Efficacy of Pelvic Floor Muscle Training for Postoperative Patients With Rectal Cancer: A Systematic Review and Meta-Analysis

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Abstract

This study aimed to assess the effectiveness of pelvic floor muscle training (PFMT) for fecal incontinence (FI) and health-related quality of life (HR-QOL) after colorectal cancer surgery. This systematic review (SR) and meta-analysis included seven randomized controlled trials (RCTs) that examined the effects of PFMT after colorectal cancer surgery, which were extracted from a database on January 2023. The primary outcomes were FI (Wexner scores), HR-QOL, and adverse events (AE). We used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to assess certainty of evidence (CoE). A total of 7 RCTs were included. Our SR results suggested that PFMT showed little to no difference in FI (mean difference 0.62 higher, 95% CI[-1.26 to 2.5, low CoE] and AE(risk ratio 5.78; 95% CI 0.28 to 117.22, low CoE). Two AE occurred in PFMT (anastomotic stenosis, suboptimal use of laxatives) and were not observed in control. HR-QOL was measured in two RCTs, using SF-12 and FIQL. Two RCTs found no trend toward a positive impact on HR-QOL. PFMT has little to no trivial difference in improving FI and increasing AE. Thus, higher-quality RCTs in colorectal cancer after surgery are needed.

Categories: Physical Medicine & Rehabilitation, Gastroenterology
Keywords: colorectal cancer, fecal incontinence, rehabilitation, pelvic floor muscle training, rectal cancer

Introduction And Background

Fecal incontinence (FI) is often a problem following colorectal cancer surgery. A recent systematic review (SR) reported a 24.1% prevalence of liquid FI and 6.9% of solid FI [1]. Postoperative FI in colorectal cancer has been shown to be associated with quality of life (QOL) [2]. Therefore, addressing FI is important after colorectal cancer surgery.

Pelvic floor muscle training (PFMT) is used as a conservative treatment for urinary and fecal incontinence [3,4]. PFMT is useful in the prevention of urinary incontinence in antenatal and postnatal women [3]. Furthermore, PFMT may be effective for FI, according to a recent SR of after colorectal cancer surgery [4]. However, this SR [4] does not include RCTs, and no meta-analyses have been carried out.

Several recent RCTs of PFMT for FI in postoperative patients with colorectal cancer have been reported, and their effectiveness has been investigated [5,6]. In addition, a recent RCT of PFMT for FI has shown that it may be effective for bowel symptoms at 6 months but not at 12 months [5]. Another RCT [6] showed significant improvement in those with baseline Wexner scores of 16 points or less. Therefore, SRs involving these RCTs provide a more reliable way of demonstrating the efficacy of PFMT. This study aimed to investigate the effect of PFMT on improving outcomes, such as FI, QOL, and adverse events after colorectal cancer surgery, through an SR and meta-analysis of RCTs.

Review

Methods

We followed the Preferred Reporting Items for SR and Meta-Analysis 2020 (PRISMA-2020) for preparing this protocol (https://osf.io/xy5w6) [7]. We registered our study protocol on the Open Science Framework (https://osf.io/kq4n/).

Inclusion criteria of the articles for the review type of studies: We included RCTs that assessed individual randomization. We did not apply any language or country restrictions. We incorporated all forms of
literature, including published and unpublished articles, and we did not exclude studies based on the observation period or publication year.

**Study participant**

**inclusion criteria:**

We included adult patients who had undergone surgery for colorectal cancer. Studies were included regardless of the intervention setting (in-hospital or out-of-hospital).

**Exclusion criteria:**

Studies involving mixed populations where a percentage of participants were non-surgically treated only or children (<18 years) were excluded unless results for non-surgically treated patients or children were presented separately.

**Intervention:**

**Definition of PFMT:**

Exercises targeting the pelvic floor muscle groups, such as the external anal sphincter, were considered PFMT [4]. We included studies on the effects of PFMT in postoperative patients with colorectal cancer, with no restrictions on when the exercises were performed, and those that examined PFMT interventions alone or in combination with patient education, biofeedback, electrostimulation, or rectal balloon. We excluded studies that used electrostimulation, rectal balloons, or biofeedback alone.

**Control:**

No treatment, usual care, or usual rehabilitation were used as controls. We included other treatments (e.g., patient education, biofeedback, electrostimulation, or rectal balloon) as controls if the same treatments were applied to intervention groups. We excluded studies where the control groups performed PFMT.

**Primary outcomes**

**FI:**

Definition: We extracted the total Wexner score (Cleveland Clinic Florida Fecal Incontinence Scale) [3].

Period: 1 to 12 months from the start of the intervention. The longest point during the period was extracted.

**HR-QOL:**

Definition: Validated disease-specific and overall HR-QOL questionnaires (e.g., EORTC QLQ-C30, EORTC-QLQ-CR29, EURO-Qol 5D, SF-36, SF-12). If sub-items such as physical component score and mental component score were clear, surveys were conducted respectively.

Period: 1 to 12 months from the start of the intervention. The longest point during the period was extracted.

**Adverse events:**

Definition: The definition of adverse events was set by the original authors.

Period: During the intervention and follow-up period.

**Secondary outcomes**

**Bowel dysfunction after surgery:**

Definition: We extracted the total low anterior resection syndrome (LARS) score [8].

Period: The period for all outcomes was 1-12 months from the start of the intervention. The longest point during the period was extracted.

**Search method**

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) via Cochrane Library, MEDLINE via PubMed, Excerpta Medica Database (EMBASE) via Dialog, Physiotherapy Evidence Database (PEDro),
Cumulative Index to Nursing and Allied Health Literature (CINAHL), WHO International Clinical Trials Registry Platform (WHO ICTRP) via their dedicated search portal, and ClinicalTrials.gov between January 12, 2023 and January 19, 2023 (https://osf.io/hevk2). We checked the reference lists of studies, including international guidelines [9-12], as well as the reference lists of eligible studies and articles citing eligible studies. We asked the authors of original studies for unpublished or additional data.

**Data collection and analysis**

Selection of the studies:

Two independent reviewers (YN, KF) screened titles and abstracts, followed by the assessment of eligibility based on the full texts. We contacted the original authors if relevant data was missing. Discrepancies are discussed by the two reviewers until they reach a consensus, or with a third reviewer (TA).

Data extraction and management:

Two reviewers (YN, KF) performed independent data extraction of the included studies using a standardized data collection form. The form included information on the author, number of participants, types of surgery, stoma, intervention, controls, and outcomes. Discrepancies were discussed by the two reviewers until they reach a consensus or with a third reviewer (TA).

Assessment of risk of bias in included studies:

Two reviewers (YN, KF) evaluated the risk of bias independently using the Risk of Bias 2 [13]. Disagreements between the two reviewers were discussed; a third reviewer (TA) acted as an arbiter.

Measures of treatment effects:

Relative risk ratios and 95% confidence intervals (CIs) for binary variables were pooled for the presence of adverse events. The mean or standardized mean differences and the 95% CIs were pooled for the continuous variables (e.g., FI, HR-QOL, and bowel dysfunction after surgery). Adverse events were summarized based on the definition in the original article.

Handling of missing data:

We requested the original authors to retrieve data that were not presented. The intention-to-treat (ITT) analysis was performed for all dichotomous data as much as possible. For continuous data, missing data were not imputed based on the recommendation by Cochrane Handbook [14]. Converted data from available data based on the method in the Cochrane Handbook [14].

Assessment of heterogeneity:

The statistical heterogeneity was evaluated by visual inspection of the forest plots and calculating the I2 statistic. When there was substantial heterogeneity (I2 > 50%), the reason for the heterogeneity was assessed. Cochrane chi-squared test (Q-test) was performed for the I2 statistic, and statistical significance was set at P < 0.10 [15].

Assessment of reporting bias:

We searched the clinical trial registry system (ClinicalTrials.gov and ICTRP) to explore registered but not published trials. The potential publication bias was assessed by visual inspection of the funnel plot. We did not perform an Egger test due to the small sample size.

Meta-analysis:

We used Review Manager software (RevMan 5.4) and employed a random-effects model.

Summary of findings table:

Based on the Cochrane Handbook [14], a table showing the summary of findings was made for FI, HR-QOL, adverse events, and bowel dysfunction after surgery [15]. Corresponding risks were adopted from the median of included trials. The quality of evidence was evaluated based on the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach for each summary of findings.

**Difference between protocol and review**
Due to insufficient data, we could not perform planned subgroup analyses for the following variables: age (<65 vs. >65 years) and concomitant treatment (PFMT only versus PFMT with concomitant therapy). In addition, we were also unable to conduct the intended sensitivity analyses for the primary outcomes: exclusion of studies.

**Results**

We searched 1,876 abstracts (Figure 1). After removing duplicates, we screened 1648 abstracts. During the full-text screening, we excluded six studies due to incorrect population, 11 for incorrect intervention, two for incorrect design, and one for withdrawal (https://osf.io/689wu). We identified seven RCTs [5,6,16-20] that met all the eligibility criteria (Figure 1; Table 1).

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of Participants</th>
<th>Types of surgery</th>
<th>Stoma</th>
<th>Intervention</th>
<th>Controls</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Asnong [5]  | 104                    | TME              | Yes 90(87) No 14(13) | a: One month after restoration of transit  
b: 12 weeks c: consisting of 9 individual treatments during the first 6 weeks once a week and 3 sessions over the last 6 weeks  
d: Assessment and evaluation of bowel symptoms with a stool diary, combined with patient education, biofeedback, electrical stimulation, and rectal balloon training | Did not receive any PFMT                                                 | LARS category LARS score  
COREFO questionnaire NRS regarding the subjective bother of bowel symptoms  
A stool diary (frequency of bowel movements, stool consistency, urgency/incontinence/soiling episodes, fragmentation of stool)  
SF-12 Adverse events                                                     |
| Heijden [6] | 95                     | LAR              | Yes 44(46) ileostomy 42(95) Colostomy 2(5) | a: Within 3 months after LAR or within 6 weeks after stoma closure  
b: 3 months c: NA  
d: Biofeedback, Functional electrostimulation, Rectal balloon training | Usual care (Use of bulking agents, advice on lifestyle, fluid intake, use of fibers, diet, toilet posture.) | Wexner score LARS score FIQL  
EORTC colorectal-specific QoL questionnaire (EORTC-QLQ-CR29) Safety Analysis |
| Lin [16]    | 53                     | LAR              | Yes 53(100) | a: Day before discharge from the hospital  
b: Followed up for 9 months c: 20 contractions and relaxations 4 set/day  
d: Given exercise DVD | Pamphlet of post-surgical care | Wexner scale                                                              |
Bowel frequency  
Fecal incontinence score                                                  |
EORTC Colorectal QoL Questionnaire  
QLQ-CR38 Defecation diary LARS score Perioperative parameters  
Morbidity Mortality                                                       |
| Schiemer [19] | Protocol       | TME              | NA    | a: NA b: 3 months c: 12 times d: PFMT by specialized physiotherapists | no PFMT | LARS score QLQ-C30 score |

**TABLE 1: Characteristics of included studies**

n (%), TME, Total mesorectal excision; LAR, lower anterior resection; Ta-TME, transanal total mesorectal exision; PFMT, pelvic floor muscle training; NA, Not Applicable; LARS, Low anterior resection syndrome; COREFO, Colorectal Functional Outcome Questionnaire; NRS, Numeric Rating Scale; SF-12, Short Form 12; FIQL, Fecal Incontinence Quality of Life Scale; QoL, Quality of life; EORTC, European Organisation for Research and Treatment of Cancer.
The seven RCTs included 252 patients who underwent surgery for colorectal cancer and received PFMT post-operatively. The types of surgery included total mesorectal excision, lower anterior resection, and transanal total mesorectal excision. The duration of the intervention ranged from 3 to 9 months, and the frequency of the intervention ranged from once a week to every day. Patient education, biofeedback, electrical stimulation, and rectal balloon training were included as concomitant treatments for PFMT. Most studies had a high overall risk of bias (Figure 1).

**Primary outcomes**

The evidence suggests that PFMT in patients with colorectal cancer after surgery compared with control has little to no difference in FI (two studies, 148 participants): mean difference (MD) 0.62 higher, 95% CI -1.26 to 2.5; I² = 0%; low certainty evidence (Figures 2A, 3A; Table 2).
HR-QOL was measured in two studies [5,6]. One study used the SF-12, and the other used FIQL, with very low certainty of evidence (Figures 2B, 3B; Table 2). We decided not to perform a meta-analysis on HR-QOL because of heterogeneity. In two studies, there was no trend toward a positive impact on HR-QOL.
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>Nr of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal incontinence (Wexner score)</td>
<td>MD 0.62 higher (1.26 lower to 2.5 higher)</td>
<td>-</td>
<td>148 (2 RCTs)</td>
<td>☐ ☐ ☐ Low^a,b</td>
<td></td>
</tr>
<tr>
<td>HR-QOL (SF-12, FIQL)</td>
<td>not pooled</td>
<td>not pooled</td>
<td>198 (2 RCTs)</td>
<td>☐ ☐ ☐ Very Low^a,b,c</td>
<td>Only two studies reported HR-QOL data and the pooling of data was inappropriate due to heterogeneity of outcome measures. Therefore, individual study results are reported separately.</td>
</tr>
<tr>
<td>Adverse events</td>
<td>0 per 1,000 (0 to 70)</td>
<td>20 per 1,000 (95% CI 0.28 to 117.22)</td>
<td>199 (2 RCTs)</td>
<td>☐ ☐ ☐ Low^a,b</td>
<td></td>
</tr>
<tr>
<td>Bowel dysfunction after surgery (LARS score)</td>
<td>MD 0.16 lower (2.78 lower to 2.47 higher)</td>
<td>-</td>
<td>199 (2 RCTs)</td>
<td>☐ ☐ ☐ Very Low^a,d</td>
<td></td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference; PFMT: pelvic floor muscle training; HR-QOL: Health related Quality of life; SF-12: Short Form 12; FI: Fecal Incontinence related Quality of Life; LARS: Low anterior resection syndrome


**TABLE 2: Summary of findings: PFMT compared to control for health problem in colorectal cancer**

PFMT may result in little to no difference in adverse events (two studies, 199 participants): risk ratio 5.78; 95% CI 0.28 to 117.22; low certainty evidence (Figures 2C, 3C; Table 2). No serious adverse events were reported [5,6]. Two PFMT patients (anastomotic stricture, suboptimal laxative use) were referred to the outpatient clinic [6].

**Secondary outcome**

The effect of PFMT in patients with colorectal cancer after surgery is uncertain on bowel dysfunction after surgery (two studies, 199 participants): SMD, -0.16; 95% CI -0.24 to 2.47; I^2 = 0%; very low certainty evidence (Figures 2D, 3D; Table 2).

**Discussion**

To the best of our knowledge, this is the first SR and meta-analysis of RCT of PFMT in patients following colorectal cancer surgery. We employed a rigorous methodology, adhering to a previously established written protocol based on the PRISMA 2020 statement, and included an extensive search for supporting data. Our SR included seven trials that included 252 patients. PFMT was utilized either alone [16] or in combination with biofeedback, electrical stimulation, and rectal balloon training [5,6]. The follow-up period extended from 3 to 9 months from the initiation of the intervention. Our SR revealed that PFMT following surgery for colorectal cancer is unlikely to result in a no or trivial difference in FI. It is also unlikely to lead to an increase in adverse events. Moreover, the results on HR-QOL in the reviewed studies were inconsistent.

The results of the meta-analysis, including the RCT in this SR, show that there are still many unknowns about PFMT for postoperative patients with colorectal cancer. The available evidence suggests that PFMT in patients with colorectal cancer after surgery results in little to no difference in FI. A previous SR that did...
not include RCTs showed that pelvic floor muscle rehabilitation after anterior resection of colorectal cancer is potentially beneficial [4]. Another SR has shown that PFMT is effective for bowel dysfunction but has incorporated quasi-RCTs and RCTs [21]. The results of our review, which included only RCTs, revealed that despite a multi-month intervention, ranging from 3 to 9 months, no clear benefits were achieved. Therefore, further RCTs are necessary, as well as interventions over a longer period of time than the intervention period of the studies included in this review.

PFMT in patients with colorectal cancer after surgery may result in little to no difference in adverse events. Treatment options for FI following colorectal cancer surgery include medications, fiber supplements, PFMT, and sacral nerve stimulator implantation (SNS) [22]. In our review, we found that initiating PFMT 3 months after low anterior resection (LAR) or 4-6 weeks after stoma closure did not lead to any serious adverse events. In our SR, adverse events in 99 patients who underwent PFMT were anastomotic stenosis (one case, 1%) and inappropriate laxative use (one case, 1%). Sacral nerve stimulator implantation (SNS) is one of the treatments for FI [22], and complications in 665 patients undergoing SNS included pain or local discomfort (57 cases, 6%), lead displacement or breakage (26 cases, 4%), and infection (22 cases, 3%) [23]. PFMT may be considered for FI after colorectal cancer surgery because of its low adverse events rate.

Our study has two limitations. The outcomes based on only RCTs in our SRMA had a low to very low certainty of the evidence, which indicates a need for higher-quality RCT to provide more robust and reliable findings. Our SR identified a notable gap in the reporting of HR-QOL outcomes in studies involving PFMT in colorectal cancer patients following surgery. Expert opinion on the core information set for colorectal cancer surgery highlights the importance of assessing the quality of life, including aspects such as physical and sexual functioning, FI, and urgency [24]. Furthermore, this finding underscores the necessity for conducting RCT with HR-QOL outcomes that specifically focus on evaluating physical and sexual functioning, FI, and the sense of urgency in this patient population. In addition, our review also revealed a lack of clarity regarding the optimal duration and frequency of interventions. Addressing this knowledge gap, we need to specifically investigate the most effective and appropriate duration and frequency of PFMT intervention in postoperative colorectal cancer patients and plan future RCTs that incorporate HR-QOL as an outcome.

In conclusion, the findings of the SR suggest that PFMT has little to no trivial difference in impact on improving FI and is associated with fewer adverse events. Our review emphasizes the importance of conducting high-quality RCT to address the limitations and uncertainties regarding the optimal duration and frequency of PFMT interventions. Furthermore, extending the duration of the PFMT intervention would be necessary to ensure its success.

Conclusions

In conclusion, the findings of the SR suggest that PFMT has little to no trivial difference in impact on improving FI and is associated with fewer adverse events. Our review emphasizes the importance of conducting high-quality RCT to address the limitations and uncertainties regarding the optimal duration and frequency of PFMT interventions. Furthermore, extending the duration of the PFMT intervention would be necessary to ensure its success.

Additional Information

Disclosures

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

References


