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Abstract: OBJECTIVE: The aims of this study were to investigate the convergent and discriminative validity and reliability of the low anterior resection syndrome (LARS) score in an international setting. BACKGROUND: The LARS score is a simple self-administered questionnaire measuring bowel dysfunction after rectal cancer surgery. The score is intended to be commonly used in international research and clinical practice in the future. Therefore, a thorough validation in an international setting is of utmost importance. METHODS: The LARS score was translated using methods in keeping with current international recommendations. A total of 801 patients operated for rectal cancer in Sweden, Spain, Germany, and Denmark completed the LARS score questionnaire, including an anchor question assessing the impact of bowel function on quality of life. A subgroup of 218 patients completed the LARS score twice. Data were analyzed per country. RESULTS: The LARS score has demonstrated a high convergent validity in terms of a high correlation between LARS score and quality of life (P < 0.001). Sensitivity ranged from 67.7% to 88.3% and specificity from 58.1% to 86.3%. The LARS score was able to discriminate between groups of patients differing with regard to radiotherapy, surgery, and age (P < 0.05). The score also demonstrated high reliability at test-retest with narrow limits of agreement and no statistically significant difference between scores at the first and second test. CONCLUSIONS: The Swedish, Spanish, German, and Danish versions of the LARS score have proven to be valid and reliable tools for measuring LARS in European rectal cancer patients.

# International Validation of the Low Anterior Resection Syndrome Score

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**Objective:** The aims of this study were to investigate the convergent and discriminative validity and reliability of the low anterior resection syndrome (LARS) score in an international setting.

**Background:** The LARS score is a simple self-administered questionnaire measuring bowel dysfunction after rectal cancer surgery. The score is intended to be commonly used in international research and clinical practice in the future. Therefore, a thorough validation in an international setting is of utmost importance.

**Methods:** The LARS score was translated using methods in keeping with current international recommendations. A total of 801 patients operated for rectal cancer in Sweden, Spain, Germany, and Denmark completed the LARS score questionnaire, including an anchor question assessing the impact of bowel function on quality of life. A subgroup of 218 patients completed the LARS score twice. Data were analyzed per country.

**Results:** The LARS score has demonstrated a high convergent validity in terms of a high correlation between LARS score and quality of life ($P < 0.001$). Sensitivity ranged from 67.7% to 88.3% and specificity from 58.1% to 86.3%. The LARS score was able to discriminate between groups of patients differing with regard to radiotherapy, surgery, and age ($P < 0.05$). The score also demonstrated high reliability at test-retest with narrow limits of agreement and no statistically significant difference between scores at the first and second test.

**Conclusions:** The Swedish, Spanish, German, and Danish versions of the LARS score have proven to be valid and reliable tools for measuring LARS in European rectal cancer patients.

**Keywords:** bowel dysfunction, functional outcome, low anterior resection syndrome score, rectal neoplasms, validation

Up to 60% of rectal cancer patients undergoing low anterior resection (LAR) suffer from bowel dysfunction, severely affecting their quality of life (QoL).[1–4] The complex of symptoms consisting of incontinence for flatus and/or feces, urgency, constipation, fragmentation, and frequent bowel movements is referred to as the low anterior resection syndrome (LARS). Several studies have addressed the symptoms of LARS after rectal cancer, but a significant variability exists in the reporting of outcomes after anterior resection.

In a systematic review of 48 studies of long-term functional outcomes after anterior resection for rectal cancer, the authors reported that 65% of the studies did not use a validated assessment tool. Hence, the intended meta-analysis was limited by the significant heterogeneity of the primary data.[1]

To facilitate the monitoring of relevant functional LAR outcomes in daily clinical practice and in clinical trials, a uniform terminology and a common international tool for measuring bowel function after LAR are required. This realization has led to the development of a simple self-administered scoring system assessing the severity of LARS—the LARS score (Fig. 1). The LARS score measures the most important aspects of LARS, and the selection of the 5 included items was primarily based on patients' perceptions of the influence of bowel function on QoL—and not merely on the opinions of professionals. The development and validation of the LARS score in a Danish population has been published by Emmertsen et al.[5] The Danish validation was based on a 27-item questionnaire, from which the LARS score was developed. However, the current version of the LARS score consisting of 5 items has not yet been validated.

As cultural and linguistic differences may affect the equivalence of various language versions of the LARS score, it is crucial that the score is translated according to current international recommendations and that the validation is carried out in an international setting. To cover the major part of Europe, this study includes a Spanish (SPA) population to represent the southern part of Europe, a German (GER) population to represent Central Europe, and a Swedish (SWE)/Danish (DEN) population to represent the northern part of Europe.

The main aims of this study were to investigate convergent and discriminative validity and to explore the test-retest reliability of the translated versions of the LARS score in several European populations of rectal cancer patients.

## METHODS

### Translation

The original Danish version of the LARS score was initially translated to English and subsequently from English to Swedish, Spanish, and German. The translations to each language were done by 2 independent professional translators whose mother tongue was the target language. The translators discussed any discrepancies between the 2 versions until a final consensus was reached. A common version was then established, and this version was back-translated to the original language by a third independent translator whose mother tongue was the language of the original version. The third translator, doing the back-translation, was not familiar with the original version. The back-translations were done to check whether the original meaning of each question was preserved. The translations aimed at conceptual equivalence rather than a word-for-word translation and the process followed the recommendations of the WHO and the European Organisation for Research and Treatment of Cancer (EORTC).[6–8] The

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**FIGURE 1.** LARS score questionnaire.

selected translators were not healthcare professionals, but the final versions were checked and accepted by the investigators at each of the participating centers.

## Participants

Patients operated for rectal cancer from Sweden, Spain, Germany, and Denmark and who were 18 years old or above were included. All the participants had undergone either a curative total mesorectal excision (TME) or a curative partial mesorectal excision (PME) for rectal cancer in the period from 1st January 2001 to 31st December 2009.

Exclusion criteria included the presence of stoma and/or known disseminated or recurrent disease. For the purposes of this study, all included patients are referred to as *participants*.

Participants were identified through local and national databases by the local investigators at each of the participating centers. Subjects to be approached were selected randomly from the pool of eligible subjects. Demographic and clinical information was obtained from databases.

Participants were approached during the period extending from 1st March 2011 to 1st April 2012 to ensure a minimum duration of 14 months after surgery to allow their bowel function to have regained stability.[2,9] At the outset, it was decided to include more patients in Spain due to historically low response rates to questionnaires.

## Questionnaire

All participants were sent the LARS score questionnaire (Fig. 1) along with an invitation to participate in the study. In addition, a separate question to assess their QoL ("Overall, how much

does your bowel function affects your quality of life?") was sent with the LARS score questionnaire. The available responses were "Not at all"/"A little"/"Some"/ "A lot." This extra question was added for validation purposes only, to enable the investigation of the association between LARS score and QoL.

## Test-retest

To examine the test-retest reliability of the score, a randomly selected subgroup of participants was mailed the LARS score questionnaire twice. The second test was mailed to the participants 1–2 weeks after the completion of the first test. If the time interval between the completions of the 2 tests was outside the predefined interval of 1–9 weeks, data were excluded from the analysis. As a test-retest analysis is only relevant if the subject of interest is stable, participants were explicitly asked if they had experienced any significant change in bowel function between the first and the second test.[10] Participants confirming a change in bowel function were excluded from the test-retest analysis. Nonresponders were further contacted once, either by mail or by phone.

## Statistical Analysis

The LARS score was computed and categorized into 3 groups: no LARS (0–20 points), minor LARS (21–29 points), or major LARS (30–42 points), according to the guidelines.[5] To facilitate the analysis of convergent validity, ie, the association between the LARS score and QoL, participants were further categorized into 3 "QoL groups": no, minor, or some/major impact of bowel function on QoL.

The association between the LARS score and QoL was illustrated by means of tables depicting the percentage of perfect fit,

moderate fit, and no fit between the LARS group and the QoL group. It was considered a perfect fit if both the patient perception of QoL and the LARS score matched completely (eg, "No LARS/No impact on QoL"). A mismatch in 1 category was deemed moderate fit and a total mismatch was regarded as no fit.

Discriminative validity was evaluated by means of comparisons of groups expected to differ with regard to LARS: +/– radiotherapy, type of surgery (TME/PME), and age older or younger than the median age of the study population, ie, 68.8 years.

The sensitivity and specificity for identifying patients with some/major impact on QoL with a cutoff at 30 points at the LARS score scale were computed and reflect the ability of the LARS score to predict impact of bowel function on QoL.

In the analysis of the test-retest reliability, the extent of agreement between the numerical value of the LARS score at the first and second test was demonstrated on a Bland Altman plot with limits of agreement. The correlation between the numerical value of the LARS score at the first and second test was assessed by intraclass correlation coefficient. The difference between the numerical value of the LARS score at the 2 tests was tested by means of the Student *t* test. Furthermore, for each of the 5 individual questions of the score, the agreement between the first and second response was explored by means of computing the percentage of perfect, moderate, and no agreement. A perfect agreement was assigned when participants ticked off exactly the same category at the first and second test, moderate agreement was assigned when responses differed by only 1 category, and no agreement was assigned when responses differed by 2 or 3 categories at the 2 tests.

Radio- and chemotherapy were treated as dichotomous variables: no treatment at all versus treatment before and/or after surgery. Age was both treated as a continuous variable and dichotomized to younger or older than the median age of the total study population (68.8 years).

Differences were tested per country by means of the Student *t* test, $\chi^2$ test, Kruskall-Wallis test, or Wilcoxon rank-sum test, dependent on data type and distribution. All *P* values < 0.05 are considered statistically significant. All statistical analyses were performed using STATA 11 (StataCorp LP, College Station, TX).

### Ethics

The study was approved by the local ethics committees in all participating centers.

## RESULTS

### Translation

The double-forward translations revealed only minor discrepancies, which were easily solved by discussion between the translators. All backward translations confirmed that the original meaning of each of the 5 questions was retained. Investigators at each of the participating centers accepted the final version of the LARS score. Only 1 minor correction was proposed by the Swedish investigators concerning the translation of "liquid stool."

### Participants

A total of 1073 patients were initially approached. Twelve were excluded: 8 recently had a stoma and 4 had a recurrence, leaving 1061 approached patients eligible for the study. Out of the 1061 eligible patients, 810 responded, and only 9 of those returned incomplete questionnaires (completion rate 98.9%). Thus, 801 of the 1061 approached and eligible patients were included in the statistical analysis (75.5%); see Table 1 for results per country. Clinical and demographic data are shown in Table 2. Out of the 343 subjects initially approached in the test-retest part of the study, 240 responded (70%). Eleven were subsequently excluded because they reported a significant change in

bowel function between tests, and another 11 were excluded due to a time period between tests outside of the predefined acceptable period of 1–9 weeks. Thus, a total of 218 subjects were included in the test-retest analysis [Sweden: n = 48, Spain: n = 59, Germany: n = 49, Denmark: n = 62].

### Responders versus Nonresponders

There was no statistically significant difference between responders and nonresponders in any country with regard to gender, type of surgery, or radio- or chemotherapy. However, in Spain, the responders were on average 3.5 years [95% confidence interval (CI): 1.1–5.8] younger than the nonresponders (*P* < 0.01), and a lower proportion of Spanish responders were classified T3–T4 with a risk difference of 13.7% (95% CI: 3.0–24.5) and *P* = 0.02. Also, tumor level was on average 1.2 cm (95% CI: 0.01–2.3) higher in Danish nonresponders compared with Danish responders (*P* = 0.05). No difference was found with regard to age, tumor (T) stage, or tumor level in the remaining countries.

### Convergent Validity

Table 3 shows a comparison between the calculated LARS scores and the self-reported impact of bowel function on QoL for participants in all the countries. Furthermore, the percentages of perfect, moderate, and no fit between the LARS group and the QoL group for each country are summarized in Table 4. It is clear that "no fit" was found in 4.3% in Swedish data, 6.0% in Spanish data, 7.7% in German data, and 2.3% in Danish data.

Boxplots illustrating the association between the numerical LARS score value and the QoL group are displayed in Figure 2. In all countries, there was a statistically significant difference in the LARS score between the 3 QoL groups (*P* < 0.001), ie, the higher the LARS score, the more the impact of bowel function on QoL.

The sensitivity (95% CI) of the LARS score was: Sweden: 81.9% (76.4–87.4), Spain: 77.9% (71.9–83.9), Germany: 67.7% (61.4–74.1), and Denmark: 88.3% (84.0–92.6).

The specificity (95% CI) of the LARS score was: Sweden: 58.15 (51.0–65.2), Spain: 78.6% (72.6–84.5), Germany: 86.3% (81.6–90.9), and Denmark: 75.9% (70.2–81.6).

### Discriminative Validity

In all countries, patients receiving radiotherapy had a statistically significant higher LARS score than those who did not (*P* < 0.01), and patients who had undergone a TME operation had a statistically significant higher LARS score than those who had undergone a PME operation (*P* < 0.01). Patients below the median age of the study population (68.8 years) had a statistically significant higher LARS score compared with those who were older, with *P* values of 0.03 in Sweden, Spain, and Germany and of <0.001 in Denmark. Differences between groups are demonstrated in Figure 3.

### Test-Retest Reliability

Median (range) days between the first and the second test were 21 (15–42) days in Sweden, 23 (11–61) days in Spain, 18 (8–63) days in Germany, and 16 (12–48) days in Denmark.

Figure 4 shows the agreement between the first and the second numerical value of the LARS score by means of a Bland Altman plot. The 95% limits of agreement were –8.2 to 7.9 in Sweden, –8.6 to 10.4 in Spain, –7.6 to 10.0 in Germany, and –13.8 to 13.0 in Denmark. Intraclass correlation coefficients were 0.94, 0.92, 0.93, and 0.86 in Sweden, Spain, Germany, and Denmark, respectively. There was no systematic difference in the LARS score at the first and second test in Sweden (*P* = 0.85), in Spain (*P* = 0.18), in Germany (*P* = 0.08), or in Denmark (*P* = 0.66), ie, there was no tendency toward

**TABLE 1.** Patient Inclusion

| Country | Approached | Responders | Nonresponders | Excluded Responders* | Included in Analysis |
|---|---|---|---|---|---|
| Sweden | 243 | 188 | 55 | 0 | 188 (77.4%) |
| Spain | 329 | 190 | 139 | 4 | 186 (56.5%) |
| Germany | 242 | 211 | 31 | 3 | 208 (86.0%) |
| Denmark | 247 | 221 | 26 | 2 | 219 (88.7%) |
| Total | 1061 | 810 | 251 | 9 | 801 (75.5%) |

*Excluded because of incomplete questionnaires.

**TABLE 2.** Clinical and Demographic Information

|  | Sweden | Spain | Germany | Denmark |
|---|---|---|---|---|
| No. participants | 188 | 186 | 208 | 219 |
| Males, n (%) | 96 (51.1) | 125 (67.2) | 129 (62.0) | 92 (42.0) |
| Age in years at time of survey, mean (SD) | 67.9 (10.0) | 67.2 (10.2) | 65.7 (9.9) | 70.2 (9.5) |
| Tumor stage |  |  |  |  |
| T0–T2, n (%) | 98 (52.1) | 101 (54.3) | 149 (71.6) | 79 (44.1) |
| T3–T4, n (%) | 90 (47.9) | 85 (45.7) | 59 (28.4) | 100 (55.9)* |
| Years since operation, mean (SD) | 5.2 (2.4) | 4.2 (1.9) | 5.9 (2.1) | 6.9 (1.7) |
| Type of surgery |  |  |  |  |
| TME, n (%) | 170 (90.4) | 135 (72.6) | 166 (79.8) | 132 (60.3) |
| PME, n (%) | 18 (9.6) | 51 (27.4) | 42 (20.2) | 87 (39.7) |
| Tumor level in cm, mean (SD) | 9.9 (3.0) | 9.3 (3.3) | 8.7 (3.5) | 10.2 (3.0)† |
| Radiotherapy, n (%) | 144 (76.6) | 131 (70.4) | 114 (54.8) | 43 (19.6) |
| Chemotherapy, n (%) | 50 (26.6) | 150 (80.7) | 116 (55.8) | 34 (15.5) |

*Forty missing (operated before the implementation of TNM classification in the Danish Colorectal Cancer Group database).
†Two missing.

**TABLE 3.** Fit Between the QoL Group and LARS the Score Group

| Impact of Bowel Function on QoL | No LARS (0–20 Points) | Minor LARS (21–29 Points) | Major LARS (30–42 Points) |
|---|---|---|---|
| SWE (n = 188) |  |  |  |
| No | 19 (10.1%) | 1 (0.5%) | 2 (1.0%) |
| Minor | 17 (9.0%) | 24 (12.8%) | 42 (22.3%) |
| Some/major | 6 (3.2%) | 9 (4.8%) | 68 (36.2%) |
| SPA (n = 183) |  |  |  |
| No | 16 (8.7%) | 9 (4.9%) | 4 (2.2%) |
| Minor | 18 (9.8%) | 12 (6.6%) | 11 (6.0%) |
| Some/major | 7 (3.8%) | 18 (9.8%) | 88 (48.1%) |
| GER (n = 207) |  |  |  |
| No | 22 (10.6%) | 1 (0.5%) | 1 (0.5%) |
| Minor | 31 (15.0%) | 15 (7.3%) | 10 (4.8%) |
| Some/major | 15 (7.3%) | 26 (12.6%) | 86 (41.6%) |
| DEN (n = 218) |  |  |  |
| No | 41 (18.8%) | 9 (4.1%) | 3 (1.4%) |
| Minor | 33 (15.1%) | 24 (11.0%) | 31 (14.2%) |
| Some/major | 2 (0.9%) | 7 (3.2%) | 68 (31.2%) |

**TABLE 4.** Fit Between the LARS Score Group and the QoL Group

| SWE (n = 188) |  |
|---|---|
| Perfect fit | 59.0 (51.7–66.1) |
| Moderate fit | 36.7 (29.8–44.0) |
| No fit | 4.3 (1.9–8.2) |
| SPA (n = 183) |  |
| Perfect fit | 63.4 (56.0–70.4) |
| Moderate fit | 30.6 (24.0–37.8) |
| No fit | 6.0 (3.0–10.5) |
| GER (n = 207) |  |
| Perfect fit | 59.4 (52.4–66.2) |
| Moderate fit | 32.9 (26.5–39.7) |
| No fit | 7.7 (4.5–12.2) |
| DEN (n = 218) |  |
| Perfect fit | 61.0 (54.2–67.5) |
| Moderate fit | 36.7 (30.3–43.5) |
| No fit | 2.3 (0.7–5.3) |

Values are in percentages with exact 95% CI.

scoring either higher or lower at the second test compared with the first.

Results of the investigation of the agreement between the answers at the first and second test in each of the 5 individual items of the score are displayed in Table 5. "No agreement," ie, responses differed for more than 2 categories at the 2 tests, was nonexisting in German data, and was found only in 2.1% in question 2 in the Swedish data. The proportion of "no agreement" was also very low in Spanish and Danish data, ranging from 1.6% to 6.9%.

## DISCUSSION

This study has validated the LARS score (Fig. 1) in 4 populations of rectal cancer patients across Europe. The score has proven to be easily translated and has demonstrated convincing psychometric properties regarding convergent validity, discriminative validity, and reliability.

When developing international tools, semantic equivalence between different language versions is crucial. Therefore, the LARS score was translated using meticulous methods in accordance with current international recommendations.[6,7] The objective nature of all

5 items of the score, in combination with simple and straightforward phrasing, simplified the process of translation and no difficulties were met. Hence, the English, Swedish, Spanish, German, and Danish versions of the LARS score can be considered semantically equivalent.

This study clearly demonstrates that the LARS score is accurately associated with self-reported QoL in all 4 participating countries. High proportions of perfect and moderate fit between the LARS group and the QoL group were found (Table 4), and the numerical value of the LARS score was significantly higher with increasing levels of impact of bowel function on QoL (Fig. 2). Sensitivity and specificity were high in most countries, ie, the LARS score was, to a great extent, able to predict the patients' self-reported impact of bowel function on QoL. It should be noted that a 100% sensitivity/specificity is not desirable, because this would indicate that LARS and QoL are *exactly* the same thing. Nevertheless, the German sensitivity and the Swedish specificity were somewhat lower than those of the other countries. Given the meticulous translation procedure, this disparity is probably not due to a lack of semantic equivalence between the various language versions of the LARS score. A true difference in the association between LARS and QoL in different

cultures cannot be ruled out, but a more plausible explanation is a cross-cultural difference in how patients interpret the QoL question. An investigation of the LARS score's correlation to a validated measure of QoL would help in clarifying this. Therefore, we are currently working on examining the relationship between the LARS score and the EORTC QLQ-C30.[11]

Apart from the abovementioned deviation/discrepancy, the results are comparable to the ones published by Emmertsen et al.[5] The findings are important, because a high association between the LARS score and the self-reported impact of bowel function on QoL was a prerequisite for items to be selected for the score during the process of development. This requirement was introduced because the authors wished to develop a score based predominantly on the patient's perspectives rather than solely on the opinions of professionals.

The applicability of the LARS score would be limited without the ability to discriminate between subgroups known to differ in terms of LARS. Therefore, we investigated this aspect concerning radiotherapy, surgery, and age, and the results confirm that the score is able to discriminate between groups (Fig. 3). Results on test-retest reliability showed narrow limits of agreement and no statistically significant differences between the numerical value of the LARS score at the first and second test (Fig. 4). Furthermore very high proportions of moderate and perfect agreement between answers at
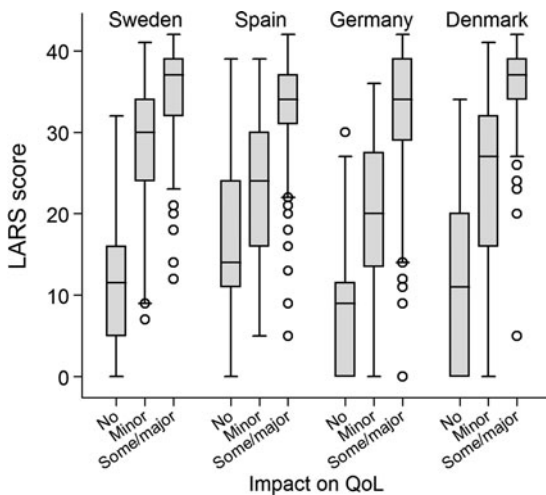


**FIGURE 2.** Boxplot showing the relationship between the LARS score and the QoL group per country. In all countries, the differences in LARS scores between the QoL groups were statistically significant (*P* < 0.001).
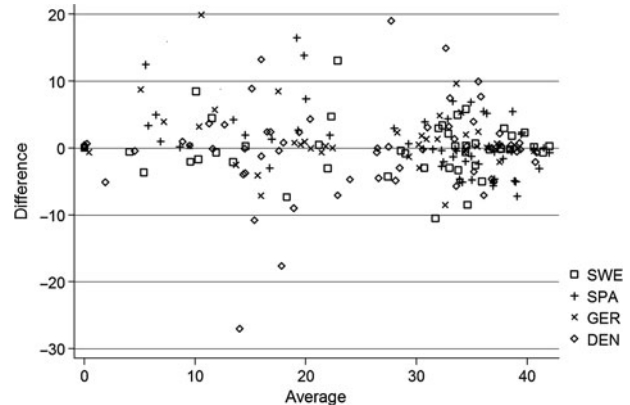


**FIGURE 4.** Bland Altman plot (jittered) illustrating the difference between the numerical LARS score values at the first and second test.
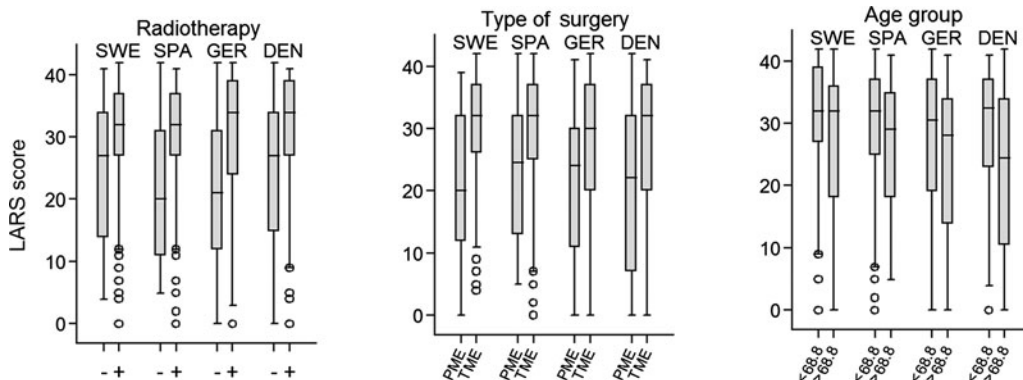


**FIGURE 3.** The LARS score in clinical subgroups: −/+ radiotherapy, type of surgery (PME/TME), and younger or older than the median age of the study population (68.8 years). All differences were statistically significant (*P* < 0.05).

**TABLE 5.** Agreement Between Response at the First and Second Tests for Each Question of the LARS Score

| Agreement | Sweden (n = 46–48) | Spain (n = 56–58) | Germany (n = 47–49) | Denmark (n = 61–62) |
|---|---|---|---|---|
| Q. 1 | | | | |
|   Perfect | 83.0 (69.2–92.4) | 65.5 (51.9–77.5) | 79.6 (65.7–89.8) | 77.0 (64.5–86.8) |
|   Moderate | 17.0 (7.6–30.8) | 27.6 (16.7–40.9) | 20.4 (10.2–34.3) | 16.4 (8.2–28.1) |
|   No | 0 (0–7.5)* | 6.9 (1.9–16.7) | 0 (0–7.3)* | 6.6 (1.8–15.9) |
| Q. 2 | | | | |
|   Perfect | 77.1 (62.7–88.0) | 74.1 (61.0–84.7) | 85.7 (72.8–94.1) | 83.9 (72.3–92.0) |
|   Moderate | 20.8 (10.5–35.0) | 24.1 (13.9–37.2) | 14.3 (5.9–27.2) | 12.9 (5.7–23.9) |
|   No | 2.1 (0.0–11.1) | 1.7 (0.0–9.2) | 0 (0–7.3)* | 3.2 (0.4–11.2) |
| Q. 3 | | | | |
|   Perfect | 69.6 (54.2–82.3) | 82.1 (69.6–91.1) | 89.4 (76.9–96.5) | 80.6 (68.6–89.6) |
|   Moderate | 30.4 (17.7–45.8) | 16.1 (7.6–28.3) | 10.6 (3.5–23.1) | 17.7 (9.2–29.5) |
|   No | 0 (0–7.7)* | 1.8 (0.0–9.6) | 0 (0–7.5)* | 1.6 (0.0–8.7) |
| Q. 4 | | | | |
|   Perfect | 76.1 (61.2–87.4) | 72.4 (59.1–83.3) | 80.9 (66.7–90.9) | 72.6 (59.8–83.1) |
|   Moderate | 23.9 (12.6–38.8) | 25.9 (15.3–39.0) | 19.1 (9.1–33.3) | 25.8 (15.5–38.5) |
|   No | 0 (0–7.7)* | 1.7 (0.0–9.2) | 0 (0–7.5)* | 1.6 (0.0–8.7) |
| Q. 5 | | | | |
|   Perfect | 87.5 (74.8–95.3) | 72.4 (59.1–83.3) | 85.7 (72.8–94.1) | 71.0 (58.1–81.8) |
|   Moderate | 12.5 (4.7–25.2) | 24.1 (13.9–37.2) | 14.3 (5.9–27.2) | 27.4 (16.9–40.2) |
|   No | 0 (0–7.4)* | 3.4 (0.4–11.9) | 0 (0–7.3)* | 1.6 (0.0–8.7) |

Values are in percentages with exact 95% CI.
*One-sided 97.5% CI.

the first and second test in each of the 5 LARS score items were found (Table 5).

The LARS score has, with a few exceptions, demonstrated similar validity and reliability across countries, and these results do furthermore correlate well with the results obtained in the original validation in Danish patients.[5] This confirms that the score performs equally well in several European countries despite cultural differences.

Response rates were high, and nonresponders were similar to responders with regard to all available clinical and demographic data in all countries except Spain. Even though the response rate was somewhat lower in Spain, the theoretical risk of selection bias is minimized by a final inclusion of participants with demographic and clinical features similar to the other countries. The statistically significant differences with regard to age and tumor stage between Spanish responders and nonresponders can be considered clinically irrelevant due to the small degree of difference. Therefore, we think that our results apply well to the total populations of patients operated for rectal cancer in all of the participating countries.

In the test-retest analysis, the interval between the tests ranged up to 9 weeks. This long interval was chosen to decrease the risk of participants copying their first set of answers for their second. A potential disadvantage is an actual increase in numbers of patients having a true change in bowel function. We minimized the risk by excluding participants who reported a significant change in bowel function between the tests.

There was a good compliance across all items with only <1% missing values. Importantly, it demonstrates that the LARS score is easy to understand and easy to complete.

During the last few decades, numerous instruments have been described to assess bowel dysfunction. Nevertheless, in a recent systematic review, the quality of the majority of these instruments was questioned due to the lack of proper psychometric validation.[12] In the review, frequently used scores, such as the Wexner fecal incontinence score,[13] Cleveland constipation score[14], and St Marks incontinence score[15], were categorized as the lowest possible "grade C." In this study, we have attempted to address the crucial issue of validation by adapting and following a robust and systematic approach to the validation of the LARS score.

Future perspectives for the LARS score are, first, to investigate and identify what constitutes a clinically relevant difference and to explore sensitivity to change on the LARS score system. The next step would be to compare the LARS score with validated QoL instruments such as EORTC QLQ-C30.[11] Furthermore, we encourage the translation of the LARS score to more languages, followed by a validation, if the score is intended for use in cultures dissimilar to the European culture.

Needless to say, validated universally acceptable assessment tools are crucial for assessment of LARS. The LARS score offers a quick, easy, and accurate option for measuring LARS in rectal cancer patients, and the current study has shown its applicability across several European countries. Therefore, it has the potential of being a valuable time-saving screening tool in clinical practice by effectively identifying patients with LARS in need of further attention or examination. Furthermore, the LARS score will be useful in clinical research whenever LARS needs to be accurately quantified.

In this study, the LARS score was tested in a large group of patients operated for rectal cancer, but because LARS arises from surgery rather than from the cancer, the LARS score will also be useful in groups of patients undergoing rectal surgery for reasons other than cancer.

## CONCLUSIONS

In conclusion, the English, Swedish, Spanish, German, and Danish versions of the LARS score can be considered semantically equivalent. The Swedish, Spanish, German, and Danish versions of the LARS score have demonstrated high convergent and discriminative validity and reliability. We propose a systematic implementation of the LARS score for both research and clinical purposes.

### Addendum

The English version of the LARS score is shown in Figure 1 in this article, and the Swedish, Spanish, German, and Danish versions of the LARS score can be obtained by contacting the first author.

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