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Original Article

Validation of Portuguese version of the low anterior resection syndrome score

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ABSTRACT

Objective: The authors aim to perform a thorough translation with cultural adaptation of the patient reported outcome tool, Low Anterior Resection Syndrome (LARS) Score, to the Portuguese language (LARS-PT) in the Portuguese population with rectal cancer, after proctectomy with anastomosis.

Methods: According to the current international recommendations, we designed this study encompassing three main phases: (i) cultural and linguistic validation to European Portuguese; (ii) feasibility and reliability tests of the version obtained in the previous phase; and (iii) validity tests to produce a final version. The questionnaire was completed by 154 patients from six Portuguese Colorectal Cancer Units, and 58 completed it twice.

Results: Portuguese version of LARS score showed high construct validity. Regarding the test-retest, the global Intraclass Correlation showed very strong test-retest reliability. Looking at all five items, only items 3 and 5 present a moderate correlation. LARS score was able to discriminate symptoms showing worse quality of life, in patients submitted to preoperative radio and chemotherapy.

Conclusions: LARS questionnaire has been properly translated into European Portuguese, demonstrating high construct validity and reliability. This is a precise, reproducible, simple, clear and user-friendly tool for evaluating bowel function in rectal cancer patients after sphincter saving operation.

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Validação da versão em português do escore da síndrome da ressecção anterior baixa

Palavras-chave:
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Disfunção intestinal
Escore da síndrome da ressecção anterior baixa
Qualidade de vida
Validação

RESUMO

Objetivo: Os autores pretendem fazer uma tradução minuciosa e culturalmente adaptada para a língua portuguesa do escore da Síndrome de Ressecção Anterior Baixa (*Low Anterior Resection Syndrome* [LARS]), um instrumento de desfecho relatado pelo paciente, na população portuguesa com câncer retal após proctectomia com anastomose.

Métodos: De acordo com as recomendações internacionais atuais, o estudo foi projetado abrangendo três fases principais: (i) validação cultural e linguística para o português europeu; (ii) testes de viabilidade e confiabilidade da versão obtida na fase anterior; e (iii) testes de validade para produzir a versão final. O questionário foi preenchido por 154 pacientes de seis unidades portuguesas de câncer colorretal e 58 pacientes completaram duas vezes.

Resultados: A versão em português do escore LARS mostrou alta validade de construto. A correlação intra-classe global apresentou confiabilidade muito forte no teste-reteste. Considerando-se todos os cinco itens, apenas os itens 3 e 5 apresentam uma correlação moderada. O escore LARS foi capaz de discriminar sintomas com pior qualidade de vida em pacientes submetidos a radio- e quimioterapia pré-operatória.

Conclusões: O questionário LARS foi traduzido corretamente para o português europeu, demonstrando alta validade de construto e confiabilidade. Trata-se de uma ferramenta precisa, reproduzível, simples, clara e fácil de usar para avaliar a função intestinal em pacientes com câncer retal após operações poupando o esfíncter.

Introduction

Colorectal cancer is the third most frequent diagnosed malignancy followed by prostate in males, breast in females, and by lung cancer in both genders.[1,2] On this matter, one out of three are located in the rectum, one-third on its distal part, and approximately half of patients die from their cancer.[3,4] The incidence and mortality rates vary according to distinct gradients of human development levels, presenting a stabilizing or decreasing trend in highly developed countries, where rates remain amongst the highest in the world.[1]

During the last decades, several improvements in Rectal Cancer (RC) treatment were achieved, but surgery remains the favoured form of treatment. These developments have resulted in markedly increased survival.[5] A tailored treatment was possible since the introduction of routine accurate high-resolution preoperative RC imaging and the standardized proctectomy with Total Mesorectal Excision (TME).[6]

Nowadays, not only oncological outcomes are relevant for colorectal surgeons, but also long-term functional outcomes and Quality of Life (QoL). Knowledge about functional gastrointestinal and genitourinary patient-reported outcomes are crucial in order to select the optimal treatment and to manage functional sequela.[7,8] Despite the rectal reconstruction technique and the use of neoadjuvant therapy, 60% to 90% of patients undergoing proctectomy develop some sort of bowel dysfunction.[9,10]

The syndrome of defecatory dysfunction that occurs after proctectomy, also called "Low Anterior Resection Syndrome (LARS)", is a constellation of symptoms, with variable incidence and degrees, which includes increased bowel frequency, urgency, fragmentation, faecal incontinence, nocturnal defecation, difficulty in discriminating between gas and stools, and incomplete evacuation.[8,11–13]

Several measurement instruments have been used to evaluate bowel dysfunction after anterior resection, but mostly are focused on the incontinence aspect of LARS.[14–18] One of the drawbacks of these tools was the fact that they are based on a linear scale, and the impact on QoL might not be so foreseeable and linear. Additionally these scores only look into one facet of LARS, not considering it as a complex dysfunction.

Recently, Emmertsen and Laurberg developed and validated a symptom-based scoring system, named LARS score that takes into account four aspects of bowel function.[19] This quick, simple and user-friendly self-administered questionnaire objectively measures patient symptoms, and provides information for the LARS management. It consists of five simple questions regarding incontinence for flatus or liquid stool, urgency, clustering and frequency. Scored according to the impact of each of these symptoms in patients' QoL, they are weighted and presented in a summative score ranging from 0 to 42. Patients are ranked into three severity groups: no LARS (0–20 points), minor LARS (21–29 points) and major LARS (30–42 points). Until now, this score has been translated and validated in several languages, worldwide.[11,13,20,21]

The aim of our study was to perform a thorough translation with cultural adaptation of this patient-reported outcome tool (LARS score) to the European Portuguese language (LARS-PT). We assessed its psychometric properties in a Portuguese

sample, in order to build up and validate a suitable tool for daily clinical practice and research in Portugal.

Methods

This study encompassed three main phases: (i) cultural and linguistic validation to European Portuguese; (ii) feasibility and reliability tests of the version obtained in the previous phase; and (iii) validity tests to produce a final version.

After obtaining a written permission from the original author, we followed the forward/backward translation process.[22] The English version of the LARS score was then initially translated into Portuguese by two independent professional translators whose mother tongue was Portuguese. Our group discussed any conceptual discrepancies between the two versions, and we reached a final consensus, the preliminary Portuguese version. A third independent English translator, unfamiliar with the background objectives of the study, then performed a back-translation of this version.

After comparing the original and the backward versions, the investigators revised, checked and agreed upon the Portuguese version. For the face validation process, two clinicians revised this new version and some changes were made accordingly. In addition, a cognitive debriefing sample of ten patients with low literacy level were selected from two participating centres, in order to assess its feasibility, comprehensiveness, length, adequacy, redundancy and text clarity. The final version of LARS-PT was linguistically reviewed to correct possible grammatical errors.

The participants involved were recruited from six Portuguese hospitals, with colorectal cancer units (CRCU), between November 2016 and June 2017. Our study comprised voluntary patients operated for RC, over 18 years old that had undergone either a curative total or Partial Mesorectal Excision (PME), from January 1, 2005 to April 30, 2015. We established a minimum duration of fourteen months after surgery to allow their bowel function to have regained stability. Patients were excluded if they had stoma, disseminated or recurrent disease, any type of bowel dysfunction not related to RC treatment (inflammatory bowel disease, irritable bowel syndrome, amongst others), or mental health problems.

Eligible participants were identified through local medical records of RC patients by the local investigators at each of the participating centres and the patients to be approached were selected randomly from the pool of eligible subjects. The six local clinical researchers collected demographic and clinical information from local databases. Patients received the LARS-PT questionnaire along with an invitation to participate in the study. In addition, we also administered the Portuguese versions of the two quality of life measures EORTC QLQ-C30 and EQ-5D-5L, and a separate "bothersome" question also aiming to assess their QoL ("Overall, how much does your bowel function affect your quality of life?"). The answers from the "bothersome" question were classified according to the inconvenience, where 1 is none and 5–7 is extremely inconvenient.

In most of CRCU, patients who had a T3 tumour with a threatened circumferential margin or T4 tumour (any N) were submitted to neoadjuvant long-course chemoradiotherapy. Moreover, in some CRCU, patients with T3 (any N) cancer or T1 or T2 cancer with node positive underwent short-course radiotherapy (5 × 5 Gy) before surgery. The operative procedure included midline laparotomy or minimally invasive approach, high ligation of the inferior mesenteric vessels, mobilization of the splenic flexure, and colorectal resection with standard TME or PME (depending on the tumour location). All the patients included in the study had negative distal and circumferential margins on histological examination.

In our study, we tested the temporal stability by a randomized subgroup of patients and asked them to fill the LARS-PT questionnaire, between one to two weeks after the completion of the first round. The interviews were face-to-face or by phone, depending upon the local facilities and the resources available. We excluded any retest if the time gap between the completions of both tests was outside the predefined acceptable interval of one to twelve weeks. Furthermore, we did not consider for test-retest analysis, patients who had mentioned a relevant change in bowel function in the revaluation period. Intraclass Correlation Coefficient (ICC) was used and was considered significant if higher than 0.7.[23]

It includes the analysis of the content validity, the construct validity and the criteria validity. The cultural and linguistic adaptation process guarantees the content validity. The construct validity tests whether the theoretical framework of the measurement instrument is confirmed by the Portuguese version. This includes hypotheses regarding known sociodemographic and clinical variables, as well as the correlations with a measurement instrument that measures similar concepts. The criterion validity represents the degree of agreement between the measurement instrument and another reference measure. In this study, we used the previously referred bothersome question.

In this study, all statistical analyses were performed using SPSS v22, considering a significance level of 0.05.

Demographic and clinical variables were analyzed by using descriptive statistics. For comparative analyses, we used nonparametric tests, namely, Mann–Whitney *U* and Kruskal–Wallis *H* tests.

To evaluate the criterion validity, Chi-squared test was used to test the independence between these variables and the LARS classified score.

Results

Both translations of LARS demonstrated minor discrepancies easily solved, and discussion of the back translation corroborated the original meaning of the five questions. Cognitive debriefing involved six males and four females, seven aged 65 or more, and all of them with medium to low education. None of the ten patients revealed difficulties in understanding the items. This guaranteed the content validity of this measure. The final Portuguese version can be found in https://www.escp.eu.com/images/news_and_reports/2018/lars-scoring-tool/Portuguese-Portugal-LARS-Questionnaire.pdf.

From November 2016 to June 2017, 154 patients answered the questionnaire LARS-PT. Demographic and clinical information obtained by the six local clinical researchers is presented in Table 1.

Table 1 – Sociodemographic and clinical sample characteristics.

Variable		*n*	%
Participants		154	100.0
Gender	Male	89	57.9
	Female	65	42.1
Age (years)	<65 years	60	39.0
	65–74 years	46	29.9
	>75 years	48	31.2
	Mean ± SD	68.1 ± 10.9	
	Min–max	36–89	
Family status	Married	126	82.9
	Single	5	3.3
	Widow	13	8.6
	Divorced/separated	8	5.3
Labour status	Active	38	25.7
	Non-active	110	74.3
Education	Less than basic	14	9.2
	Basic (years 1–9)	100	65.8
	Secondary (years 10–12)	18	11.8
	Higher	20	13.2
Stage, TNM	I	38	28.8%
	II	24	18.2%
	III	70	53.0%
Tumour localization	Upper third	45	31.0%
	Middle third	76	52.4%
	Lower third	24	16.6%
Type of anastomosis	Mechanic	136	94.4%
	Manual	8	5.6%
Neoadjuvant radiotherapy	Yes	71	49.0%
	No	74	51.0%
Length of the postoperative period	<3 years	63	44.1%
	≥3 years	80	55.9%
	Mean ± SD	10.3 ± 3.7	
	Min–max	0.0–10.3	
Type of surgery	TME	97	71.3%
	PME	39	28.7%
LARS score	No LARS	52	34.2%
	Minor LARS	37	24.3%
	Major LARS	63	41.4%
	Mean ± SD	23.9 ± 12.4	
	Min–max	0–42	

From Table 1, is evident that our sample had a slight majority (57.9%) of male patents, only 39.0% of the patients had less than 65 years of age, the majority were married (82.9%), professionally non-active (74.3%), and with less than ten years of education (75.0%).

Their tumour was mainly in Stage III (53.1%) and located in the middle third (52.4%), half underwent neo-adjuvant therapy (51.0%) and the mean length of the postoperative period was about 10 years. The type of mesorectal excision was mainly (71.3%) TME.

LARS scores ranged between 0 and 42 with a mean value of 23.9 ± 12.4, a little bit more than one-third (34.2%) with no LARS, 24.3% with minor LARS and 41.8% with major LARS.

Moreover, Table 2 presents the description of the quality of life indicators of our sample.

From Table 2 we notice that, in general, the patients of this study felt a very good quality of life. This is evident from the EORTC-QLQ-C30 functional scales with mean scores between 83.7 and 86.7, from the quality of life questions with a mean of 73.3, and from both index and VAS scale with mean values, respectively, 0.90 and 74.5. Corroborating with these results, and looking at the intensity of the symptoms, we evidence only a light disturbance from sleep, fatigue, pain, diarrhoea and constipation.

Regarding the test-retest, 58 patients repeated the LARS questionnaire, up to three weeks after the completion of the first questionnaire. Table 3 shows the reliability scores.

The global ICC shows very strong test-retest reliability. Looking at all five items, only items 3 and 5 present a moderate correlation.

Validity

To test the construct validity of LARS we looked at the sociodemographic and clinical variables. The results of the tests are presented in Table 4.

Looking at the results from Table 4, we can notice that the sociodemographic variables (gender, age, family status, and labour status) do not have any influence on the LARS final score. In addition, the length of the postoperative period seems to not have any influence on LARS sores. On the contrary, having neo-adjuvant radiotherapy increases LARS scores.

Still addressing construct validity, we looked at the correlations between LARS scores and the various dimensions of EORTC QLQ-C30 as well as EQ-5D-5L index and the EQ-5D-VAS. The results of the corresponding correlation coefficients are presented in Table 5.

From Table 5, as expected, we can see that the major correlation resides on the dimension 'social function' of the EORTC QLQ-C30's functional scales and, mainly on the symptoms pain, and diarrhoea. Financial impact also showed to have a very significant correlation on LARS scores. On the other hand, quality of life showed a very small correlation and EQ-5D-5L was unable to find any significant correlation with the LARS score.

Finally, the independence test between "bothersome" question and the classified LARS scores revealed a Chi-squared statistics of $X^2 = 16.8$ ($\alpha = 0.002$) showing that LARS classification is coherent with how much bowel function affects quality of life. That is, individuals who reported no bother at all, also had a LARS score less than or equal to 20, meaning no LARS. On the other hand, individuals with major LARS were the ones that mentioned their QoL being largely affected by bowel function.

Discussion

Historically, the most relevant outcomes in RC management were mortality and local recurrence, but currently, the evaluation of functional results and QoL of the patients submitted to LAR is a matter of great importance.

Dysfunctions after proctectomy, mainly in LAR, occur in a great number of patients, and affect not only the bowel

Table 2 – Quality of life scores.

QoL measure	Dimension	Min	Max	Mean	SD
EORTC-QLQ-C30	Physical function	0.0	100.0	83.7	19.6
Functional scales	Role physical	0.0	100.0	85.9	24.9
	Emotional function	25.0	100.0	85.9	16.9
	Cognitive function	16.7	100.0	86.1	17.0
	Social function	0.0	100.0	86.7	22.0
EORTC-QLQ-C30	Fatigue	0.0	88.9	18.0	21.1
Symptom scales	Nausea and vomiting	0.0	50.0	1.2	6.9
	Pain	0.0	100.0	14.9	22.1
	Dyspnoea	0.0	66.7	1.5	8.0
	Sleep disturbance	0.0	100.0	18.5	25.6
	Appetite loss	0.0	66.7	5.0	14.7
	Constipation	0.0	100.0	11.1	20.2
	Diarrhoea	0.0	100.0	12.4	20.9
	Financial impact	0.0	100.0	9.8	19.8
	Quality of life	16.7	100.0	73.3	19.0
EQ-5D-5L	Index	16	1.00	0.90	0.16
	VAS	10	100.0	74.5	0.19

Table 3 – Reliability scores.

Items	ICC	95% CI
Item 1	0.763	0.600–0.860
Item 2	0.863	0.769–0.919
Item 3	0.652	0.413–0.794
Item 4	0.761	0.596–0.859
Item 5	0.669	0.441–0.804
LARS total score	0.864	0.771–0.920

ICC, Intraclass Correlation; CI, Confidence Interval.

function but also the genitourinary function, in high figures, up to 70 or even 90%, when we look to bowel dysfunction. These symptoms often arise immediately after surgery and may decrease over the months, reaching a plateau within the first two years.[24] In fact, up to 80% of patients undergoing a LAR or a very LAR will experience postoperatively a constellation of symptoms collectively referred as LARS.[5,25] Although most of the functional impairments are clinically recovered in the first year after the proctectomy, long-term studies are now reporting the presence of adverse symptoms up to 15 years after resection.[20,26]

LARS score, despite being considered user-friendly, had not been tested in the Portuguese population, yet. Our group followed a rigorous protocol in accordance with current international recommendations, similar to that used in the international validation of the LARS score by Juul et al., to

Table 4 – Sociodemographic and clinical determinants of LARS scores.

Hypothesis	Variable	Value	Mean rank	Statistics	Sig.
H1	Gender	Male	73.7	$U = 2568$	0.354
		Female	80.4		
H2	Age (years)	<65 years	84.3	$H = 3.359$	0.186
		65–74 years	78.1		
		>75 years	68.5		
H3	Family status	Married	76.8	$U = 1599$	0.849
		Non-married	75.0		
H4	Labour status	Active	74.5	$U = 2088$	0.993
		Non-active	74.5		
H5	Neoadjuvant radiotherapy	Yes	81.5	$U = 2022$	0.017
		No	64.8		
H6	Anastomosis	Mechanic	69.8	$U = 184$	0.002
		Manual	117.5		
H7	Length of the postoperative period	≤2 years	69.2	$U = 1406$	0.622
		>2 years	73.8		
H8	Type of surgery	TME	70.3	$U = 1718$	0.405
		PME	64.1		

U, Wilcoxon *W*; *H*, Kruskal–Wallis *H*; Sig, asymptotic Sig (2 tailed).

Table 5 – Criterion validity of LARS.

QoL measure	Dimension	LARS scores	*p*-value
EORTC-QLQ-C30	Physical function	−0.116	0.153
Functional scales	Role physical	−0.125	0.123
	Emotional function	−0.131	0.105
	Cognitive function	−0.122	0.134
	Social function	−0.163	0.044
EORTC-QLQ-C30	Fatigue	0.130	0.110
Symptom scales	Nausea and vomiting	0.062	0.448
	Pain	0.206	0.011
	Dyspnoea	0.015	0.856
	Sleep disturbance	0.086	0.289
	Appetite loss	−0.054	0.507
	Constipation	0.073	0.367
	Diarrhoea	0.353	0.000
	Financial impact	0.189	0.020
	Quality of life	−0.150	0.064
EQ-5D-5L	Index	−0.116	0.153
	VAS	−0.089	0.274

ensure semantic equivalence among different languages and to enable the use in different populations worldwide.[20,21,27] We developed this research in six CRUC with patients coming from five public health system institutions and one private hospital. With this method, we guarantee an adequate, balanced national representativeness, including patients with low educational and income levels. None of them exhibited difficulty to understand the items of the questionnaire during the cultural adaptation, proving the practical feasibility of this tool. Overall, we found a good compliance across all items, which demonstrate the user-friendliness of the LARS score.

In our study, LARS score was easily validated for the Portuguese population of patients with RC, and has shown concluding psychometric properties. Considering the construct validity, we have proved a strong association between the LARS-PT score and the self-reported QoL. Patients with poor QoL, due to impaired bowel function, demonstrated higher numerical values on LARS-PT questionnaire. Moreover, LARS-PT score presented a convergent agreement with overall health and with all EORTC QLQ-C30 functional scales, showing that patients with worse LARS classification have lower QoL reported by EORTC QLQ-C30.

The current study provided some evidence for the good discriminate validity of the measures. That is clearly highly important, since the utility of the LARS-PT score would be hampered without the ability to discriminate between patients with different clinical characteristics, known to diverge in terms of LARS symptoms. In this topic, the Portuguese version of LARS score was able to identify groups with worse intestinal functional outcomes after LAR. Known variables such as gender, age, level of the tumour, preoperative therapy, type of procedure (TME vs. PME), temporary diverting stoma and postoperative period length could impair gastrointestinal function after sphincter saving surgery in RC population.[5,24,28] LARS-PT score showed ability to detect differences between patients submitted or not to neo-adjuvant treatment. In our study, we did not prove that LARS symptoms improve with time. By contrast, there were no statistically significant differences related with gender, age, family status or labour status.

Also criterion validity tested with the bothersome question showed that LARS classification is coherent with how much bowel function affects quality of life ($X^2 = 16.8$; $p = 0.002$).

The evaluation of test-retest reliability of LARS-PT score was done from a sample of 58 patients, with the interval between the two surveys ranging from 10 to 21 days. This interval was deemed appropriate, as it avoids not only the first survey effect but also the changes in bowel function, even though participants who reported a significant change in bowel function between the tests were excluded. After repeating the evaluation, no differences were registered in LARS-PT questions and score. The global ICC estimated (ICC = 0.864) demonstrates a very strong test-retest reliability, and when we look at all five items, only items 3 and 5 present a moderate correlation (ICC of 0.652 and 0.669, respectively).

Limitations of this study were the small sample size and its retrospective observational nature, mainly the fact that the anorectal function was not assessed before surgery. The preoperative use of LARS score and the regular surveillance in the early and late postoperative period may contribute to clarifying some aspects of LARS pathophysiology. Some preoperative factors, like neo-adjuvant therapies, gender, age or tumour location, may affect postoperative function, so it is crucial to guide an appropriate preoperative discussion outlining risk and options. The question is: "Can we predict bowel function before proctectomy?" Recently, Battersby et al. developed the POLARS score, and with this instrument, patients with RC can be preoperatively informed of their likely postoperative bowel function, based on the LARS scores evaluation.[29] Additionally it can be used as an adjunct for clinical assessment prior to the multidisciplinary team discussion, helping to guide treatment decisions.

This study has the advantage of having compared the LARS score with a validated general and symptoms-based QoL instruments such as EQ-5D-5L and EORTC QLQ-C30. As we abovementioned, the majority of instruments used to assess bowel function after LAR, measure only faecal incontinence, omitting other symptoms at least so relevant, and with high correlation with QoL, such as urgency or clustering. These symptoms are most closely correlated with QoL, in a patient-centred perspective. Validation of this tool enables the dissemination of the measurement of bowel function after LAR, employing a quick and comprehensive clinically applicable instrument. Therefore, it will help clinicians to understand the impact of LARS symptoms in QOL, from the patient viewpoint.[10,26,29]

In conclusion, LARS questionnaire has been properly translated into Portuguese, demonstrating high construct validity and reliability. Our LARS version is a precise, reproducible, simple, clear and user-friendly tool for evaluating bowel function in RC patients after sphincter saving operation. Thereby should be systematically applied for both clinical and research settings.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the Portuguese ethical standards: Authorization was obtained from the Portuguese Data Protection Authority (CNPD) and Local Ethical Committee approval. Informed consent was obtained from all patients included in the study.

Conflicts of interest

The authors declare no conflicts of interest.

Appendix A. Portuguese LARS collaborative group

Portuguese LARS Collaborative Group includes:

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