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Validity assessment of the POLARS score tool in the prediction of post rectal cancer surgery LARS score in a population-based Swedish cohort

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ABSTRACT

Objective Low anterior resection syndrome (LARS) is one of the most common functional impairments after rectal cancer surgery with a high impact on quality of life. The Pre-Operative LARS score (POLARS) nomogram and its online tool has been developed to predict the degree of postoperative LARS. The aim of this study was to analyse how accurately the POLARS score could predict LARS scores when compared with actual patient-reported LARS (PR-LARS) scores in a population-based Swedish cohort.

Design This retrospective cohort study included patients who underwent curative rectal cancer surgery between 2007 and 2013 in Stockholm County and were identified using the Swedish Colorectal Cancer Registry (SCRCR). Information regarding preoperative risk factors, patient and treatment characteristics, and presence of LARS postoperatively were collected from patient charts, SCRCR and patient questionnaires. The POLARS model formula was used to predict LARS scores, which then were compared with the actual PR-LARS scores. Individual LARS score differences between the two estimates were shown with a modified Bland-Altman plot of difference.

Results The cohort included 477 patients, of whom 359 (75%) of patients were categorised as having no/minor LARS based on the POLARS score. The correctly identified patients by the POLARS score were 80/255 (31%) in the major LARS group and 184/222 (83%) no/minor LARS group. The sensitivity was 31% for major LARS and the positive predictive value was 68%.

Conclusion The POLARS score has a low sensitivity for major LARS in this Swedish cohort. Other methods to predict the risk of LARS need to be developed.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The most common functional impairment after rectal cancer surgery is low anterior resection syndrome (LARS) which has a major impact on quality of life. A tool for postoperative LARS score has been developed, the Pre-Operative LARS score nomogram and online tool.

WHAT THIS STUDY ADDS

⇒ In the current study, the formula was applied to assess the accuracy. During this process, a few minor errors were found in the formula and were adjusted.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ With these adjustments, the predicted postoperative LARS scores were in closer proximity to the actual patient-reported values. The improved formula can be used in a wider patient population.

INTRODUCTION

Rectal cancer accounts for 35% of colorectal cancer in Europe with an incidence of 15–25 cases/100 000 population per year.[1] Advancements in treatment strategies including total mesorectal excision (TME), radiotherapy (RT) and multidisciplinary team management (MDT), have over the past decade facilitated a significant improvement of oncological outcomes for rectal cancer patients.[2–4] More patients undergo sphincter-preserving surgery, with a colorectal or coloanal anastomosis and giving the patients the potential benefit of avoiding a permanent stoma.[5] However, a low anastomosis may result in varying degrees of bowel dysfunction, commonly referred to as low anterior resection syndrome (LARS).[5] A multifactorial aetiology is suggested with sphincter dysfunction and compliance of the neorectum as potential causes.[6–8] The symptoms associated with LARS are urgency, emptying difficulties, incontinence for flatus and/or faeces and frequent bowel movements. These symptoms can be recognised with a validated self-administered LARS-score questionnaire.[9 10] The severity of bowel dysfunction is reflected in a summative score by which the patients can be divided into three groups; no LARS, minor LARS and major LARS.[5] The prevalence of LARS is reported at 70%–90% and a

recent Swedish study suggested 77%.[11] Major LARS is seen in 26%–56% of patients after rectal cancer surgery.[12–15] In a previous follow-up study, half of the patients suffered from major LARS and the prevalence remained unchanged even after 7–16 years of follow-up.[16] Furthermore, it has been reported that LARS can improve postoperatively but persists relatively stable after 36-month follow-up. However, further investigations for long-term LARS needs to be performed.[17] Almost 85% of patients with LARS experience a negative impact on quality of life (QoL) and around 40% still remains after 5 years.[18]

A predicting tool for a postoperative LARS score has been designed, the Pre-Operative LARS (POLARS) score. The POLARS score was developed in a UK cohort and validated in a Danish cohort.[9] Six different variables are used to predict the POLARS score: age at surgery, gender, TME/partial mesorectal excision (PME), tumour height, defunctioning stoma and preoperative RT.[9] A preoperatively identified correct LARS score could have the potential to advance treatment options and guide postoperative surveillance and follow-up.

The aim of this study was to analyse how accurately the POLARS score could predict LARS scores when compared with actual patient-reported LARS scores (PR-LARS) in a population-based Swedish cohort.

METHODS

Study population

The cohort has been identified through a search in the Swedish Colorectal Cancer Registry (SCRCR). The SCRCR is a mandatory national registry where all patients with diagnosed colorectal cancer are reported with baseline characteristics among all ages. Patients who were alive at the time of the registry search on 4 April 2017 were included. Demographic data and data concerning surgery and other treatments have been obtained from the SCRCR.[11 19 20] Data regarding recurrent and/or disseminated disease and dementia was obtained through a manual review of the patients' medical records. The presence of a stoma was collected by questionnaires.

The inclusion criteria for the study were age over 18 years and curative cancer surgery with TME or PME between January 2007 and December 2013 in Stockholm County, Sweden. The exclusion criteria were death, recurrent and/or disseminated disease, dementia and the presence of a stoma. In total 477 patients were included in this analysis (figure 1).

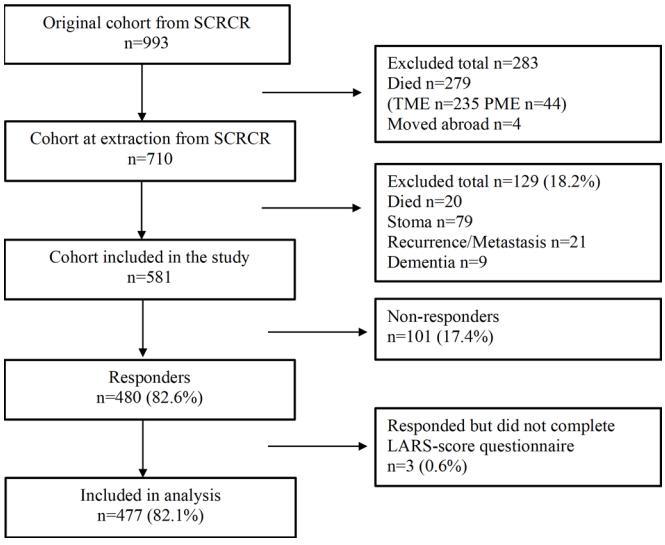

Figure 1 Flow chart. Number of patients eligible for the study at the time of data extraction from SCRCR (Swedish National Quality Registry). LARS, low anterior resection syndrome; PME, partial mesorectal excision; TME, total mesorectal excision.

POLARS score

For the patients, who met the inclusion criteria and responded to the LARS questionnaire, a predicted LARS score was estimated with the POLARS score. The POLARS score can be calculated by two different methods, (a) the POLARS nomogram and (b) the POLARS model formula.[9] For the calculations the following six variables were required: age at surgery, gender, TME/PME, tumour height, defunctioning stoma and preoperative RT.

1. In the POLARS nomogram each definite value of the variables had a corresponding point in the nomogram, which was measured and noted. The patients received a summated count which was converted into a LARS score with the nomogram.
2. The POLARS model formula used was: POLARS score=44.9561+(−0.2117×age)+(−1.014×gender)+(−1.9655×PME)+(0.6374×height)+(0.7817×stoma)+(3.3049×preoperative RT).[9] During this process, large differences between the estimates from the formula and the nomogram were discovered. Compared with the calculations from the POLARS nomogram, patients received higher scores for PME than TME and likewise higher scores for tumours situated further from the anal verge. A closer inspection revealed a few errors in the formula presented by Battersby *et al* when compared with the formula implemented in the JAVA script. These were the following: males should be coded as 1 instead of 0, PME needed to be coded as 1 instead of TME and a missing minus sign in front of the regression estimate for tumour height.[9] The JAVA script used an age range between 35 and 75 years which was not mentioned in the manuscript. With the adjusted POLARS model formula: POLARS score=44.9561+(−0.2117×age)+(−1.014×gender)+(−1.9655×TME)+(−0.6374×height)+(0.7817×stoma)+(3.3049×preoperative RT) more accurate values could be estimated.

The LARS score estimates calculated with the corrected POLARS model formula (b) was used for all analyses in this study and will be named as POLARS score.

The total LARS score adds up to 42 points and is divided into three groups: no LARS (0–20), minor LARS[21–29] and major LARS (30–42). One analysis was done with the comparison across these three groups and a further

Table 1 Patient baseline characteristics (n=477)

Age at surgery, years* (SD)	64 (9.95)
Range	38–93
Follow-up time since surgery, years (SD)	6.68 (2.10)
Range	3.39–10.99
Gender	
Male (%)	273 (57.2)
Tumour level from anal verge, cm (range)	11 (4–15)
Type of surgery	
TME, n (%)	379 (79.5)
PME, n (%)	98 (20.5)
Preoperative radiotherapy, n (%)	320 (67.1)
Defunctioning stoma,† n (%)	394 (82.6)

*Values in mean years.
†Defunctioning stoma that was closed.
PME, partial mesorectal excision; TME, total mesorectal excision.

analysis with only two groups, no/minor LARS and major LARS.

Endpoints

The estimated POLARS score was compared with the PR-LARS score.

Statistics

Patient characteristics were presented with descriptive statistics, where continuous variables were shown as means and categorical variables with frequencies and percentages. The comparative analysis between the POLARS score and PR-LARS score was displayed with cross tables. The sensitivity, specificity and positive predictive values were calculated. A modified Bland-Altman plot was used to compare the differences between the individual POLARS scores and PR-LARS scores,[21] where the latter were plotted on the x-axis. Statistical analysis was conducted using the statistical software SAS (V.9.4, SAS Institute, Gary, NC).

RESULTS

The basic characteristics of the 477 included patients are shown in table 1. The mean follow-up time since surgery was 6.7 years (range 3.4–11.0 years). TME surgery was carried out in 379 (80%) of the patients. Preoperative RT was given to 320 (67%) of the patients and 394 (83%) had a defunctioning stoma that was later closed. The mean time for stoma reversal for all patients was 211 days.

Accordance of the POLARS score and the PR-LARS score (no, minor and major LARS groups)

Major LARS was identified in 118 patients using the POLARS score, whereas 255 of the patients reported major LARS. Among all 255 patients that reported major LARS, 80 (31%) patients were classified as major LARS using the POLARS score.

The POLARS score identified 313 patients with minor LARS, compared with 114 patients that actually reported minor LARS. Among the 114 patients that reported minor LARS, 77 (68%) patients could be identified using the POLARS score. The group 'minor LARS' represents the group with the highest proportion of correct agreement between the POLARS derived LARS score and PR- LARS score.

According to the POLARS score, 46 patients would belong to the no LARS group. This number can be compared with 108 patients that in reality belonged to the no LARS group according to their reported LARS scores. There were 24 (22%) patients that were classified as no LARS with both methods (table 2).

Accordance with the POLARS score and PR-LARS score (no/minor and major LARS groups), sensitivity, specificity and positive predictive values

The results regarding major LARS in this analysis are the same as reported in table 2 and described in the previous paragraph.

Table 2 Patient-reported LARS score (PR-LARS score) by POLARS score (no, minor and major LARS groups)

		POLARS score			
		No LARS	Minor LARS	Major LARS	Total
PR-LARS score	No LARS				
	Frequency (n)	24	70	14	108
	Row (%)	22.22	64.81	12.96	22.64
	Minor LARS				
	Frequency (n)	13	77	24	114
	Row (%)	11.4	67.54	21.05	23.9
	Major LARS				
	Frequency (n)	9	166	80	255
	Row (%)	3.53	65.1	31.37	53.46
	Total	46	313	118	477

LARS, low anterior resection syndrome; POLARS, Pre-Operative LARS score; PR-LARS, patient-reported LARS.

Table 3 Patient-reported LARS score (PR-LARS) and POLARS score (no/minor and major LARS groups)

		POLARS score		
		No/Minor LARS	Major LARS	Total
PR-LARS score	No/Minor LARS			
	Frequency (n)	184	38	222
	Row (%)	82.88	17.12	
	Major LARS			
	Frequency (n)	175	80	255
	Row (%)	68.63	31.37	
	Total	359	118	477

Sensitivity: 31.37%, specificity: 82.88%, positive predictive value: 67.80%.
LARS, low anterior resection syndrome; POLARS, Pre-Operative LARS score; PR-LARS, patient-reported LARS.

According to the POLARS score, 359 patients would belong to the group no/minor LARS. This can be compared with 222 patients who reported no/minor LARS, of whom 184 (83%) patients could be identified using the POLARS score.

The sensitivity for the POLARS score was 31% and the specificity was 83%. The total positive predictive value in the cohort was 68% (table 3).

Difference between POLARS and PR-LARS

The POLARS score and the PR-LARS scores displayed a correlation mainly in the minor scale of the LARS questionnaire (score 21–29). This can also be seen in table 2. The POLARS score predicts most of the patients 313/477 (66%) as minor LARS.

In figure 2, the slope of the differences vs PR-LARS score indicates that the POLARS score deviates at the low and high scores in PR-LARS. Patients that reported high LARS scores received a lower LARS score by the POLARS score. A similar inverse relationship was observed in patients that reported a low LARS score.

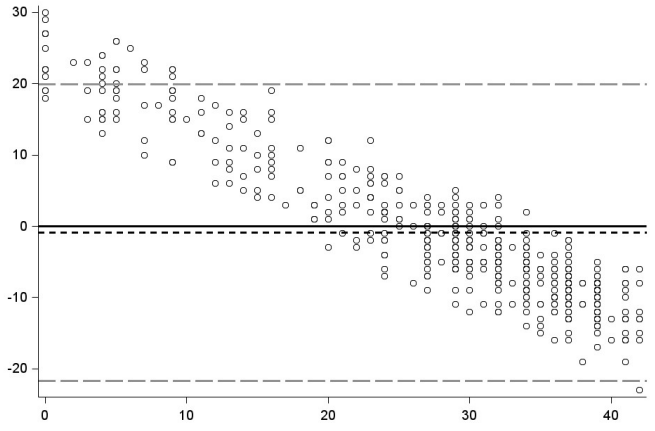

Figure 2 The Bland-Altman plot is based on individual LARS scores and shows the calculations of the differences between POLARS scores and PR-LARS scores. These values are plotted against the PR-LARS scores. The solid line (=0) represents that there is no difference between POLARS scores and PR-LARS. The dotted line displays the mean agreement of these individually calculated differences between the POLARS scores and PR-LARS scores. The 95% CI is between −22 and 20, dashed line. LARS, low anterior resection syndrome; POLARS score, Pre-Operative LARS score; PR-LARS, patient-reported LARS.

DISCUSSION

The aim of the POLARS score is to preoperatively identify patients at risk of developing major LARS. However, in this large Swedish cohort study of 477 rectal cancer patients, the POLARS score had a low sensitivity of 31% for major LARS and only identified less than half of the patients. In general, the scores generated by the POLARS score were lower than the PR-LARS scores in patients with major LARS, whereas the opposite was observed for patients who reported low LARS scores.

The POLARS score was developed in a retrospective cohort from the UK and validated in a retrospective cohort from Denmark.[9] Previously, it has been shown that LARS stabilises after 1.5 years and remains constant thereafter.[17] The follow-up time in the UK (5.2 years), Danish (4.7 years) and the current study (6.7 years) are all longer than that, therefore the difference in follow-up time should not affect the results. One of the reasons for the insufficient sensitivity for the POLARS score in the present cohort could be the different calendar years. The participants in the POLARS study were recruited between 2001–2012 in the UK and 2001–2007 in Denmark, while the Swedish cohort was recruited between 2007 and 2013. Oncological and surgical changes in the management of rectal cancer have occurred during this time. Preoperative RT is a known risk factor for postoperative bowel function following low anterior resection[17] and there are differences in the treatment protocols for neoadjuvant RT. The proportion of patients receiving preoperative RT was 32% and 20% in the UK and Danish cohorts, respectively[9] compared with a significantly higher proportion in the Swedish cohort, 67%. Even if the calculations are adjusted for preoperative RT as a variable, it can be seen as less reliable since more exact doses are not included. Regarding surgical technique, the Swedish and UK cohorts showed equally that 80% of the patients

were operated on with the TME technique and most patients received a defunctioning stoma, while TME was less common in the Danish cohort (59%) and only 55% received a stoma.[9 22]

In a previous study by Bogacki *et al*, the accuracy of the POLARS score was assessed in 66 patients who underwent laparoscopic surgery due to rectal cancer.[23] The predicted LARS score correctly classified the patients in 39% of the cases. In accordance with the present results, most of the patients were in the minor LARS group. The correctly assigned patients in minor LARS were similar with 14/48 (29%) by Bogacki *et al* and 77/313 (24%) in this study.

It is challenging to choose suitable variables for a predictive score and to give them a 'correct' weight. One possible explanation for the limited predictive value of the POLARS score in the current cohort could be the selected variables included in the nomogram. Recently, research groups from China and Japan have made an attempt to develop a predictive tool for a postoperative LARS score. Different variables were used by the two studies to estimate the postoperative LARS score. Paku *et al* included only three variables: sex, age and tumour distance from the anal verge, while Yan *et al* included the following five variables: sex, preoperative chemoradiation, tumour height, defunctioning ileostomy and postoperative anastomotic leakage. Similarly, as in the POLARS score, all variables are weighted differently in the calculations. These different strategies illustrate the difficulties in selecting the 'right' variables for a predictive nomogram of postoperative LARS.[9 24 25]

Another variable that is not included in any of the mentioned predictive tools is the patient's baseline bowel function that is, before surgery and before experiencing symptoms of the rectal cancer tumour itself. Naturally, the precancer bowel function could impact the postoperative bowel function and a previous study showed that 15%–25% of the healthy population experienced major LARS symptoms.[26 27] In addition, LARS score affects patients' QoL related to bowel dysfunction irrespective of how high the LARS score is and varies individually.[11] Moreover, the QoL and bowel dysfunction may be affected by other underlying causes such as obstructed defecation syndrome. Preoperative bowel function may affect the patients' expectations and has been shown to be a contributing factor in determining the degree of experienced LARS.[28 29] However, characterising the baseline bowel function can be a challenge as the tumour can conceal the original function at the time of cancer diagnosis. Hence, there would be a risk of recall bias. Despite this, we believe that including features of baseline bowel function in a future predictive tool may improve the accuracy.

The primary strength of the present study is the large patient population with 477 patients included with an 83% response rate to the LARS questionnaire. The study had excellent follow-up data on recurrences, presence of stoma and dementia. To our knowledge, no population-based cohort study has assessed the POLARS score to this extent. A further strength is that the POLARS score was calculated with the corrected POLARS model formula. These values showed greater accordance with the actual PR-LARS scores compared with the calculations based on the POLARS nomogram.

A limitation of the study is that the POLARS study truncated the nomogram at 80 years of age to increase generalisability.[9] In this study, the 22 patients over 80 years of age were not excluded, as they represented only 6% of the cohort. These patients received 0 points for age in the POLARS score. A further limitation of the study owes to the retrospective study design of the current study. The LARS questionnaire itself, which was used for the assessment of LARS can also be seen as a limiting factor since it is a subjective symptom analysis. Currently there are new recommendations and ongoing work to design a new scoring tool to assess bowel dysfunction.[30]

In conclusion, LARS scores calculated with the POLARS score in a population-based Swedish cohort revealed a low positive predictive value of 68% for major LARS. The POLARS score is questionable in predicting major LARS after rectal cancer surgery in Sweden. Other methods to predict the risk of LARS need to be developed.

Contributors BR: study concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript for important intellectual content. CN, EP, GJ-P, PL: study concept and design; analysis and interpretation of data; critical revision of the manuscript for important intellectual content. AJ: study concept and design; analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; statistical analysis. MA-N: study concept and design; acquisition of data, analysis and interpretation of data; drafting of the manuscript, critical revision of the manuscript for important intellectual content; study supervision, guarantor.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the local ethical committee of the Karolinska Institutet (2016/1604-31/2 and 2017/605-32). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Not applicable.

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