



Research Article

Physiotherapy and Anterior Resection Syndrome (Paris) Trial

A Feasibility Study to Assessing if a Preoperative Education and Physiotherapy Session Before an Anterior Resection, and a 3 Month Pelvic Floor Muscle Rehabilitation Programme Prior to Ileostomy Reversal are Feasible

I.Vogel^{1*}, H. de Berker¹, G. McCabe¹, A. Powell-Chandler², B. Rees¹, J.Torkington¹, C. O'Neill³, J.A. Cornish¹

¹Department of Surgery, University Hospital of Wales, Cardiff, UK

²Department of Surgery, Royal Glamorgan Hospital Llantrisant, Llantrisant, UK

³Swansea Trials Unit, Swansea University, UK

*Corresponding author: Irene Vogel, University Hospital of Wales, Department of Surgery, Heath Park Way, CF14 4XW, Cardiff, UK

Citation: Vogel I, de Berker H, McCabe G, Powell-Chandler A, Rees B, et al. (2022) Physiotherapy and Anterior Resection Syndrome (Paris) Trial a Feasibility Study to Assessing if a Preoperative Education and Physiotherapy Session Before an Anterior Resection, and a 3 Month Pelvic Floor Muscle Rehabilitation Programme Prior to Ileostomy Reversal are Feasible. J Surg 7: 1574. DOI: 10.29011/2575-9760.001574

Received Date: 14 September, 2022; **Accepted Date:** 23 September, 2022; **Published Date:** 26 September, 2022

Abstract

Purpose: There is a lack of evidence on the effectiveness of conservative treatments for Low Anterior Resection Syndrome. The aim of the study was to assess the feasibility of a preoperative education and physiotherapy session, and a 3 month pelvic floor muscle Rehabilitation Programme (PFR) prior to ileostomy reversal.

Methods: This was a mixed methods study of rectal cancer patients undergoing a low anterior resection (October 2017–September 2018) in 2 centres. The primary outcome measure was the proportion of eligible patients approached that were consented and undergoing the intervention. The secondary outcomes included patient compliance with PFR, and acceptability (using semi-structured interviews).

Results: Of the 25 eligible patients, 9 were recruited. All attended the educational and pre-operative PFR, with only 1 patient completing the PFR programme prior to closure due to delays in ileostomy reversal. Timing of the intervention before surgery was a burden for some, and engagement of key family members was critical. The use of pre-surgery and early post-surgery PFR was possible, but many patients found it difficult to adhere to. Barriers to compliance were delays in reversal of ileostomy and physiotherapist availability to perform PFR.

Conclusion: This study highlights key concepts which should be considered when designing the optimal management pathway for LARS management. Patients are interested in information on LARS and PFR to improve bowel function after colorectal surgery. However, this must be provided at the appropriate point in the patient pathway. The timing of physiotherapy after initial surgery is an important determinant of uptake; this study suggests it should be offered after ileostomy reversal.

Keywords: Anterior resection; Low anterior resection syndrome; Pelvic floor rehabilitation; Rectal cancer

Introduction

Bowel cancer affects approximately 43,000 patients per year in the UK, with the majority of the cancers located in the rectum. [1] An anterior resection is the gold standard surgical procedure for patients with rectal cancer where sphincter preservation is possible. [2] Up to 75% of patients after an anterior resection experience impaired bowel function in the first 12 months after surgery. [3] Symptoms are often referred to as Low Anterior Resection Syndrome (LARS) and include urgency, clustering, difficulty emptying and incontinence. [4] These symptoms remain present in up to 50% of patients for more than 10 years after surgery, and they have a significant effect on quality of life (QoL). [5-7] Up until recently there has been no guidelines on the management of LARS but the consensus statement from the MANUEL project has been published this year (REF) confirms the lack of high quality evidence for any for any of the current treatment options. The management guidelines for low anterior resection syndrome, the MANUEL project, was unable to recommend a particular treatment for LARS [8].

Treatments currently offered are those for faecal incontinence; dietary modification, use of anti-motility agents, transanal irrigation and Pelvic Floor Rehabilitation (PFR). The impact of PFR on bowel function in patients following rectal surgery has been assessed in a limited number of studies. A systematic review conducted by Visser et al. (2014) identified 5 relevant studies with a total of 321 patients and reported that PFR was associated with improved bowel function and quality of life after LAR. [9] These studies report an improvement in symptoms between 50-80%, but used non-validated tools to assess bowel function. The studies included were of small sample size and generally of weak study design. No strong evidence is available for the use of post-operative PFR and there no data about optimal timing of the initiation of PFR. All of these studies described postoperative PFR interventions. The Physiotherapy and Anterior Resection Syndrome (PARiS) study was designed to assess the feasibility of providing a patient education session and a PFR programme prior to anterior resection for rectal cancer and prior to reversal of the ileostomy. The educational session involved teaching patients about pelvic floor exercises, bowel issues that they may experience after surgery and provided simple lifestyle advice. The programme was delivered by a pelvic floor physiotherapist and a bowel specialist nurse. The original study protocol included interviewing patients to assess their satisfaction with the elements of the programme. However, the study ran into a number of problems with set-up and recruitment which meant that the qualitative component was increased to understand the barriers

to recruitment for the study.

Methods

This was a single-arm, non-randomised, prospective mixed methods feasibility study assessing the acceptability of a preoperative educational session and a 3 month pelvic floor muscle rehabilitation programme (PFR), for patients undergoing anterior resection, prior to reversal of ileostomy for rectal cancer, in Cardiff and Vale and Cwm Taf University Health Boards.

Study Population

All patients with rectal cancer planned to receive an anterior resection between October 2017 and September 2018 were eligible for this study.

Inclusion Criteria

- Rectal cancer
- Planned anterior resection
- Age >18 years
- Suitable and capable of performing PFR

Intervention

Educational Session: After screening and consent, patients attended a preoperative educational session. These were segregated according to gender and lasted an hour. Patients were provided with an overview of normal anatomy and bowel function, how it is changed by surgery, low anterior resection syndrome, conservative management options and what the study involved. During this session baseline information and baseline QoL and bowel function questionnaires were also collected.

Qualitative Interviews: All patient who agreed to be contacted, were invited for semi-structured interview to gather their opinions of the educational session and to explore how they found aspects of the PFR programme including; the pelvic floor exercises, the diary or application and the physical examination required for pelvic floor assessments. The interview topic schedule created guided the interviews, but allowed freedom for the patient to discuss areas of importance to them.

PFR Programme: Patients could attend the baseline pelvic floor examination and introduction to PFR on the same day as the educational session or at a later date. This was conducted by a physiotherapist. Digital vaginal examination was performed to assess power, range of movement, endurance, agility, release and technique of the pelvic floor muscle activity for the women included in the study. Individualised programmes were provided at this visit by the physiotherapist based on their assessment. Patients were instructed to start pelvic floor exercises immediately and to continue until their operation. If the resting muscle tone was high, a series of down training sessions were completed prior to starting

the above programme. Patients were asked to recommence the exercises as soon as they were able to after their operation. Median time from baseline assessment to surgery was 2 weeks. Patients were asked to complete three sets of muscle exercises per day: fast pelvic floor contractions (10 repetitions three times per day), slow pelvic floor contractions (10 repetitions three times per day) and submaximal pelvic floor contraction (practice often throughout the day). If unable to do this, the participant's programme was adapted to meet their ability and they were advised to progress to the maximum programme as able. Patients were given the option of recording their pelvic floor exercises with either a paper diary or the 'Squeezy' mobile application (Living With Ltd, UK). Compliance was assessed by reviewing the number of entries. The Clinician version of the Squeezy application allowed the team to monitor the exercises performed prospectively as information was recorded each time the exercises were performed. Patients attended two follow-up visits at 6 weeks and 3 months post-anterior resection for pelvic floor assessment and completion of bowel function and QoL questionnaires. The programme was completed at 3 months, with patients having the option to continue the exercises if they wished.

Outcome Assessment

Primary Outcome: The primary outcome was the proportion eligible patients who consented to the programme and attended the educational session.

Secondary Outcomes: The secondary outcomes were patient compliance with PFR, acceptability of the PFR programme, and functional/quality of life scores.

Patients' compliance to the PFR programme was assessed by reviewing the patient's paper diary or Cx Squeezy log. The acceptability of the intervention was assessed by qualitative interviews. Pelvic floor tone was assessed by one physiotherapist at each site using the validated Oxford Grading System, a validated tool using digital examination during a maximal voluntary contraction to evaluate muscle strength.[10] Bowel function was assessed with validated bowel function questionnaires. (LARS score [11], St Mark's faecal incontinence) [12] QoL was assessed using 2 validated questionnaires; European Quality of Life Five Dimension (EuroQol-5D) which is a generic QoL tool that generates a single index value for health status [13] and the European Organization for Research and Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30 V3.0) which is a cancer-specific quality of life tool [14].

Data Analysis

Descriptive data were reported as median with Interquartile Range (IQR). Due to lack of sufficient data no comparative analysis were made. Interview data content analysis was performed using NVivo V.10 with double coding undertaken by a member of the

research team with qualitative data analysis experience. The codes identified included: timing, family support, understanding of the mechanics of the disease, self-care and co-producing care.

Results

Of the 25 patients were eligible for inclusion, 16 (64%) declined to participate. Common reasons for declining included "too much to deal with", "not interested at the moment" and "reluctant to attend additional appointments". The remaining 9 (36%) patients that were planned for a low anterior resection with defunctioning ileostomy for rectal cancer were included in the study. Baseline characteristics are presented in Table 1. The median age was 71 years (IQR 57-75) and the majority of the included patients were male (78%). Before surgery, 4 patients (44%) had a bowel-related problem. These were urgency (n=2), constipation (n=1), and faecal incontinence (n=1). Five patients (56%) had impaired pre-operative pelvic floor tone with modified Oxford grading of 3. Of all patients 5 (56%) presented without LARS, 1 (11%) with minor LARS, and 3 (33%) with major LARS. The global health status according to QLQ-CR30 and ED-5D were good. Table 1.

Characteristic	Patients N = 9
Median age (IQR), years	71 (57-75)
Male gender, n (%)	7 (78)
Pre-operative performance status, n (%)	
- One	6 (67)
- Two	2 (22)
- Three	1 (11)
Bowel related problem before surgery, n (%)	4 (44)
Pelvic floor tone, n (%)	
Lift of muscles	5 (56)
Good contraction	3 (33)
Strong resistance	1 (11)
Global scale QLQ-CR30, median (IQR)	83 (75-92)
ED-5D, median (IQR)	0.88 (0.82-1.0)
LARS, n (%)	
No LARS	5 (56)
Minor LARS	1 (11)
Major LARS	3 (33)
Started PFR after educational session, n (%)	7 (78)

Table 1: Baseline characteristics.

All of the participants completed pre-operative education. Two of the patients who completed the educational session did not undergo anterior resection with bowel continuity, and thus were excluded from the PFR programme and further follow up. Post-operative anastomotic leak occurred in two patients, both went back for theatre for a wash out and rectal drainage. One patient had a pelvic abscess that was treated conservatively with antibiotics. Following these complications, all 3 patients withdrew from the study. Of the remaining 4 patients, only one patient completed PFR for a period of 3 months. This patient had a pre-operative Modified Oxford Scale of 3; this was unchanged at 6 week and 3 month follow-up. At 3-month follow-up, 1 patient had undergone ileostomy reversal, and 6 patients were still awaiting reversal.

One of the main logistical issues encountered was the availability of a physiotherapist trained to provide the intervention. At Site 1, the incumbent physiotherapist left their post shortly after initiation of the study; a replacement physiotherapist had to be trained and went on sick leave not long after starting. Site 2 experienced difficulties in patient recruitment because there were several trials open at the same time amongst the same cohort of rectal cancer patients. The burden of the study in terms of attendance for the session and physiotherapy meant that many patients did not wish to consent preoperatively but did express interest in attending the educational session after surgery. Some patients withdrew consent to continue in the study following post-operative complications. Six patients agreed to be contacted for interview, of which 4 completed the interview. These were two men that completed the trial and two female patients who had initially declined to participate in the intervention. Timing: The patients who agreed to take part in the study felt that the “timing was spot on” and provided them with an opportunity to proactively engage in their own care at a difficult time. Non-participants felt that the study was “too much too soon”. They reported feeling too overwhelmed by the burden of the diagnosis to take on additional information or appointments.

Family support/independence: Participants who completed the study were able to drive themselves to and from appointments. The non-participants relied on others for transport to appointments and for help with diaries. They felt that their participation in the study would have been a burden for their family and they did not feel able to take this on at the time. Self-care: For the patients who participated in the study, the idea of doing something to help themselves was important. Performing the exercises and being in the study provided a focus and a “job to do”. Unlike the non-participants, those participating described themselves as generally fit and both felt they had a positive outlook on life. Co-producing care: Those who participated in the educational session and the PFR programme were clear that being involved in the study gave

them a chance to be actively involved in their own care. The non-participants felt that they did not know how to weigh up being involved in the study.

Discussion

This study highlighted that patients are interested in information on LARS and pelvic floor exercises to improve bowel function after colorectal surgery, but that it is important to choose the appropriate point in the patient pathway to do this and that this may vary between patients. The use of a pre surgery and early post-surgery PFR programme was possible but difficult for many patients to adhere to. The patients who were involved liked the concept and felt it gave them a degree of control over their treatment, but for others it was too much to do at a difficult time early after their diagnosis, when their cancer treatment had not yet started. The focus at the beginning of treatment is on survival and cancer cure; patients rarely anticipate that they will have potential functional problems. [15] It has been reported that only one third of patients (32.7%) will visit a health professional for advice or treatment for bowel problems after surgery [16] and this may be related to lack of information on what is normal and what can be treated, as well as the stigma of bowel issues. Tackling this issue may increase patient appetite to participate in a PFR programme.

The limitations of this study were the poor recruitment rates due to timing of the intervention before and in the early post-operative period. This was a burden for some patients because they need time to process the idea they had cancer. Others indicated that pre-operative PFR gave them a chance to get ready for the surgery and felt like they were doing something positive to help themselves. There were difficulties in delivering a physiotherapy programme due to staffing issues and the lack of qualified physiotherapist to deliver the PFR. Furthermore, the delays in closure of ileostomy resulted in unrestored bowel continuity at the end of the study duration for the majority of the patients. The effect of the PFR programme on bowel function was therefore not possible to evaluate. The qualitative work allows us to draw some broad insights into the reasons for poor patient participation, although limited by the small numbers involved. For the patients that did participate, the men were better at engaging, but their professional background and access to a car for travel to appointments was important to their engagement. who declined to participate cited lacked the ability to travel independently, and cited concerns that involvement would burden their family members. This may be remedied by involving family members in discussions about the trial. Alternatively, providing remote-access resources for patients to use at a time of their convenience (online/booklets/videos) with the option to book physiotherapy appointments might increase engagement.

There were difficulties in delivering a physiotherapy

programme due to staffing issues and the lack of qualified physiotherapist to deliver the PFR. The lack of physiotherapists trained in pelvic floor rehabilitation is a problem that is recognized by the UK Pelvic Floor Society, with the consensus that access to specialist care is variable and often inappropriate.[17] There are currently around 800 specialist pelvic floor physiotherapists in the UK and only one post graduate physiotherapy course in the UK dedicated to this topic.[18] Plans to increase training opportunities in the UK and courses are essential to expand the current workforce.[19] Notwithstanding the important role of trained physiotherapists, the Squeazy app is a tool that can provide support for patients that wish to train their pelvic floor muscle at any time in their post-operative period. This may be particularly useful for those units with limited access to specialist physiotherapy. The app has been designed by physiotherapists, and approved by the National Health Service (NHS), and can be tailored to a specific exercise programme by the physiotherapists and set to remind patients when to do their exercises. In addition there is a licensed Clinician version, that maintains a prospective time record of the number of exercises completed. This can be reviewed remotely by the team looking after the patient. The majority of the patients in this study waited for longer than 3 months for ileostomy closure. This finding has led to the development of the CLOSE IT study [20] and subsequent quality improvement work on expediting to ileostomy reversal. [21] Patients with a clear sense of when they will return to passing stool per rectum may be more inclined to pro-actively engage in a PFR programme. These delays meant that this study was unable to evaluate the impact of the programme on QoL and bowel function.

Nearly all patients will experience bowel dysfunction initially following surgery and 25-50% will experience severe bowel dysfunction on a long-term basis. [5,6] The most common change in the study group was increased frequency of bowel movements, with half stating that their current frequency was more than twice per day.[16] Although few studies have been published on rehabilitation in patients suffering from LARS, results are encouraging. Muscle training might improve timing and strength of automatic contractions, resulting in reduced leakages. [8] This emphasises the importance of strategies for increasing engagement and compliance with PFR programmes. The despite the growing interest, management of LARS is often empirical and symptom-based, using existing therapies for faecal incontinence, faecal urgency and rectal evacuatory disorders. The 'Management guidelines for low anterior resection syndrome' (MANUEL) project provides an up-to-date practical summary of the available evidence concerning LARS, initiated by experts in LARS from several nations (Denmark, France, Austria, Italy, the Netherlands and the UK).[8] Their conclusion was that whilst few studies have been published on rehabilitation in patients suffering from LARS,

results are encouraging. Muscle training might improve timing and strength of automatic contractions, resulting in reduced leakages. Biofeedback can help patients by optimizing their motor response through visual and hearing signals, lowering the threshold for the discrimination of a rectal sensation. Rectal balloon training may improve rectal sensitivity by stepwise reductions in rectal balloon distension. Despite this, the different protocols used regarding duration of training, method and application modality still do not allow firm conclusions. Future studies assessing the efficiency of PFR are warranted.

Conclusion

This study highlighted that patients are interested in information and pelvic floor exercises to improve bowel function after colorectal surgery. However it is important to choose the appropriate point in the patient pathway to do this. We have amended the patient pathway for bowel dysfunction following the valuable lessons learnt in this study.

References

1. <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/incidence>
2. Hughes DL, Cornish J, Morris C (2017) LARRIS Trial Management Group. Functional Outcome Following Rectal Surgery-Predisposing Factors For Low Anterior Resection Syndrome. *Int J Colorectal Dis* 32: 691-697.
3. Bryant CL, Lunniss PJ, Knowles CH, Thaha MA, Chan CL (2012) Anterior Resection Syndrome. *Lancet Oncol* 13: E403-408.
4. Keane C, Wells C, O'Grady G, Bissett IP (2017) Defining Low Anterior Resection Syndrome: A Systematic Review Of The Literature. *Colorectal Dis* 19: 713-722.
5. Chen TY, Wiltink LM, Nout RA, Meershoek-Klein Kranenbarg E, Laurberg S, et al. (2015) Bowel Function 14 Years After Preoperative Short-Course Radiotherapy And Total Mesorectal Excision For Rectal Cancer: Report Of A Multicenter Randomized Trial. *Clin Colorectal Cancer* 14: 106-114.
6. Sturiale A, Martellucci J, Zurli L, Vaccaro C, Bruscianno L, et al. (2017) Long-Term Functional Follow-Up After Anterior Rectal Resection For Cancer. *Int J Colorectal Dis* 32: 83-88.
7. Van Heinsbergen M, Janssen-Heijnen ML, Leijtens JW, Slooter GD, Konsten JL (2018) Bowel Dysfunction After Sigmoid Resection Underestimated: Multicentre Study On Quality Of Life After Surgery For Carcinoma Of The Rectum And Sigmoid. *Eur J Surg Oncol* 44: 1261-1267.
8. Christensen P, Im Baeten C, Espín-Basany E, Martellucci J, Nugent KP, Zerbib F, et al. (2021) Management Guidelines For Low Anterior Resection Syndrome - The MANUEL Project. *Colorectal Dis* 23: 461-75.
9. Visser WS, Te Riele WW, Boerma D, Van Ramshorst B, Van Westreenen HL (2014) Pelvic Floor Rehabilitation To Improve Functional Outcome After A Low Anterior Resection: A Systematic Review. *Ann Coloproctol* 30: 109-114.

Citation: Vogel I, de Berker H, McCabe I G, Powell-Chandler A, Rees B, et al. (2022) Physiotherapy and Anterior Resection Syndrome (Paris) Trial A Feasibility Study to Assessing if a Preoperative Education and Physiotherapy Session Before an Anterior Resection, and a 3 Month Pelvic Floor Muscle Rehabilitation Programme Prior to Ileostomy Reversal are Feasible. *J Surg* 7: 1574. DOI: 10.29011/2575-9760.001574

10. Laycock J, Jerwood D (2001) Pelvic Floor Muscle Assessment: The PERFECT Scheme. *Physiotherapy* 87: 631-642.
11. Emmertsen KJ, Laurberg S (2012) Low Anterior Resection Syndrome Score: Development And Validation Of A Symptom-Based Scoring System For Bowel Dysfunction After Low Anterior Resection For Rectal Cancer. *Ann Surg* 255: 922-928.
12. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA (1999) Prospective Comparison Of Faecal Incontinence Grading Systems. *Gut* 44: 77-80.
13. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, et al. (1992) Validating The SF-36 Health Survey Questionnaire: New Outcome Measure For Primary Care. *BMJ* 305: 160-164.
14. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, et al. (1993) The European Organization For Research And Treatment Of Cancer QLQ-C30: A Quality-Of-Life Instrument For Use In International Clinical Trials In Oncology. *J Natl Cancer Inst* 85: 365-376.
15. Van Der Heijden JAG, Thomas G, Caers F, Van Dijk WA, Slooter GD, et al. (2018) What You Should Know About The Low Anterior Resection Syndrome - Clinical Recommendations From A Patient Perspective. *Eur J Surg Oncol* 44: 1331-1337.
16. Nikoletti S, Young J, Levitt M, King M, Chidlow C, et al. (2008) Bowel Problems, Self-Care Practices, And Information Needs Of Colorectal Cancer Survivors At 6 To 24 Months After Sphincter-Saving Surgery. *Cancer Nurs* 31: 389-398.
17. <https://thepelvicfloorsociety.co.uk/qa-governance/accreditation-of-pelvic-floor-units/ACBGBI-PF-Consensus-Report-2014>.
18. <https://evidence.nih.gov/alert/pepfm-training-for-prolapse-delivered-by-non-specialists/>
19. <https://www.pelvicfloorreport.com/pelvic-floor-services-in-2021-and-beyond>.
20. Dukes' Club Research Collaborative (2021) Factors Impacting Time To Ileostomy Closure After Anterior Resection: The UK Closure Of Ileostomy Timing Cohort Study (CLOSE-IT). *Colorectal Dis* 23: 1109-1119.
21. Vogel I, Vaughan-Shaw PG, Gash K, Withers KL, Carolan-Rees G, et al. (2021) Improving The Time To Ileostomy Closure Following An Anterior Resection For Rectal Cancer In The UK. *Colorectal Dis* 2021.