CONSENSUS STATEMENT

International Consensus Definition of Low Anterior Resection Syndrome

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BACKGROUND: Low anterior resection syndrome is pragmatically defined as disordered bowel function after rectal resection leading to a detriment in quality of life. This broad characterization does not allow for precise estimates of prevalence. The low anterior resection syndrome score was designed as a simple tool for clinical evaluation of low anterior resection syndrome. Although the low anterior resection syndrome score has good clinical utility, it may not capture all important aspects that patients may experience.

OBJECTIVE: The aim of this collaboration was to develop an international consensus definition of low anterior resection syndrome that encompasses all aspects of the condition and is informed by all stakeholders.

DESIGN: This international patient-provider initiative used an online Delphi survey, regional patient consultation meetings, and an international consensus meeting.

PARTICIPANTS: Three expert groups participated: patients, surgeons, and other health professionals from

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5 regions (Australasia, Denmark, Spain, Great Britain and Ireland, and North America) and in 3 languages (English, Spanish, and Danish).

MAIN OUTCOME MEASURE: The primary outcome measured was the priorities for the definition of low anterior resection syndrome.

RESULTS: Three hundred twenty-five participants (156 patients) registered. The response rates for successive rounds of the Delphi survey were 86%, 96%, and 99%. Eighteen priorities emerged from the Delphi survey. Patient consultation and consensus meetings refined these priorities to 8 symptoms and 8 consequences that capture essential aspects of the syndrome.

LIMITATIONS: Sampling bias may have been present, in particular, in the patient panel because social media was used extensively in recruitment. There was also dominance of the surgical panel at the final consensus meeting despite attempts to mitigate this.

CONCLUSIONS: This is the first definition of low anterior resection syndrome developed with direct input from a large international patient panel. The involvement of patients in all phases has ensured that the definition presented encompasses the vital aspects of the patient experience of low anterior resection syndrome. The novel separation of symptoms and consequences may enable greater sensitivity to detect changes in low anterior resection syndrome over time and with intervention.

KEY WORDS: Consensus definition; Low anterior resection syndrome; Patient reported; Rectal resection.

Internationally, colorectal cancer is the third most common cancer with 1.8 million cases reported in 2018.[1] The introduction of stapling devices and other techniques has facilitated a rise in sphincter-saving surgery for rectal cancer.[2] Total mesorectal excision and radiotherapy have dramatically improved oncological outcomes.[3,4] Improved survival has heightened awareness of survivorship issues, including bowel dysfunction.[5] Consequently, clinicians and researchers have been urged to look beyond survival and recurrence as the sole measures of treatment success.[6] Core outcomes sets that specify a minimum set of outcomes to be measured have been proposed to reduce the heterogeneity of outcome reporting and reporting bias in clinical trials.[7] The proposed core outcomes set for colorectal cancer surgery includes quality of life and functional outcomes, highlighting the importance of these outcomes.[7]

The term low anterior resection syndrome (LARS) describes "disordered bowel function after rectal resection, leading to a detriment in quality of life."[8] Although pragmatic, this definition can incorporate a vast array of symptoms from fecal incontinence and urgency, to evacuation difficulties. Consequent heterogeneity in reporting makes it impossible to accurately identify the prevalence of LARS.[9–11] Development of a validated patient-reported outcome measure, the LARS score, has improved the standardization of reporting.[12] Prevalence of LARS using this tool is reported to be 41% (95% CI, 34%–48%).[13] The LARS score has good psychometric properties and has been validated in multiple languages.[14–17] However, the LARS score may significantly underestimate the impact of evacuatory dysfunction and may not accurately assess the impact of symptoms on an individual patient's quality of life.[18]

Like most patient-reported outcome measures, the LARS score was initially produced by expert clinician researchers who then consulted patient populations.[12] Active involvement of all major stakeholders, especially patients, early in the construction of any outcome measure is necessary to ensure that the resulting tool is fit for purpose, as outlined by the COMET[19] and COSMIN[20] guidelines. The aim of this study is to use an international patient-provider initiative with robust methodology to produce a consensus definition of LARS. This is the first phase of a wider project to construct a tool to accurately identify survivors who have LARS, assess severity, and enable evaluation of treatment approaches.

MATERIALS AND METHODS

Scientific Committee

A Scientific Committee of patients and clinicians was convened to oversee the study. Clinician representatives were also lead investigators for each region involved in the study: Australasia, Denmark, North America, Spain, Great Britain and Ireland. Two patient representatives formed part of the Scientific Committee and contributed directly to conception, methodology, recruitment, interpretation, and presentation of results. Ethical approval for this study was granted by the University of Auckland Human Participants Ethics Committee (Ref 019179).

Participants

Three groups of experts were enrolled in this study: patients (panel A), surgeons (panel B), and other health care professionals (panel C). There is no agreed method of determining required sample size for a consensus method Delphi survey,[21] so a minimum recruitment target was set to balance the need for breadth of opinion and international involvement with resources available. Recruitment target was 120 patients (24 per region), 60 surgeons, and 60 other health care professionals (12 of each per region). Regional lead investigators were responsible for recruitment in their region. Maximum diversity sampling (nonprobabilistic purposeful sampling) was used to recruit a wide range of perspectives. The study was advertised via social media through charitable colorectal cancer organizations

and peer support groups. Patient participants could volunteer by registering online. Care was taken to enroll patient participants who did not have a clinician-patient relationship with lead investigators. All participants completed an enrollment registration form to obtain demographic details and, for patients, eligibility criteria and treatment information. Participants who completed a registration form were deemed to have given their consent to participate in the study; an additional consent form was not required.

Panel A

Patients were eligible to participate if they had undergone an anterior resection for rectal cancer more than 12 months earlier with or without diverting ileostomy, providing any ileostomy had then been closed for at least 6 months and that adjuvant treatment had been completed. Patients who did not meet the inclusion criteria, who were receiving ongoing treatment for recurrent or metastatic disease, or who had cognitive impairment, were excluded. Poor bowel function was not a requirement for eligibility; patients with good bowel function were also encouraged to participate.

Panel B

Surgeons were recruited via lead investigators in consultation with relevant societies: Association of Coloproctology of Great Britain and Ireland (ACPGBI), Royal Society of Medicine Section of Coloproctology (RSM Coloproctology), Colorectal Surgical Society of Australia and New Zealand (CSSANZ), Colon and Rectal Surgery Section of Royal Australasian College of Surgeons (RACS), European Society of Coloproctology (ESCP), and American Society of Colon and Rectal Surgeons (ASCRS).

Panel C

Other specialists who treat or conduct research into LARS were identified by lead investigators and invited to participate. This panel included specialist nurses, biofeedback specialists, physiotherapists, gastroenterologists, oncologists with special interest in functional outcome after rectal cancer treatment, and pelvic floor specialists with an interest in managing LARS.

Longlisting of Potential Outcomes

Systematic review of literature published between 1986 and 2016 that reported functional outcomes after sphincter-preserving rectal resection was undertaken to produce a comprehensive list of bowel function outcomes that were then tested in a pilot study. The results of this review have been published[9] and were used in round 1 of the Delphi survey. Participants were invited to add novel items during round 1.

Phase 1: Online Delphi Survey

Delphi methodology aims to produce a convergence of opinion using multiple iterative rounds of a questionnaire.[22,23] The Delphi survey consisted of 3 rounds, available to participants in 3 languages: Danish, English, and Spanish. The first round was sent to all eligible registered participants; patients, health care professionals, and surgeons. Subsequent rounds were only sent to participants who completed the previous round and were accompanied by a graphical summary of how each expert group responded to each question ("item") in the previous round (See Appendix A, http://links.lww.com/DCR/B127). *Survey Monkey* platform was used to manage surveys. Patient representatives sent newsletters to maintain participant engagement and highlight focus on patient perspective.

In each survey, participants were asked to rank each item on a 1 to 9 point Likert scale from *Not Important* (1) to *Essential* (9) for the definition of LARS, with an additional response option *Unable to comment* (0) (see Appendix A for the format of a question, http://links.lww.com/DCR/B127). Likert rankings of 7 to 9 in any round were considered to indicate high-priority items, ratings of 4 to 6 indicated moderate-priority items that were important but not critical for the definition, and rankings of 1to 3 were low priority. The Scientific Committee applied a priori decision rules to determine which items progressed to the next round (see Appendix B, http://links.lww.com/DCR/B128). During the first round, participants were invited to provide additional items important for the definition of LARS. Thematic analysis of all additional items was undertaken and these items were included in round 2 (see Appendix C for questions included in each round, http://links.lww.com/DCR/B129). Round 3 incorporated items that met consensus criteria for "high priority" in round 1 or round 2 and items that had not met consensus in round 2.

Phase 2: Patient Consultation Meetings

Each region convened a patient consultation meeting to elicit detailed information on patient views by using the nominal group technique.[24] A uniform template of phase 1 results was prepared, and the discussion was centered around items that had not met consensus in the Delphi survey. The meetings allowed discussion of items that may have been misrepresented or divided votes due to overlap. Face-to-face meetings were held in London, Barcelona, and Aarhus. Because of geographical constraints, 2-hour teleconference meetings were held for Australasian and North American patient expert panels using the *Zoom* web-based conferencing platform. Online meetings were recorded and transcribed.

Phase 3: Consensus Meeting

Participants who completed all 3 Delphi survey rounds were invited to attend the international multidisciplinary consensus meeting held in Nice, France, at the 2018 Annual ESCP meeting. Feedback from all patient consultation meetings was presented before discussion to achieve final consensus. Polling was used to assess whether items

that had met "high priority" consensus during the Delphi survey were required for the definition and to determine whether related items could be amalgamated.

Data Analysis

Descriptive statistics including percentages and median (range) are presented. The χ^2 test was used for comparisons between categorical data. Correlations were assessed using the nonparametric Spearman rho (ρ) test. IBM SPSS Statistics for Macintosh Version 24.0 and GraphPad Prism v.7 for Mac OS X (GraphPad Software, La Jolla, CA) were used for the statistical analyses.

RESULTS

The study methodology and number of participants at each stage are summarized in Figure 1.

Participants

Three hundred twenty-five participants registered: 156 patients, 96 colorectal surgeons, and 73 health care professionals; 55 from Australasia, 53 from Denmark, 44 from Spain, 93 from Great Britain and Ireland, and 80 from North America. Details of participants registered for each expert panel are shown in Table 1. Participants completing each Delphi survey round were invited to participate in the next rounds, so the response rate denominator is the number of participants in the previous round. Overall response rates were 86% (278/325) for round 1, 96% (268/278) for round 2, and 99% (265/268) for round 3. Response rates for each region and expert panel are shown in Figure 2.

Delphi Survey

Round 1 contained 37 items. The patient panel produced the most discriminatory rankings, but overall group and patient panel rankings were similar. Eight items were ranked "high priority" (scores of 7–9 out of 9) by the majority (67%) of all 3 panels and a further 5 items were ranked "high priority" by the majority (67%) of the patient participants, so these items progressed directly to round 3. *Incontinence (of any kind): unintended passage of solid, liquid or gaseous fecal material* was removed because it was redundant (the responses to this were highly correlated with the responses to the questions regarding solid stool incontinence ($\rho = 0.84$) and liquid fecal incontinence ($\rho = 0.88$)). Two items that met the criterion for high priority were amalgamated to reduce splitting of the vote between related items ($\rho = 0.59$): *Stool frequency: number of bowel movements per 24 hours* and *Stool frequency > 4 per 24 hours*. No items in round 1 met the consensus criterion for "low priority"; therefore, all other items were represented in round 2 for further consideration (see Appendices C and D, http://links.lww.com/DCR/B129 and http://links.lww.com/DCR/B130).

Round 2 included 24 items that did not meet consensus in round 1 and 15 new items generated by both patients and clinicians from round 1. The patient panel again produced the most discriminatory rankings. Patient representatives on the steering group raised concerns that certain items were being ranked lower because of wording issues and split voting. The steering group recognized that patients were less likely than clinicians to discard important symptoms and so the majority criterion was lowered from 67% to 55% to ensure important items were not lost before the final round of voting. Eighteen items progressed to round 3 based on the criteria that the majority (55%) of patient panelists ranked an item as high priority and less than 33% of panelists ranked it as a low-priority item.

Round 3 included 29 items: 11 from round 1 and 18 items from round 2. Two items were reworded based on survey feedback and advice from patient representatives. *Inability to cope with bowel function* was reworded to *need to use coping strategies to manage bowel function. Effect on sexual function* was reworded to *impact on sexuality and sexual life*. A discernible cutoff point was evident above which the proportion of participants giving a high-priority ranking sharply increased, and the proportion of participants giving a low- or moderate-priority ranking sharply decreased. This cutoff point (majority of 70%) was the criterion on which all items were assessed for inclusion in round 3. Appendix E, http://links.lww.com/DCR/B131, shows expert panel and overall rankings for all items.

Eighteen items met consensus criteria: clustering/fragmentation, incomplete emptying, difficulty emptying, stool frequency, soiling, fecal incontinence, urgency, inability to defer defecation, variable/unpredictable bowel function, dissatisfaction with bowel function, preoccupation with bowel function, toilet dependence, need to use coping strategies to manage bowel function, fear and/or anxiety over bowel control, effect on quality of life, effect on overall well-being, effect on lifestyle/daily activities, and effect on social activities.

Patient Consultation Meetings

In total, 42 patients participated in 5 meetings. Carers also attended and contributed. One important concept identified as missing was *effect on mental health/psychological consequences of changes in bowel function*. There was general agreement that pain related to defecation or to the urge to defecate was important despite variable interpretations of *tenesmus*. There was agreement that *impact on sexuality and sexual life* and *effect on ability to perform usual work* are very important but needed rewording. Patients suggested expanding *effect on ability to perform usual work* to include roles within family, community,

and other organizations, not just paid employment. There was agreement that the impact of LARS on sexuality was not solely due to changes in sexual function, but related more broadly to the impact on intimacy. Change in stool consistency was considered important, but *diarrhea* was mostly inevitable and was not itself the problem, whereas *unpredictability of bowel movements* and *paste-like stool consistency* made it difficult to evacuate. There was general agreement that some items may be amalgamated because they represented similar underlying concepts.

Final Consensus Meeting

Thirty-five Delphi participants attended the facilitated consensus meeting (Fig. 3). Discussion was structured around items that had met consensus but had potential to be amalgamated and items for which there were significant

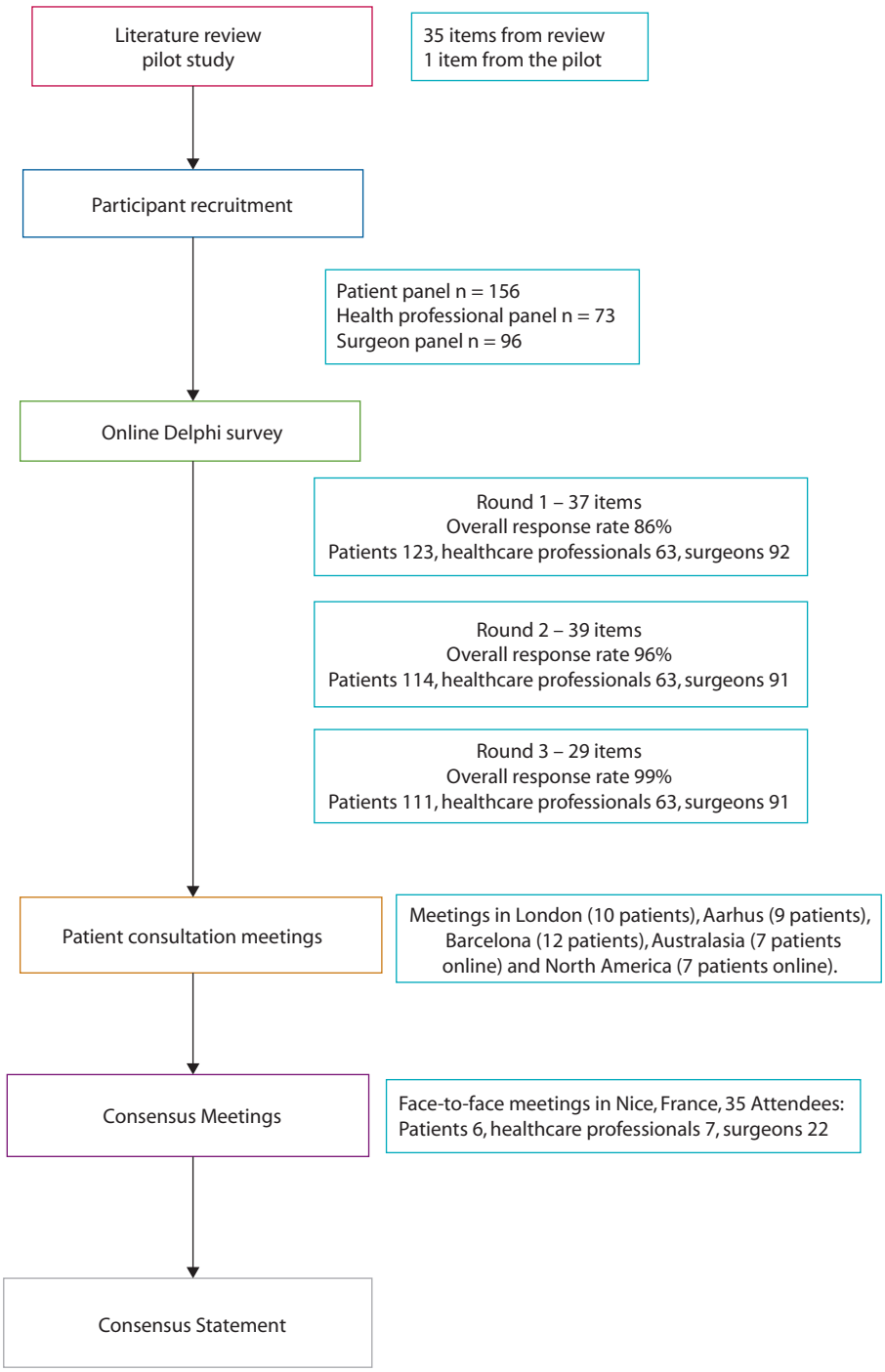

FIGURE 1. Study methodology.

TABLE 1. Participant characteristics

Characteristics	*Patient panel (n = 155)*	*Health professional panel (n = 73)*	*Surgeon panel (n = 96)*
Sex (female %/male %)	66/34	92/8	31/69
Age, %			
20–29 y	0	5	1
30–39 y	6	10	8
40–49 y	19	28	28
50–59 y	32	39	31
60–69 y	30	18	25
70–79 y	13	0	8
Years in practice, median (range)		20 (1–42)	11 (1–40)
Year since surgery, median (range)	3 (1–15)		
Treatment included radiotherapy, %	55		
Treatment included chemotherapy, %	69		
Temporary stoma, %	86		
Satisfied with bowel function, %			
Yes	21		
Sometimes	36		
No	43		

discrepancies in ranking among groups. Real-time electronic polling was used to identify whether a consensus had been reached after discussion of each item. The criterion for consensus was 70% of attendees.

Visual aids were used to ensure that patient voice was present during the meeting, including continuous PowerPoint presentation of patient participant quotes as well as posters of statements from patient participants during previous phases. The meeting opened with presentations from each regional lead investigator summarizing the patient consultation meetings. During group discussion of each item, patient representatives were invited to articulate the patient voice.

Consensus meeting discussion clarified that symptoms should be differentiated from impact or consequences of LARS. Figure 4 describes outcomes throughout each phase of the study (details in Appendix F, http://links.lww.com/DCR/B132). Eight symptom complexes and 8 consequences were agreed on as the most important priorities for definition of LARS (Fig. 5). To meet the definition of LARS, a patient must have had an anterior resection (sphincter-preserving rectal resection) and have at least 1 of these symptoms that results in at least 1 of these consequences. Increased stool frequency was compared to preoperative stool frequency. Repeated painful stools includes pain on urge, on passing a bowel movement, and/or after passing a bowel movement. Emptying difficulties include difficulty emptying the bowel for any reason, a feeling that the bowel has not completely emptied after passing a bowel movement, and need to return to the toilet multiple times to empty the bowel. Fecal incontinence is defined as the unintended passage of a large volume of fecal material. Fecal urgency is the need to rush to the toilet to defecate and/or the inability to delay passing a bowel movement. Soiling is the involuntary passage of a small amount of material onto clothing or sanitary item.

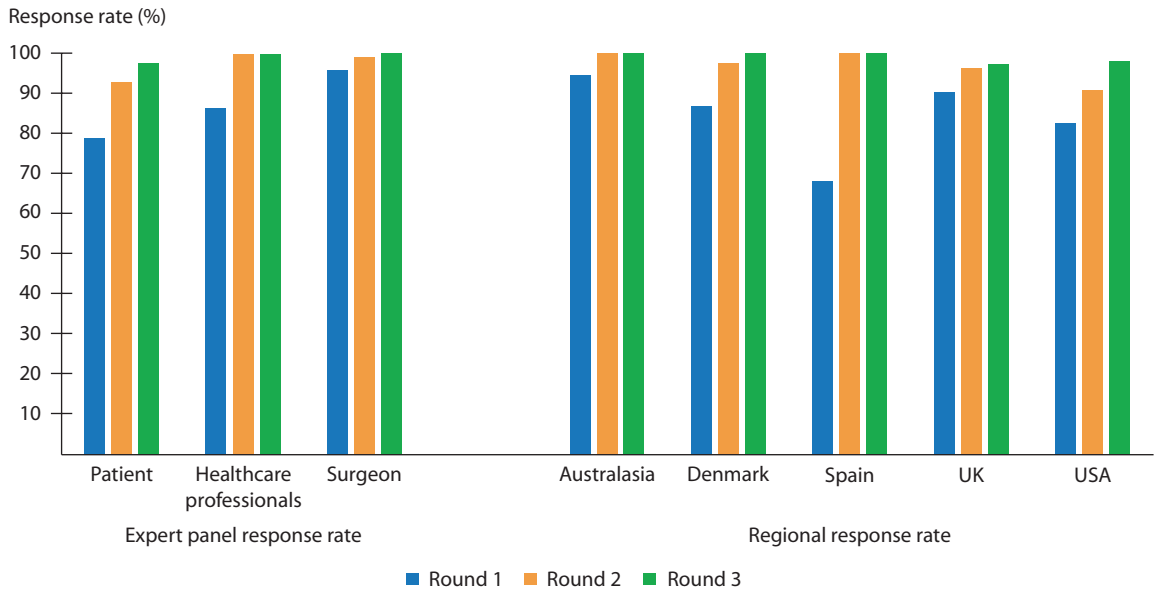

FIGURE 2. Response rate for each group. Round 1 (left, blue bar) to round 3 (right, green bar). The response rate is given as a percentage above each bar (the denominator for the response rate calculation is the number of participants who completed the previous round).

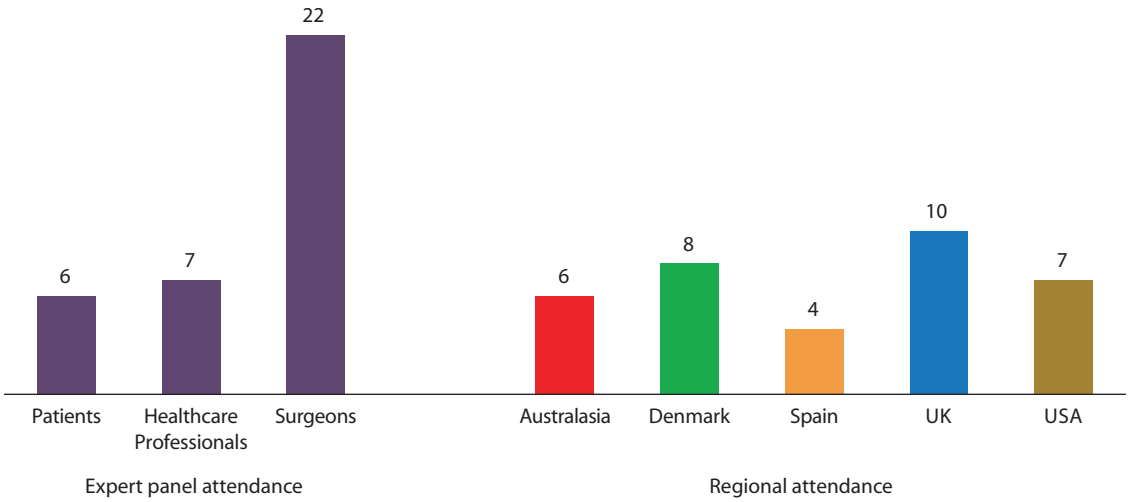

FIGURE 3. Attendance at the final consensus meeting by group and by region.

DISCUSSION

This international patient-provider initiative used robust methodology throughout 3 phases to reach a consensus definition of LARS. This is the first attempt to define LARS that from conception has incorporated multiple stakeholders and prioritized patient views. The major finding of this consensus definition is that both symptoms and consequences are important. The study has identified 8 symptom complexes and 8 consequences that are considered to be of the highest priority when defining LARS.

Low anterior resection syndrome has previously been pragmatically defined as "disordered bowel function after rectal resection, leading to a detriment in quality of life."[8] This broad definition does not allow the precise measurement of LARS. The LARS score was developed to overcome inconsistencies in reporting functional outcome and was designed to be a quick clinical evaluation tool to screen patients for LARS.[12] The LARS score has been widely

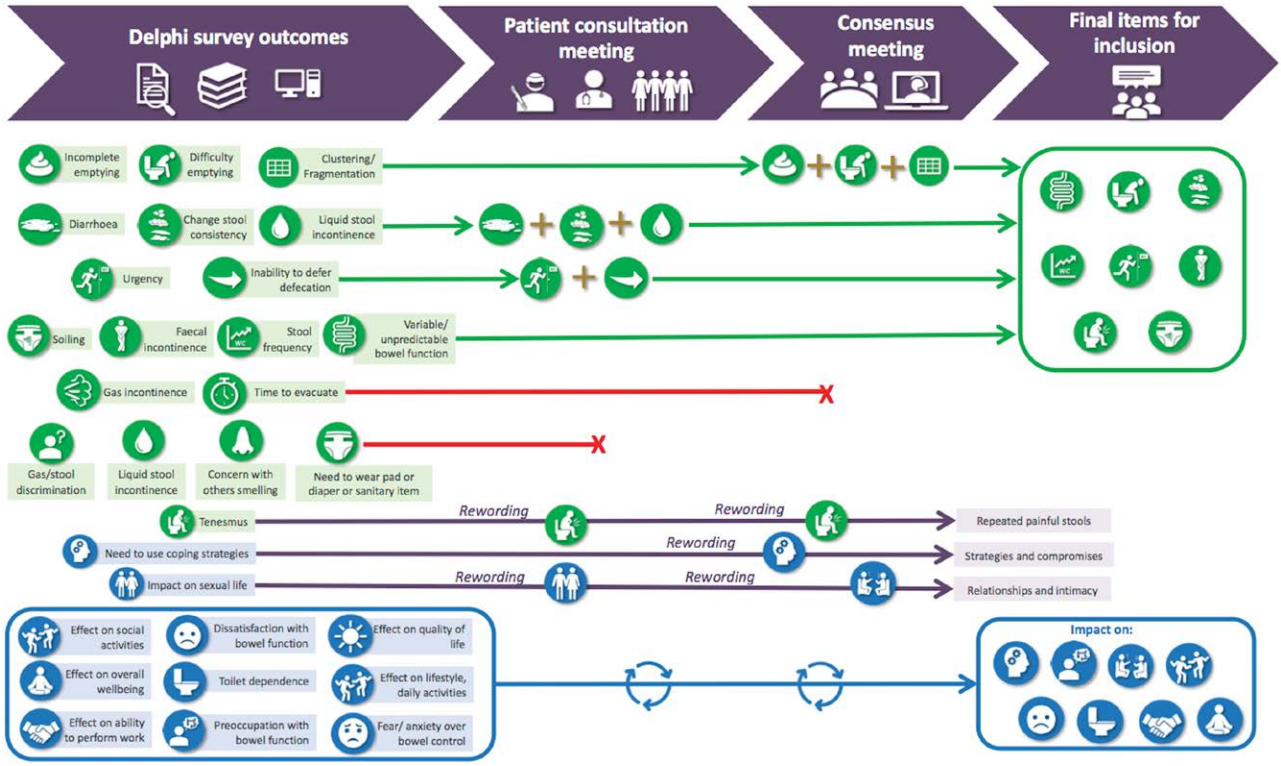

FIGURE 4. Priorities identified in each phase of the study.

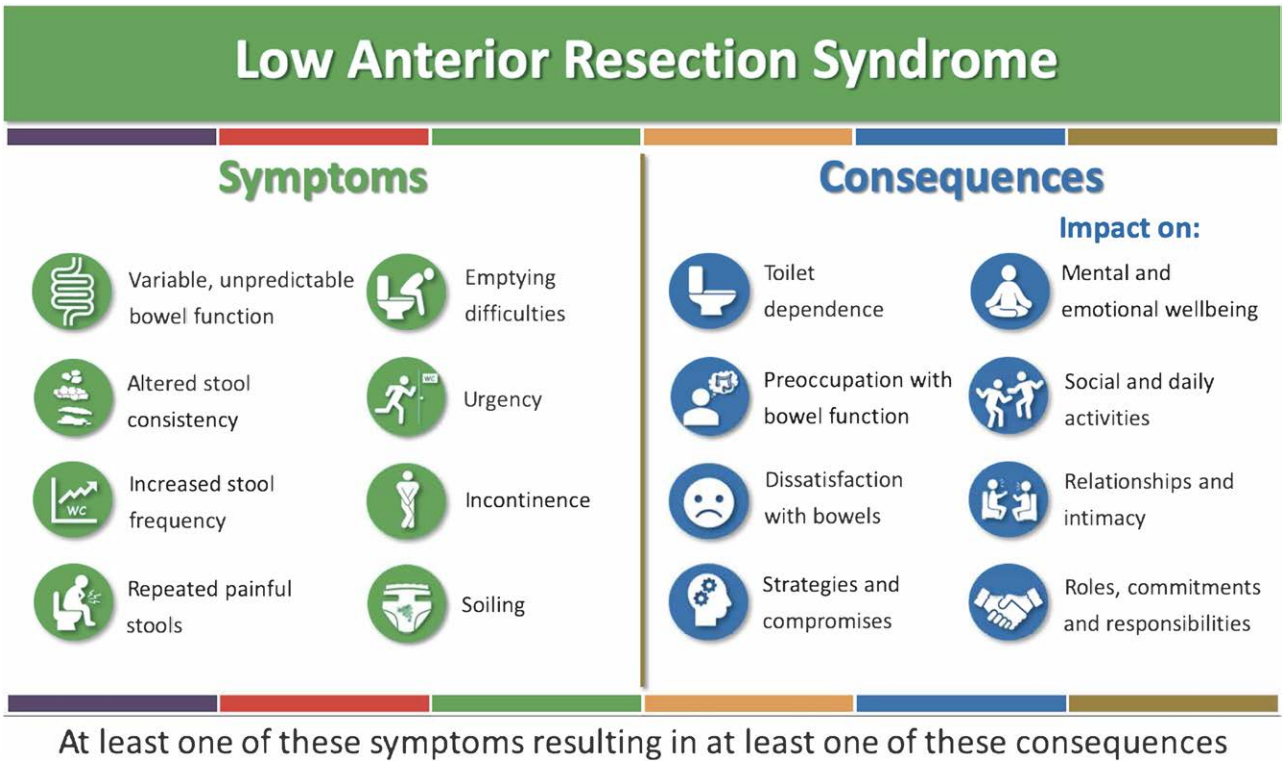

FIGURE 5. Consensus definition of low anterior resection syndrome. To meet the definition, a patient must have had an anterior resection (sphincter-preserving rectal resection) and experience at least 1 of these symptoms that results in at least one of these consequences.

adopted but appears to suffer from insensitivity to evacuatory dysfunction and may overestimate the impact on quality of life for some patients.[18] Weighting of the LARS score response categories makes the LARS score differentially responsive to change in certain dimensions (such as urgency) and may mean that more subtle improvements on other dimensions are not documented. There is also a high rate of LARS in the general population. When the LARS score was applied to the Danish population, 19% of women and 10% of men aged between 50 and 79 years experience symptoms that meet the criteria for major LARS.[25] This reflects the high sensitivity but low specificity of the LARS score. The more comprehensive Bowel Function Instrument (BFI) developed at Memorial Sloan Kettering Cancer Centre was also designed to measure bowel dysfunction after sphincter-preserving surgery but has not been used widely in the literature.[26]

The major methodological difference between this work and previous attempts to measure LARS is the patient-provider approach. Patients were not only participants, but also investigators. Active steps were taken throughout to ensure that the patient perspective was recognized and amplified. This key factor is likely to have contributed to a more efficacious definition that accurately captures real-world clinical experience. Engagement of the wider patient community through advertising the project via social media and involvement of patient participants active in peer support groups may allow wider dissemination of the proposed definition.

The overarching difference between the current results and the previously published LARS score and BFI is that the outcome is a definition not a scoring system. However, there is some overlap that is worthy of comment. Both the LARS score and BFI enquire about stool frequency, incontinence, urgency, and clustering or fragmentation, which is consistent with the proposed definition. The BFI also investigates diarrhea or loose stool, soiling, emptying difficulties (incomplete evacuation), and whether patients have to alter their activities because of bowel function, which are all concepts that reached consensus in the current work. However, the LARS score and the BFI include flatus incontinence, which did not reach consensus for inclusion in the proposed definition. The BFI also inquires about dietary restrictions and distinguishes between daily and nocturnal symptoms, which was not borne out in the consensus work. The LARS score incorporated quality of life by weighting the response categories based on a statistical association with the overall effect of bowel function on the quality of life, whereas the BFI simply included a question about altering activities because of bowel function. The consensus work suggests that the impact on LARS is such an important component that it is necessary to specify the various dimensions that may be impacted by the symptoms of LARS.

There are multiple novel components identified in this work that may be due to the early and consistent inclusion of the patient perspective. In particular, the concept of variable or unpredictable bowel function and altered stool consistency may align better with patient experience. Patient participants reported that diarrhea was less of an issue than unpredictable movements and paste-like consistency that makes evacuation difficult. Clear differentiation into symptoms and consequences is novel. Further work is needed to transform the definition presented here into a scoring system, but we suggest that inclusion of specific patient-centered consequences may allow development of a refined tool with greater discrimination of changes that occur over time and with treatment.

Our study attempted to obtain a broad range of opinion from all important stakeholders across a diverse cultural, ethnic, and geographical area, but it was limited by the resources available. Ideally, more than 5 geographical regions could have participated. Strategies were used to enhance the patient voice including: preference to patient panel rankings in the Delphi survey; patient consultation meetings were held to allow proxies to take the patient voice to the consensus meeting; and visual aids were used to prompt awareness of the patient voice during the consensus meeting. However, these strategies are not substitutes for the presence of patient representatives, and we must acknowledge the dominance of the surgical panel at final consensus despite attempts to mitigate this issue. There was a possibility for sampling bias, in particular, in the patient panel, because social media was used extensively in patient participant recruitment. However, many patient participants were active members or even conveners of support groups, and they endeavored to present majority opinions from their wider groups.

The LARS score was designed as a simple tool for clinical evaluation of LARS, and, although developed with robust methodology, it was not developed on the basis of an accepted definition of LARS. This has resulted in the LARS score's inability to capture evacuatory dysfunction.[18] To produce a more robust scoring system, we have developed a sequential approach; the initial phase is this consensus definition based on broadly agreed upon priorities of LARS, the second will involve transformation of these priorities into questions with weighting, and finally the new tool will be assessed in both cross-sectional and longitudinal validation studies. We have not attempted to present a new "LARS score" in this article, merely the results of the initial phase. Before moving on to the transformation, we need to assess whether the priorities we have presented are acceptable to the wider community. We aimed to develop a definition that aligned with the patient experience so that it will enable greater recognition of LARS in routine clinical practice. The production of an easily recognizable visual aid will hopefully allow for greater awareness of LARS from both patients and clinicians, and will hopefully enable more patients to receive professional help for their symptoms. We do not expect the work presented here to directly improve the assessment of the prevalence of LARS, nor the assessment of LARS over time or with treatment, but we will base subsequent work toward these aims on the priorities identified here.

CONCLUSION

This is the first attempt to define LARS using robust methodology that included multiple stakeholders, particularly patients. This novel approach has identified that both symptoms and consequences are important priorities in LARS. Acknowledging this by transforming these important priorities into a new tool to measure LARS may enable better identification of rectal cancer survivors who experience bowel dysfunction, more accurately assess severity, and enable more precise evaluation of treatment approaches for LARS.

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Lars International Collaborative Group

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