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Original Article (online only)

**Acceptability and benefit of rectal irrigation in patients with Low Anterior Resection Syndrome: a qualitative study**

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**Authors' contributions:** JC, CM and JT were responsible for the concept and design of the study. CO provided input into the qualitative aspects of the study, and all authors provided input and advice throughout the study, including interpretation of results. ZD, DH, KE, JT and CL were responsible for the collection and/or the analysis of patient data. GM was responsible for collection of qualitative data and analysis, and manuscript preparation. ZD double coded qualitative data. All authors reviewed and edited manuscript drafts and approved the final version of the manuscript.

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## **Abstract**

**Aim:** Low Anterior Resection Syndrome (LARS) following rectal cancer surgery impairs the patient's quality of life (QoL). Rectal Irrigation has been demonstrated to be effective for anterior resection syndrome but many surgeons do not suggest it as a treatment. This feasibility study aimed to explore treatment acceptability and the benefit of rectal irrigation in patients who developed LARS following an anterior resection for rectal cancer.

**Methods:** This was a qualitative study, involving semi-structured interviews. Twenty-one patients diagnosed with LARS following anterior resection for rectal cancer in a single tertiary centre were offered rectal irrigation as a treatment option. Qualitative interviews (n=17) were conducted at baseline to explore patient reported impact of LARS on QoL, treatment acceptability and factors influencing the decision to accept/decline treatment. Follow up interviews were carried out at six months for the treatment group only (n=12), to assess its practicality and impact on QoL.

**Results:** Qualitative interview findings suggest rectal irrigation is an acceptable method of treatment for LARS. Participants who perceived their symptoms to be more severe or poorly controlled were most likely to consider rectal irrigation as a treatment option. The patients who completed treatment reported improvements in their QoL, the ability to control the time of defaecation being the key benefit.

**Conclusion:** Clinicians should consider offering rectal irrigation as a treatment option to patients presenting with bowel dysfunction following anterior resection as it can improve symptoms. Patients who perceive that their symptoms are severe are more likely to consider treatment.

## **What does this paper add to the literature?**

This study found that rectal irrigation is an acceptable method of treatment for the symptomatic relief of low anterior resection syndrome (LARS). Control of LARS symptoms with frequent use of rectal irrigation can improve quality of life and it should be offered as a treatment option.

## Introduction

Recent advances in the management of colorectal cancer have improved patient survival. However, with improved survival, there is increasing recognition of long term functional side effects following rectal cancer treatment. Anterior resection with sphincter preservation is currently the standard of care for the management of low to mid rectal cancers [1]. Between 60-90% of patients following an anterior resection report severe post-operative bowel dysfunction in the first 12 months, with 1 in 4 patients experiencing effects for a longer period. Symptoms include urgency, frequency, faecal incontinence and flatulence [2] and it is often termed Low Anterior Resection Syndrome (LARS) [3-6]. For these patients who have undergone curative oncological resection, it is essential that effective treatment strategies are identified in order to ensure that patients can experience a good quality of life (QoL).

Patients with LARS often rely on strategies such as the use of pads, self-medication with laxatives and changes to diet in an attempt to control symptoms [7,8]. Biofeedback can be used to help patient with improving evacuation or incontinence and is often the first line treatment option. Rectal irrigation could also offer a potential solution for the management of LARS symptoms. A survey of colorectal surgeons across the USA and Spain suggested that less than one third of surgeons would consider offering rectal irrigation as a form of treatment for LARS and very few would offer it as a first line treatment [8].

The procedure involves the use of water to irrigate the recto-sigmoid colon to initiate evacuation, thereby reducing the risk of faecal incontinence. Rectal irrigation systems such as Peristeen® (Coloplast, UK) involve a disposable rectal catheter and a control unit consisting of a pump and water bag. Once the catheter is inserted into the anus, 500-1000ml of water can be manually pumped into the bowel using the control unit and once the catheter is removed, faecal evacuation occurs. Although rectal irrigation does not resolve the aetiology behind LARS, it can be used to control symptoms including the timing of defaecation which may be of benefit to the patient [9]. Empirical evidence suggests rectal irrigation can improve QoL and provide symptomatic relief in those with faecal incontinence, chronic constipation [11] and LARS following anterior resection [11-13]. Although QoL and functional outcomes improved following the use of rectal irrigation, the evidence is restricted to quantitative studies using validated questionnaires to assess outcomes. The acceptability of rectal irrigation as a treatment option, the subjective experience of the patient using rectal irrigation and how this treatment may impact QoL have not been fully explored.

To our knowledge, no qualitative study has explored the acceptability and impact of rectal irrigation in patients with LARS. The present study aimed to assess the acceptability of rectal irrigation in patients who accept or decline treatment, including a qualitative exploration of the factors influencing their decision, impact of treatment in terms of QoL, faecal incontinence and the patient reported experience.

## **Method**

All study materials and the study procedure was developed with lay input. The lay member of the research team was asked to provide feedback on readability of information sheets and provide input on how to minimise patient workload and improve study design.

Patients were identified through a prospective database held in Cardiff and Vale University Health Board's colorectal department. All patients undergoing an anterior resection for rectal cancer (between January 2009 and January 2014), who were aged 18 years or older and had bowel continuity restoration for a minimum of 12 weeks were eligible for the study (Figure 1). Patients were excluded if they were unable to provide informed consent, had previously used rectal irrigation or were not physically capable of performing rectal irrigation treatment at home.

Local ethical approval was obtained for this study (NISCHR 15/WA/0089). Eligible participants were sent an invitation letter by post with a brief outline of the study and a LARS-score questionnaire for completion [14,15]. Non-responders were contacted by telephone. Participants with LARS syndrome defined as a score of >20 on the LARS-score questionnaire were invited to attend outpatient clinic for assessment where they were screened for contraindications precluding rectal irrigation (Figure 1). Severity of LARS symptoms were graded from mild (score 21-29) to major (score 30-42) [14,15].

Participants were invited to an outpatient clinic six weeks after the initial appointment to discuss the study and watch a demonstration of the rectal irrigation system (Peristeen®). During this appointment those who agreed to take part in the study, regardless of whether they accept (treatment group) or decline treatment (comparator group), were asked to complete a consent form for the study. Those who consented to the study were asked to complete questionnaires to assess faecal incontinence using the St Mark's questionnaire [16]. All participants were invited to take part in a qualitative interview at the point of treatment acceptance or refusal (Figure 1).

Participants in the treatment group were reviewed via telephone by the clinic nurses one and two months after the initial appointment and in outpatient clinic after three and six months, in line with existing pathways for patients who start rectal irrigation within the Trust. Participants were provided with contact details for the clinic nurses should they require additional support in between follow up telephone calls and appointments. All participants (treatment and comparator groups) were asked to complete the LARS and faecal incontinence questionnaires at six month follow up. Participants in the treatment group were invited to take part in a qualitative interview at six months or at the point of drop out (Figure 1).

We aimed to interview up to eight participants per group (treatment- completed group; treatment-dropped out group; comparator group) until data saturation (no new themes emerging). Twelve participants who accepted treatment were interviewed. One participant did not complete treatment but declined to participate further in the study and refused a follow up interview. Therefore we were unable to conduct any incomplete treatment- interviews. The six participants who refused treatment were approached for an interview and five agreed.

Semi-structured telephone interviews were conducted with a trained qualitative researcher (GM; a health psychology PhD student), supported by a topic guide. Topics for the initial interview included the nature and impact of LARS symptoms on QoL, treatment acceptability and factors influencing the decision to accept or decline rectal irrigation. Topics under discussion during the follow up interview (treatment group only) included usability of rectal irrigation, acceptability and impact of rectal irrigation on LARS symptoms and QoL. Interviews were audio-recorded with permission and transcribed verbatim.

### ***Data analysis***

The study was not powered to explore statistical differences between groups therefore no statistical analysis of the quantitative data was performed. Qualitative data were analysed thematically. Themes were generated from the data and coded using NVivo 10. Four transcripts were double coded by another member of the research team (ZD) to reduce subjectivity and potential bias with interpretation of findings. All discrepancies were resolved through discussion.

## **Results**

Of the 85 eligible participants (male, n=57; female, n=28), twenty-one participants (male, n=18; female, n=3) consented to participate in the study (25% response rate) (Table 1).

Fifteen participants accepted rectal irrigation (treatment group) and six declined treatment (comparator group). Demographics, baseline LARS and faecal incontinence scores plus six month faecal incontinence scores were similar between treatment and comparator groups (Table 1).

Of the 15 participants who accepted treatment, 12 were interviewed (80%) and five of the six (83%) participants who declined treatment were interviewed. A summary of the qualitative findings under key themes are reported, with example quotations is presented in Table 2.

### **Living with LARS**

#### ***Symptoms***

Participants reported symptoms of urgency, frequency (up to 20 times per day), incomplete evacuation, incontinence, constipation (followed by symptoms of urgency and frequency), and flatulence. Urgency, frequency and incontinence were considered most detrimental to daily life. Some participants and their spouses became in effect housebound, severely affecting QoL. For participants with symptoms of urgency and frequency throughout the night, lack of sleep and broken sleep impaired functioning during the day, affecting QoL.

#### ***Changes to daily life***

Participants often avoided social events, long journeys, playing or watching sport, and everyday outings such as food shopping where they could not be sure toilets were readily accessible. Such activities were avoided through fear of having an accident or embarrassment associated with visiting the lavatory multiple times during a social event.

#### ***Strategies to control symptoms and the need for planning***

All participants reported attempts to control symptoms through medication such as laxatives or diet manipulation. If participants attended social events or other activities, meticulous planning was involved in the days leading up to the event to ensure symptoms were controlled using diet and medication, and preparations were made to ensure they knew of the location of all available toilets in the vicinity.

### ***Impact of LARS on work***

Participants in current employment reported difficulties with managing symptoms during working hours. Participants were required to discuss their previous diagnosis of cancer and symptoms with colleagues, which was embarrassing. For example, one participant worked in transport and was required to divulge personal information about cancer diagnosis and bowel function with students on their first meeting in order to pre-warn of the urgency to stop for a toilet if required.

### ***Disclosure of symptoms***

Although LARS severely impaired QoL, participants were grateful and thankful to have survived a diagnosis of cancer and there was a perception that they should not complain about their LARS symptoms. It could be postulated that this could deter disclosure of symptoms or downplay the impact of symptoms on daily life to family and clinicians during a consultation.

### **Explanation of rectal irrigation as a treatment option**

The booklet outlining the rectal irrigation procedure and the demonstration provided during clinic was considered by participants as informative and helpful for facilitating the decision to accept or decline treatment. The section in the booklet which contained case studies of people with LARS symptoms who were using rectal irrigation and reported benefit motivated participants to try rectal irrigation. All participants expressed concern about the procedure, where worries tended to cluster around the potential for bowel perforation or pain associated with the procedure. However, concerns were often resolved during the outpatient clinic appointment with the nurse, thus reinforcing the importance of knowledge and familiarity with the procedure.

### **Refusal of rectal irrigation**

#### ***Nature of symptoms and logistical considerations***

Participants who felt they had less severe or improving symptoms, controlled by diet and medication, declined treatment. The logistics and practicalities of performing the procedure were taken into account when considering rectal irrigation. Those with one toilet in the family home or problems with integrating the procedure into their working day influenced the decision to decline treatment, especially when symptoms were manageable or improving. However, all participants would consider rectal irrigation in the future should LARS symptoms worsen. In the months following participation in the study, some participants who initially refused treatment have been in contact the clinic nurses to request to try rectal irrigation.

### ***The procedure***

For two male participants the concept of daily self-catheterisation was distressing and therefore they refused the option of irrigation.

### **Accept rectal irrigation as a treatment option**

#### ***Nature of symptoms***

Symptoms were reported as more severe for participants who accepted than declined treatment, although this was not necessarily reflected in their LARS questionnaire severity score. Those who accepted treatment were unable to control symptoms by diet or medication and were often housebound. Although many were apprehensive about the treatment procedure, LARS symptoms were so detrimental on QoL that they were 'willing to try anything' with the potential to resolve and manage symptoms. For these participants, the potential benefits of treatment and the desire for life to return to 'normality' outweighed any potential side effects.

#### **Using rectal irrigation**

Initially, participants experienced problems with using the equipment properly often resulting in trial and error with water quantities and the depth of insertion of the catheter into the anus. However, once used a few times, participants gained confidence and could use the equipment effectively and efficiently. Only one patient required additional telephone support from the nurse outside of their allocated outpatient appointment.

Most participants used rectal irrigation daily, and the time required ranged from 30 to 45 minutes. Taking into account the length of time required throughout the day and the unpredictability of bowel motions with LARS prior to using rectal irrigation, 30-45 minutes was considered by participants as a benefit, particularly when they had complete control over the time of defaecation.

#### **Impact of rectal irrigation on QoL**

For participants who completed treatment, rectal irrigation was often described as 'life changing' and all participants would highly recommend it to anyone with LARS. Participants reported regaining complete control over their bowel movements and were confident in the ability to pursue the activities which they had previously avoided such as swimming, socialising and long trips, thereby improving QoL. The benefits extended to spouses who had previously forfeited social activities to because of their partner's symptoms. Participants used phrases such as 'I have my life

back', as a consequence of using rectal irrigation as they were able to carry on with life as it was before surgery.

## **Discussion**

This was the first qualitative study to explore acceptability of rectal irrigation for patients with LARS following anterior resection for rectal cancer. Participants were initially apprehensive of rectal irrigation, although concerns were often resolved through discussion with the nurse. Treatment was acceptable for the majority of participants; however, the procedure of self-catheterisation deterred participation in a minority of participants. Other influences on treatment acceptance were perceived symptom severity: those with manageable and improving symptoms declined treatment; however, those with severe and poorly controlled symptoms accepted treatment. Rectal irrigation was reported to lead to greater perceived control over symptoms and consequently improved QoL. Functional outcomes (severity of LARS and faecal incontinence) that participants reported during interviews did not necessarily reflect those of the LARS questionnaire performed at baseline. All participants that consented to be interviewed but declined irrigation (n=5) reported severe LARS scores on the questionnaire but during the interview perceived that their symptoms were not as severe or were improving.

Our findings are in line with previous survey studies reporting a positive influence of rectal irrigation on QoL [10-13]. Through qualitative methods we were able to provide insight into the patient reported experience of using rectal irrigation and how regaining control of symptoms through the use of rectal irrigation could improve their QoL.

We found evidence that patients may experience feelings of guilt and a perception that they should be grateful to survive a diagnosis of bowel cancer. Consequently, patients may withhold full disclosure of symptoms to their clinician. It is likely that previous studies highlighting the disparity between patient and clinician views on the impact of LARS on QoL [8,17] could be explained by patients minimising or opting not to disclose symptoms to their clinical team. It is therefore imperative that patients are aware of the symptoms of LARS preoperatively and that treatment strategies are available, to facilitate recognition of LARS symptoms.

Clinicians should be aware that patients may not disclose symptoms during a consultation unless prompted. Therefore, regular assessment of bowel function to screen for LARS should be made as symptoms may vary over time. LARS screening can be done as part of the Holistic Needs Assessment which should be performed in line with NHS England Cancer Task Force guidelines. Regular LARS screening should include questionnaires to assess bowel function such as the LARS score although

these may not accurately reflect the patient perception of symptom severity. Therefore, most importantly, it is the patient's own reported experience of severity of symptoms which will determine the need for intervention.

One recent study suggested that the LARS score can under or overestimate symptoms and therefore should be used in conjunction with other scoring tools and assessments [18]. We recommend that questionnaires such as the LARS score should be used during bowel function assessments as an adjunct to prompt and guide discussion around severity of symptoms. In addition, information should be made available to increase clinician awareness of treatment options available to patients with LARS such as rectal irrigation.

There were some limitations of this study. First, as with all qualitative research the sample may not be representative of a larger group, therefore care has to be taken when attempting generalisations from these data. For instance, although female gender is a risk factor for major LARS and most previous studies have explored the use of rectal irrigation in a pelvic floor setting with females, our sample was biased towards male respondents (over 80%). Due to the low numbers of female patients interviewed we were unable to explore the reasons for a higher male response in our sample. Reasons for refusal of rectal irrigation for the female participants in this study (n=2) were mainly centred on perceptions that symptoms were improving. In male participants, either the procedure of self-catheterisation or improving symptoms was a deterrent to treatment acceptance. Therefore, we can hypothesise that female response was lower because they felt symptoms were being managed, although further research is required to explore this in more depth. In addition, 25% of those invited to participate in the study consented to take part. Although a proportion of these patients had died or reported LARS scores of <20, 31 participants did not return the questionnaire or refused to participate in the study. We were unable to collect data for reasons for refusal, although we can postulate, based on our interview findings, that patients may refuse to take part because symptoms did not affect their perceived QoL. Second, this was a qualitative project and for which there was no intention to undertake statistical analysis on the quantitative data as the sample was not powered to explore statistical associations. Finally, we were unable to collect data on reasons for drop out of treatment. The only participant who dropped out of the treatment group also withdrew from the study and could not therefore be interviewed. Future trials should explore patient characteristics for those who accept or decline treatment, including barriers and motivators to participation.

## **Conclusion**

Clinicians should consider offering rectal irrigation as a treatment option for patients presenting with bowel dysfunction following anterior resection, particularly in patients who perceive themselves as having severe symptoms. Functional scores and other tools alone may not reflect patients' perception of symptom severity. Transanal irrigation has the potential to improve symptoms of LARS and QoL.

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**Table 1.**

	Treatment group (Peristeen use) (n=15)	Comparator group (usual care) (n=6)
<b>Gender</b>		
Male, n (%)	14 (93%)	4 (67%)
Female, n (%)	1 (7%)	2 (33%)
<b>Age</b>		
Mean (range)	65 (36-79)	60 (46-71)
<b>Severity of symptoms</b>		
Major LARS (LARS score >30), n (%)	13 (87%)	6 (100%)
Minor LARS (LARS score 21-29), n (%)	2 (13%)	0
<b>Surgical intervention</b>		
Anterior resection	12 (80%)	3 (50%)
Anterior resection and defunctioning stoma	3 (20%)	3 (50%)
<b>Disease TNM staging</b>		
T3 disease, n (%)	7 (47%)	2 (33%)
T2 Disease, n (%)	4 (27%)	3 (50%)
T1 disease, n (%)	3 (20%)	1 (17%)
No residual disease (post TEMS), n (%)	1 (8%)	0
<b>Neo-Adjuvant Chemotherapy</b>		
Yes, n (%)	6 (40%)	1 (17%)
No, n (%)	9 (60%)	5 (83%)
<b>Radiotherapy</b>		
Yes, n (%)	5 (33%)	1 (17%)
No, n (%)	10 (67%)	5 (83%)
<b>Height of anastomosis (with radiotherapy)</b>		
Mean, cm (range)	9.25 (7-12)	8.5 (4-15)
<b>Smoking status</b>		
Current smoker, n (%)	1 (7%)	2 (33%)
Not current smoker, n (%)	13 (93%)	4 (67%)
<b>Loperamide use</b>		
Regular use of Loperamide, n (%)	4 (27%)	4 (67%)

No regular use of Loperamide, n(%)	11 (73%)	2 (33%)
<b>Spinal conditions</b>		
Chronic spinal conditions, n (%)	3 (20%)	1 (17%)
No spinal conditions, n (%)	12 (80%)	5 (83%)
<b>LARS score</b>		
Baseline, mean (range)	35.93 (21-42)	34.17 (32-37)
Six month follow up, mean (range)	17.73 (0-41)	32.35 (26-37)
<b>St Marks score</b>		
Baseline, mean (range)	9.73 (2-15)	9.33 (4-13)
Six month follow up, mean (range)	3.20 (0-9)	5.40 (0-9)

**Table 2.** Example quotations

Theme	Example quotation
<b>Living with LARS</b>	<p>“Unfortunately [the reversal] has left me a situation where I go [to the toilet] in the evening...anything up to 15-20 times” (<i>Male, treatment group-completed</i>)</p> <p>“If I go out for the evening...I have to find where the toilet is and then I need to go 4 or 5 times in the night. So it really is sort’ve something to do with our social life but also just not very nice...yes it does affect how much you do” (<i>Male, treatment group-completed</i>)</p>
<b>Explanation of rectal irrigation as a treatment option</b>	<p>“The nurse I dealt with, she was brilliant, really, really good. She explained it all, and then she went through what would be involved she was fantastic” (<i>Male, treatment group-completed</i>)</p> <p>“I was reading [the booklet] through the other night and it was saying a lot of people it would do them good like...that’s why I took [rectal irrigation] up” (<i>Male, treatment group-completed</i>)</p>
<b>Refusal of rectal irrigation</b>	<p>“I think I am actually, I think I’m controlling it...it’s a lot better than when I had the bag and it’s a lot better than when I had the reversal” (<i>Male, comparator group</i>)</p> <p>“At the moment I declined [rectal irrigation] because I seem to be managing okay” (<i>Female, comparator group</i>)</p> <p>“It comes down to the basic point to having to put a catheter up your rectum everyday and fill yourself with water doesn’t appeal at all. I think my symptoms would have to be quite severe for me to say yes I’d be prepared to do that” (<i>Male, comparator group</i>)”</p>
<b>Accept rectal irrigation as a treatment option</b>	<p>“You understand what the main aspect of it is and I must admit at one point I thought ‘I’ve got to do this’, but you balance that against what could be the benefits and so I thought yep I’m gonna go for it and I’m gonna do it because it is the opportunity to make your life better” (<i>Male, treatment group-completed</i>)</p>

	<p>"I thought I'd give it a go because I tried everything else and you know, so I just wanna try this and give it a go innit?" (<i>Male, treatment group- completed</i>)</p>
<p><b>Using rectal irrigation</b></p>	<p>"I was a bit nervous...to put [the catheter] up the back passage, but, after 2 or 3 days it was excellent you knew what to do then." (<i>Male, treatment group-completed</i>)</p>
<p><b>Impact of treatment on quality of life</b></p>	<p>"It's excellent, absolutely excellent it is. I can't do without it tell the truth...otherwise I can't go out because you know I'm looking for the toilet all the time" (<i>Male, treatment group- completed</i>)</p> <p>"I would say the phrase that probably sums [rectal irrigation] up best for me is life changing. Because my life compared to before [rectal irrigation] has changed vastly...it really made a major difference to me and my wife" (<i>Male, treatment group- completed</i>)</p> <p>"It's changed my whole life...my lifestyle all that kind've stuff...I'm not rushing off to the toilet all the time so a lot better in myself" (<i>Male, treatment group-completed</i>)</p>

Figure 1. Flow chart of participant recruitment and study procedure

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