid stools during the night? 10: Have you unintentionally passed solid stools during the day? 11: Have you unintentionally passed solid stools during the night?	Number of days with stool leakage during the day Percentage of total amount of stool leakage that occurs during the day Minimum frequency of stool leakage during the day Maximum frequency of stool leakage during the day Average frequency of solid stool leakage during the day Average frequency of liquid stool leakage during the day Number of days with stool leakage during the night Percentage of total amount of stool leakage that occurs during the night Minimum frequency of stool leakage during the night Maximum frequency of stool leakage during the night Average frequency of solid stool leakage during the night Average frequency of liquid stool leakage during the night
	Frequency of bowel movements	3: How often do you open your bowels?	1: How many bowel movements have you had during the day? 2: How many bowel movements have you had during the night?	Number of days with bowel movements during the day Average frequency of bowel movements during the day Percentage of total amount of bowel movements that occurs during the day Minimum frequency of bowel movements during the day Maximum frequency of bowel movements during the day Number of days with bowel movements during the night Average frequency of bowel movements during the night Percentage of total amount of bowel movements that occurs during the night Minimum frequency of bowel movements during the night Maximum frequency of bowel movements during the night
	Clustering of bowel movements	4: Do you ever have to open your bowels again within one hour of the last bowel opening?	17: After you had a bowel movement, did you have to return to the toilet within 1 h for a bowel movement?	Number of days with clustering Percentage of total amount of bowel movements with clustering
	Urgency	5: Do you ever have such a strong urge to open your bowels that you have to rush to the toilet?	3: If you needed to go urgently, did you have trouble stopping your bowel movement for longer than 15 min?	Number of days with urgency Percentage of total amount of bowel movements with urgency
	Soiling	/	12: Have you had a smear of faeces in your underwear during the day? 13: Have you had a smear of faeces in your underwear, pyjamas or night-gown at the end of the night?	Number of days with soiling during the day Average frequency of soiling during the day Minimum frequency of soiling during the day Maximum frequency of soiling during the day Percentage of total amount of soiling that occurs during the day Number of days with soiling during the night Average frequency of soiling during the night Minimum frequency of soiling during the night Maximum frequency of soiling during the night Percentage of total amount of soiling that occurs during the night

[a]LARS scores vary between 0 and 42: Question 1 (0/4/7), Question 2 (0/3/3), Question 3 (4/2/0/5), Question 4 (0/9/11), Question 5 (0/11/16).

[b]COREFO scores vary between 0 and 100: each question is scored on a Likert-scale (0–4), for the total score the mean of all questions (without Question 19) is multiplied by 25.

TABLE 3 Characteristics of the participants ($n = 95$)

Variable	Male	Female	All patients
Sex, *n* (%)	65 (68.4)	30 (31.6)	95 (100)
Mean age (years) (±SD)	57.4 (±10.9)	56.8 (±13.4)	57.2 (±11.8)
Mean body mass index (kg/m²) (±SD)	25.4 (±3.8)	23.5 (±4.5)	24.8 (±4.1)
Tumour height			
Low (0–5 cm), *n* (%)	42 (64.6)	13 (43.3)	55 (57.9)
Mid (6–10 cm), *n* (%)	15 (23.1)	12 (40.0)	27 (28.4)
High (11–15 cm), *n* (%)	8 (12.3)	5 (16.7)	13 (13.7)
Neoadjuvant therapy			
None, *n* (%)	17 (26.2)	12 (40.0)	29 (30.5)
Chemotherapy, *n* (%)	3 (4.6)	0 (0.0)	3 (3.2)
Radiotherapy, *n* (%)	3 (4.6)	2 (6.7)	5 (5.3)
Chemoradiotherapy, *n* (%)	42 (64.6)	16 (53.3)	58 (61.0)
Adjuvant therapy			
None, *n* (%)	33 (50.8)	17 (56.7)	50 (52.6)
Chemotherapy, *n* (%)	32 (49.2)	12 (40.0)	44 (46.3)
Chemoradiotherapy, *n* (%)	0 (0)	1 (3.3)	1 (1.1)
Reconstruction			
Straight coloanal anastomosis, *n* (%)	48 (73.9)	13 (43.3)	61 (64.2)
Side-to-end coloanal anastomosis, *n* (%)	9 (13.8)	11 (36.7)	20 (21.1)
Colon pouch/J-pouch, *n* (%)	8 (12.3)	6 (20.0)	14 (14.7)
Anastomosis			
Handsewn, *n* (%)	21 (32.3)	8 (26.7)	29 (30.5)
Stapled, *n* (%)	44 (67.7)	22 (73.3)	66 (69.5)
Stoma			
Yes, *n* (%)	56 (86.2)	26 (86.7)	82 (86.3)
No, *n* (%)	9 (13.8)	4 (13.3)	13 (13.7)

parameters. That is, although both of the questionnaires and the stool diary included aspects of clustering, the content of the information on these parameters that could be derived from the different measurement methods was so different that it did not overlap sufficiently to result in an association.

Regarding the items on urgency, no significant association was found between either the LARS or the COREFO questionnaire and the information provided by the stool diary, analogous to items on clustering.

Items on soiling were significantly correlated ($r = 0.638$) between the COREFO questionnaire and the stool diary, with 33.6% of the information found in the questionnaire being explained by the stool diary. No canonical correlation analysis on soiling could be done for the LARS questionnaire and stool diary, since no item on soiling is represented in one of the five questions in the LARS questionnaire.

Overall, weak to moderate correlations were found between items from the questionnaire and stool diary items. For items concerning clustering and urgency in particular, no significant associations were found, which might point to some clinical added value of the stool diary.

DISCUSSION

To our knowledge, this is the first study to investigate the association between the LARS and COREFO questionnaires compared with a stool diary for the evaluation of bowel symptoms after RC. Although the same constructs (of bowel function) are evaluated using the different measurement methods, there appears to be a difference in results obtained by evaluating complaints through fixed questions as opposed to writing events down in a diary. Only two items of the LARS questionnaire (anal incontinence for faeces and frequency of bowel movements) showed significant association when compared with the stool diary. In particular, the LARS questionnaire contained only 18.5% and 36.2% of the information available in the stool diary regarding anal incontinence for faeces and frequency of bowel movements, respectively. For the COREFO questionnaire, three items showed significant association with the stool diary. Respectively, 37.5%, 45.8% and 33.3% of the information in the stool diary regarding anal incontinence for faeces, frequency of bowel movements and soiling was included in the COREFO questionnaire. Overall, moderate associations were found, although the total amount of information overlap between the questionnaires and

TABLE 4 Characteristics of bowel complaints

	LARS questionnaire ($n = 343$)		COREFO questionnaire ($n = 344$)			Stool diary ($n = 300$)				
Variable		**(%)**			**(%)**		**(%)**			**(%)**
Anal incontinence for flatus		80.8			85.5	-				
Anal incontinence for faeces		68.5	Day Night		44.2 33.4			Day Night		46.7 27.0
Frequency of bowel movements	<1: 1–3: 4–7: >7:	3.2 29.2 44.0 23.6	Day	0–1: 2–4: 5–7: 8–10: >11:	6.7 47.1 26.7 9.0 10.5	<1: 1–3: 4–7: >7:	9.3 33.0 43.4 14.3	Day	0–1: 2–4: 5–7: 8–10: >11:	14.0 53.7 21.0 7.0 4.3
			Night	0: 1–2: 3–4: 5–6: >7	32.9 48.8 11.3 4.7 2.3			Night	0: 1–2: 3–4: 5–6: >7	27.4 70.0 2.3 0.3 0.0
Clustering of bowel movements		96.2			93.6					61.7
Urgency		84.5			78.8					72.3
Soiling	-		Day Night		70.1 54.4			Day Night		45.3 23.0

TABLE 5 Overview of results

	LARS vs. stool diary			COREFO vs. stool diary		
	***p*-value**	**Correlation coefficient**	**Proportion of variance explained by stool diary**	***p*-value**	**Correlation coefficient[a]**	**Proportion of variance explained by stool diary**
Anal incontinence for faeces	**<0.001**	0.434	18.8%	**<0.005**	0.283–0.724	37.1%
Frequency of bowel movements	**<0.001**	0.596	35.5%	**<0.001**	0.595–0.722	45.0%
Clustering of bowel movements	>0.05	–	–	>0.05	–	–
Urgency	>0.05	–	–	>0.05	–	–
Soiling	Not applicable			**<0.001**	0.638	33.6%

Note: A dash (–) indicates no significant correlation.

[a]If more than one pair of canonical variates was found to be significantly correlated, a range is displayed concerning the correlation coefficient.

Bold indicate significant *p*-value.

the stool dairy was rather limited. For items on clustering of bowel movements and urgency, no significant association was found with the information provided by the stool diary for either questionnaire. Descriptive data demonstrated the overlap and differences between the different measurement methods (Table 4).

For the detailed clinical assessment of bowel symptoms, a prospective stool diary that records many parameters provides more specific, objective and real-time information rather than estimations or predefined suggestions [7,15,20,21]. Although a stool diary is omnipresent in studies evaluating bowel complaints, few publications have described its contents [7,22,23]. The stool diary used in this study was based on clinical guidelines and designed to portray LARS symptoms, but to date, no standardized format has been developed [7,15]. At the moment, this means that it is up to the clinician to determine how much detail should be recorded in the diary. The joint report of the International Urogynecological Association (IUGA)/International Continence Society (ICS) suggested inclusion of the following elements: urgency, faecal incontinence (amount, consistency) and soiling. This is in line with most of the items that were included in the stool diary in this study. Other items suggested in the literature for inclusion were flatus incontinence, pads, straining/difficulty/time in the toilet, unsuccessful attempts to defaecate, assistive measures, laxative/rectal evacuant use, diet and fluids [23].

Many different methods have been used over the years for the assessment of LARS. Assessment on the basis of a patient's self-report or questionnaires is common, but could be misleading due

to recall bias. An example of this recall bias is demonstrated in the prevalence of clustering in Table 4. When measured via questionnaires, more than 90% of patients indicated that they experienced clustering, as opposed to 60% detected by means of a stool diary. Furthermore, the variability in bowel symptoms might not be portrayed sufficiently because of the predefined possible answers that are inherent to questionnaires [21,24,25].

We chose to include the LARS and COREFO questionnaires because of their proven reliability and validity in RC patients and their validation in Dutch [10–12,18,26]. Chen et al. [27] provided an overview of other available validated questionnaires capturing postsurgical anorectal function in RC patients. Questionnaires such as the Wexner Faecal Incontinence Score [28], the St Mark's Incontinence Score/Vaizey questionnaire/Hallböök-questionnaire [12,29] and the Faecal Incontinence Severity Index [30] have been widely used in assessing bowel dysfunction, but these questionnaires only focus on anal incontinence and therefore do not grasp the full scope of LARS. The Memorial Sloan-Kettering Cancer Center Bowel Function Instrument (MSKCC BFI) [31], on the other hand, provides an evaluation tool explicitly designed to assess bowel function after LAR for RC. However, this questionnaire has been used in very few studies, is quite extensive and has not yet been validated in Dutch [12]. The COREFO questionnaire covers a broad spectrum of colorectal complaints found in RC patients [18] and provides multiple questions per domain for analysis by canonical correlation. This could be an explanation for the slightly higher proportions of variance explained by the stool diary for items on frequency and anal incontinence for faeces compared with the LARS questionnaire, which only provides one question per domain. As stated by Emmertsen et al. [11], the LARS score was developed as a quick scoring system to evaluate bowel dysfunction after a LAR for RC, based on symptoms and impact on quality of life. Considering that the LARS questionnaire consists of only five short questions, it has been widely used ever since its development. However, precisely because of the complexity of LARS and the conciseness of the LARS questionnaire, some prudence in interpreting the LARS score is warranted. For example, Ribas et al. [32] reported that 24% of patients categorized as major LARS from the LARS score in reality did not report any effect of their bowel dysfunction on their quality of life, which translates into an overestimation of patients categorized as major LARS. Furthermore, they stated that patients with severe evacuatory dysfunction could be underestimated by the LARS score [32]. It could be argued that constipation symptoms could be partially evaluated by the LARS questionnaire by choosing 'less than once per day' as the answer for frequency; however, severe evacuatory dysfunction could still remain undetected. The LARS score has been proven to be highly sensitive for detecting LARS. However, recent studies showed that LARS is also common in the general population and therefore the score lacks specificity [17,33,34].

Finally, prospective stool diaries are widely used and have been proven to be reliable in assessing bowel patterns and faecal incontinence [23,25]. These findings corresponded to the results in this study for RC patients, given that items on anal incontinence and frequency both correlated between the questionnaires and the stool diary. As previously mentioned, items on clustering and urgency did not correlate, which prompts the question of whether an evaluation of LARS based solely on questionnaires provides sufficient insight into the complexity of the syndrome as a whole. It is known that the presence of measurement error in an instrument– reflected by a imperfect reliability – attenuates the association with other scores. Therefore, the weak association will be partially due to this phenomenon. However, for both questionnaires high reliabilities were reported and the association values were too low to be explained entirely by attenuation due to measurement error.

A question could also be posed about whether the stool diary is more likely to be at the base of the lack of association between the questionnaires and the diary. Namely, the limited correlation and overlap could perhaps indicate the better ability of questionnaires to reflect bowel symptoms. However, given that a stool diary objectively represents each occurrence in real time and a questionnaire surveys the symptoms in a more bundled manner, we are more inclined to suggest the use of a stool diary during patient follow-up, supplemented with questionnaires. Nevertheless, from a patient-centric point of view, one could argue that using shorter and faster measurement methods (i.e. the LARS and COREFO questionnaires) would be preferable. Seeing that input from patients as well as from clinicians was used in developing these questionnaires, their complaints are well represented. Yet, by using a more detailed stool diary – which could be considered to be more clinician-centric – intervention effects might surface more easily. However, since the stool diary registers the full spectrum of LARS, the gathered data on each type of complaint become more detailed. This could lead more quickly to statistical differences. Nevertheless, a clearer division between these specific complaints is helpful for adapting treatment more precisely to a patient's needs. So, although questionnaires might seem easier to use from a patient's perspective, the addition of a stool diary can provide more clinically detailed information, which benefits not only the clinician during patient follow-up but ultimately the patient as well.

A major strength of this study was that, to our knowledge, it was the first study to investigate associations between a stool diary and the LARS and COREFO questionnaires as assessment tools for bowel symptoms after LAR for RC in a representative sample. Additionally, by using the data from the different timepoints as a stacked dataset in the analyses, a more stable result was obtained. Finally, because we used three measurement methods, the evaluation of a wide range of bowel symptoms was investigated. A possible limitation of this study was that the diary used was based on clinical experience and guidelines, as no standardized form is currently available. The lack of recording flatus incontinence is also a gap in our version of the stool diary. As suggested by the joint report of the IUGA/ICS, this should be included in future versions of the stool diary [23]. Investment should be made in developing a standardized stool diary. Consequently, the determination of the minimal clinically important difference of

each aspect of the stool diary is crucial in the evaluation of clinical relevance for the patient. Then, this standardized form could be used in research as well as in clinical settings.

CONCLUSION

Although both the LARS score and the COREFO questionnaire are reliable and valid, the associations with the stool diary were not sufficiently established. Statistically, associations were weak to moderate, which means that the stool diary could have added value clinically. Especially for items on clustering and urgency, the stool diary seems to provide different, perhaps more objective, information. Therefore, in order to evaluate all aspects of LARS, we suggest the use of a stool diary together with questionnaires to get a full understanding of a patient's symptoms related to LARS.

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CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

AA: acquisition/analysis/interpretation of data, drafting of the work, critical revision of the work, final approval, agreement to be accountable, project management. AD'H: conception/design of the work, acquisition/analysis/interpretation of data, drafting of the work, critical revision of the work, final approval, agreement to be accountable, project management, fund procurement, consultation/supervision. AW: interpretation of data, critical revision of the work, final approval, agreement to be accountable. YVM: interpretation of data, critical revision of the work, final approval, agreement to be accountable. BVG: interpretation of data, critical revision of the work, final approval, agreement to be accountable. ND: analysis/interpretation of data, drafting of the work, critical revision of the work, final approval, agreement to be accountable. ADG: interpretation of data, drafting of the work, critical revision of the work, final approval, agreement to be accountable. TDV: interpretation of data, critical revision of the work, final approval, agreement to be accountable. LD: interpretation of data, critical revision of the work, final approval, agreement to be accountable. IG: conception/design of the work, acquisition/analysis/interpretation of data, drafting of the work, critical revision of the work, final approval, agreement to be accountable, project management, fund procurement, consultation/supervision.

ETHICAL APPROVAL

Approval for this trial was granted by the local ethical committee of the University Hospitals Leuven (main ethical committee, s59761) and additionally positive advice from the other centres (OLV Hospital Aalst and General Hospital Groeninge Kortrijk) was obtained. Patients signed an informed consent form.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author (anne.asnong@kuleuven.be) upon reasonable request.

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