

ORIGINAL RESEARCH

# Improvement of Fecal Incontinence and Quality of Life by Electrical Stimulation and Biofeedback for Patients With Low Rectal Cancer After Intersphincteric Resection



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## Abstract

**Objective:** To assess the efficacy and benefits of pelvic rehabilitation programs in terms of functional outcomes and quality of life for patients with fecal incontinence and defecation disorders after rectal cancer surgery.

**Design:** Prospective, observational study.

**Setting:** University hospital physiotherapy clinics.

**Participants:** Patients (N=32) who experienced fecal incontinence after sphincter-saving surgery with the intersphincteric resection (ISR) technique and could follow and cooperate with the treatment schedule were included in the present study.

**Interventions:** Pelvic rehabilitation programs included electrical stimulation (ES) and biofeedback (BF).

**Main Outcome Measures:** Functional results, Wexner score, and anorectal manometry were used to assess the clinical outcomes of rehabilitation treatment.

**Results:** Maximum squeeze pressure improved after rehabilitation training ( $P=.014$ ). There were no statistical differences in resting pressure, resting muscle electromyography, and maximum squeeze electromyography ( $P=.061$ ,  $P=.76$ , and  $P=.99$ , respectively). The mean stool frequency was 18.8 per 24 hours before the pelvic intervention program and 7.8 per 24 hours after ES and BF training ( $P<.001$ ). Of the 32 patients, 27 required antidiarrheal medications before treatment, and after completion of the training, only 9 patients still needed antidiarrheal medications ( $P<.001$ ). Significant improvements were observed in the Wexner score (17.74 vs 12.93;  $P<.001$ ).

**Conclusions:** Our data show that ES and BF are effective in the treatment of fecal incontinence, leading to improvement of quality of life for patients with low rectal cancer after ISR.

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Colorectal cancer is the third most commonly diagnosed cancer in the world.<sup>1</sup> In 2008, approximately 1.23 million new cases of colorectal cancer were diagnosed and approximately 608,000 people died of this malignant neoplasm worldwide. In Taiwan,

colorectal cancer is the most frequently diagnosed malignant neoplasm and the third leading cause of cancer death for both men and women.<sup>2</sup> Approximately 50% to 60% of rectal carcinomas are considered locally advanced rectal cancers, which are characterized with high incidence of systemic and local recurrence and low

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possibility of long-term survival.<sup>3</sup> Preoperative chemoradiation therapy (CRT) has been shown to increase probability of tumor respectability, improve sphincter preservation rates, decrease incidence of local recurrence, and improve survival.<sup>4</sup> Even with significant advances in multimodality therapy, sphincter preservation still remains a surgical challenge for patients with low-lying rectal tumors. Intersphincteric resection (ISR) is the ultimate surgical technique for increasing sphincter preservation by achieving greater distal resection margins for patients with low-lying rectal cancers.<sup>5</sup> Nevertheless, neoadjuvant CRT and partial or complete resection of the internal anal sphincter, may result in defecatory dysfunction.<sup>6</sup> Therefore, the functional outcomes for patients after surgery remain an important issue.<sup>7-9</sup>

According to recent studies, approximately 25% to 77% of patients confront defecation dysfunction and fecal incontinence after surgery.<sup>10-14</sup> Neuromuscular electrical stimulation (NMES) and biofeedback (BF) have been used to facilitate more muscle recruitment and sensory reeducation,<sup>15-17</sup> demonstrating benefits for genuine stress urinary incontinence and severe urinary incontinence after radical prostatectomy.<sup>15,18</sup> So far, little well-controlled research has been conducted to investigate the effects of these modalities on patients after ISR. The aim of this study is to assess the efficacy and the functional results of combined NMES and BF and the impact on the quality of life (QOL) for patients with fecal incontinence and defecation disorders after sphincter saving surgery.

## Methods

Radical proctectomy with the ISR technique was performed in patients with low rectal cancer, which showed no external sphincter or levator ani muscle invasion. Patients who experienced frequent defecation, urgency, incomplete evacuation, stool fragmentation, or uncontrolled loss of stool after sphincter-saving surgery with the ISR technique were selected to undergo the present rehabilitation training program. Patients were excluded if they had the following conditions: anorectal injury after surgery or secondary wounds of the anus (eg, excoriated and weeping skin detected by physical examination); local recurrence or distant metastasis in the follow-up period; neurologic disorders, which may alter sensory and motor performances; and contraindications of electrical therapy (eg, pregnancy, with a demand-type implanted cardiac pacemaker or defibrillator, or seizure history). From December 2013 through August 2014, patients who underwent sphincter-saving surgery with the ISR technique and returned for follow-up at the outpatient department were informed of this rehabilitation program. Patients who could follow and cooperate with the treatment schedule were enrolled in the present study. Informed consent was obtained from all patients. This study was approved by the Joint Institutional Review Board of Taipei Medical University (TMU-JIRB No. 201310019).

### List of abbreviations:

<b>BF</b>	<b>biofeedback</b>
<b>CRT</b>	<b>chemoradiation therapy</b>
<b>ES</b>	<b>electrical stimulation</b>
<b>ISR</b>	<b>intersphincteric resection</b>
<b>NMES</b>	<b>neuromuscular electrical stimulation</b>
<b>QOL</b>	<b>quality of life</b>

## Rectal cancer treatment

Patients with biopsy-proven adenocarcinoma and with a T3-4 rectal tumor and/or positive lymph nodes staged by pelvic magnetic resonance imaging were treated with CRT first for 5 weeks, followed by radical surgical resection. Either laparoscopic procedure or robot-assisted surgery was performed. Diverting colostomy after total mesorectal excision is not routinely used and is only used in select cases in our daily practice. Patients with primary tumor, regional lymph nodes, and distant metastasis stage II or stage III tumors received postoperative adjuvant systemic chemotherapy with 5-fluorouracil, leucovorin, oxaliplatin, or a combination of other drugs for  $\geq 6$  months.

## Clinical evaluation and anorectal manometry

Patients were evaluated by 2 physiotherapists at 2 stages: an initial assessment and 3 months after initial evaluation, respectively. The functional outcomes were assessed for patients' stool frequency, urgency, stool discrimination, abnormal evacuation, stool fragmentation, clustered defecation, use of antidiarrheal medication, and whether the patient was wearing a pad or not. Incontinence was assessed by using the patient-reported Cleveland Clinic Florida fecal incontinence grading scale, proposed by Jorge and Wexner,<sup>19</sup> which reflects fecal incontinence QOL. Five items were evaluated, including accident of solid/liquid, gas escape, pad dependency, and lifestyle alteration. According to previous studies, patients' fecal incontinence QOL and clinical outcomes were significantly correlated with the Wexner score.<sup>19,20</sup> Responsiveness, construct validity, and minimally clinical important changes also have been reported.<sup>21</sup>

Patients were given an anorectal manometry test at the beginning of and after evaluation during rehabilitation training. Patients were positioned in the left lateral recumbent position. The measuring probes used included a pressure-sensitive manometry catheter and a solid-state manometry catheter (Anuform),<sup>a</sup> which were connected to the instrument (Myomed 932<sup>a</sup>). Parameters measured were as follows: resting pressure after ISR, maximum squeeze pressure, resting muscle electromyography, and maximum squeeze electromyography. The instrument quantified the amplitude in hectopascals. Both manometry and surface electrodes are most commonly used because of their high sensitivity to the perineal region in clinical uses.<sup>22</sup>

## Neuromuscular electrical stimulation

NMES of the anal sphincter muscle was performed 2 to 3 times weekly for a total of 12 treatment sessions. NMES was performed using the same manometry catheter (Anuform), which was placed into the anal canal for 20 minutes during each treatment session. Neuromuscular stimulation was applied through 2 approaches. The primarily used method was the endoanal method, and the other method was the external approach, which was used only if the patient could not tolerate the endoanal method. The device delivered a square wave; ramp up and down time were set for 2 seconds; duration was 8 seconds; frequency was 30Hz; on/off time was 1:3; and pulse duration was 300 $\mu$ s. The goals of the NMES were muscle reeducation and isolation of muscle contraction.<sup>23-28</sup>

## Biofeedback

Instrument-assisted BF was executed after completion of NMES training for 12 sessions. Each subject attended 2 or 3 treatment

sessions per week, on alternate days, during 2 to 3 consecutive months. The target threshold ( $\mu\text{V}$ ) of the patient was first identified, and then he/she was instructed to squeeze and hold a sphincter muscle contraction for 30 to 40 seconds. The purpose of BF is to improve the coordination of the pelvic floor muscles during voluntary contraction and the defecatory perception of the rectum.<sup>26-29</sup>

## Statistical analysis

A paired *t* test was used to compare the resting pressure, maximum squeeze pressure, resting electromyography, maximum squeeze electromyography, stool frequency, and incontinence before and after treatment. To determine if the functional outcome improved, an exact McNemar test was conducted to compare the proportions for 2 dependent samples. All inferential statistics were considered statistically significant when the 2-sided *P* value was less than the significance level of .05. Statistical analyses were done using SAS version 9.3.<sup>b</sup>

## Results

Between November 2009 and December 2013, 85 patients with very low rectal malignancy received a sphincter-saving operation by the ISR technique with hand-sewn coloanal anastomosis. There were 31 patients who received a laparoscopic procedure, and 54 patients had robot-assisted surgery. Thirty-two patients were included in the present study. The demographic characteristics of the patients are listed in table 1. There were 15 women (46.9%) and 17 men (53.1%), with a mean age of 56.5 years (range, 31–70y). The average body mass index was 23.32kg/m<sup>2</sup>. The mean distance from the anal verge to the lowest border of the tumor was 3.89cm (range, 1.5–5cm). Of the patients, 25 (78.1%) received neoadjuvant CRT followed by surgery. Five out of the 32 patients received diverting stoma after surgery. The median time of stoma closure was 7 (range, 3–8) months, and the median time interval between surgery and the pelvic rehabilitation programs was 246±394 days.

## Anal sphincter pressure and electromyography

Table 2 demonstrates the clinical results of anorectal manometry and electromyography before and after NMES and BF. Maximum squeeze pressure improved significantly after rehabilitation training (*P*=.014). There were no statistical differences in resting pressure, resting electromyography, and maximum squeeze electromyography (*P*=.061, *P*=.76, and *P*=.99, respectively).

## Functional results and QOL

Table 3 presents the functional outcomes and Wexner score (continence function) of NMES and BF treatment in patients with defecatory disorders. The mean stool frequency was 18.8 per 24 hours before the pelvic intervention program and 7.8 per 24 hours after NMES and BF training (*P*<.001). Before treatment, 27 of the 32 patients required anti-diarrheal medications, and after completion of the training, only 9 patients still needed anti-diarrheal medications (*P*<.001). Thirty-one patients (96.9%) had stool fragmentation before treatment, and 24 patients (75%) had this symptom after rehabilitation training, with significant improvement (*P*=.016). In baseline, 93.8% of the patients suffered urgency, 90.6% needed pad wearing, and 28.1% had nocturnal defecation. Although there were no statistical differences after rehabilitation (*P*=.063, *P*>.99, and *P*=.125, respectively),

**Table 1** Demographic characteristics of patients post-ISR with rehabilitation

Characteristic	Value (N=32)
Age (y)	56.5 (31–70)
Sex (female:male)	15:17
Distance from anal verge (cm)	3.89 (1.5–5.0)
BMI (kg/m <sup>2</sup> )	23.32 (18.78–30.26)
Preoperative chemoradiation	
No	7
Yes	25
Histopathology	
Adenocarcinoma	30
Neuroendocrine tumor	2
Initial stage	
Stage I	3
T2 N1	2
T2 N2	1
T3 N0	6
T3 N1	12
T3 N2	5
Stage IV	1
Operative method	
Laparoscopic ISR	4
Robotic ISR	28
Protective stoma	
No	27
Yes	5
ASA class	
I	1
II	30
III	1

NOTE. Values are mean (range) or n.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; N, regional lymph nodes; T, primary tumor.

significant improvements were observed in the Wexner score (17.74 vs 12.93, *P*<.001).

## Discussion

More than 75% of patients receiving radical proctectomy and sphincter-saving surgery experience anorectal symptoms and defecatory disorders to some extent.<sup>10-14</sup> These dysfunctions may result from irradiation effects on the anal sphincter, dysfunctional pelvic floor, and anal sphincter muscle after operation, autonomic nerve insult during operation, anatomic changes of the reservoir, adjuvant treatment, food intake, physical condition, or time interval after surgery.<sup>6,13-16</sup> The first-line treatment for fecal incontinence is dietary education and solidifying liquid stools with medications. Various modalities of pelvic floor muscle rehabilitation, including Kegel exercises with or without NMES and BF, have recently been investigated. Such modalities could potentially improve the strength and coordination of sphincter muscles.<sup>30</sup> Healy et al<sup>23</sup> studied a series of 24 patients with fecal incontinence treated with low-frequency endoanal electrical stimulation (ES). According to their findings, both continence scores and manometric values improved significantly after treatment. In the study of Schwandner et al,<sup>31</sup> the authors concluded that the combination of amplitude-modulated medium-frequency ES with BF can improve anal continence. A Cochrane systematic review of

**Table 2** Anorectal manometry and EMG before and after rehabilitation training

Anorectal physiology	Pretreatment	Posttreatment	P
Resting pressure (hPa)	-4.21±7.29	-4.08±3.80	.061
Maximal squeeze pressure (hPa)	34.32±35.37	37.08±22.42	.014*
Resting EMG (hPa)	-0.47±2.21	-0.58±5.67	.760
Maximal squeeze EMG (hPa)	28.37±16.75	30.79±16.00	.990

NOTE. Values are mean ± SD or as otherwise indicated.

Abbreviation: EMG, electromyography.

\*  $P < .05$ ; significant difference before and after rehabilitation training.

randomized controlled trials showed that BF with pelvic exercises is better than exercises alone; in addition, BF plus ES is better than ES alone for the treatment of fecal incontinence.<sup>32</sup> Naimy et al<sup>33</sup> found dissimilar results. In their series of 40 women who sustained third-degree or fourth-degree perineal rupture with post-delivery anal incontinence, they concluded that neither BF nor ES treatments improved Wexner incontinence scores, reduced QOL, or reduced fecal incontinence QOL scores. Both treatments resulted in improvement of patients' subjective perception of incontinence control. In the present study, after the NMES and BF rehabilitation program training, there was significant improvement in squeeze pressure and improved bowel control and fecal incontinence QOL.<sup>20,23-26</sup>

Improved continence function (reduced fecal frequency) could result from increased squeeze pressure and muscular strength of the external sphincter muscle. Smith and Blatchford<sup>34</sup> concluded that squeeze pressure is mainly a measure of the external sphincter muscle. This improvement could contribute to several components. First, electrical stimulus improves muscle strength and increases amplitude of voluntary contraction by stimulating the hypertrophy and hyperplasia of the external sphincter muscle fiber.<sup>35</sup> Furthermore, passive exercise of the sphincter muscle teaches patients body awareness, which can help to correct and achieve good muscle recruitment.<sup>23-25</sup> The findings of this study also suggest that passive and active exercise activate the whole pelvic muscle group. On the other hand, approximately 50% to

**Table 3** Functional results and Wexner score before and after rehabilitation training

Parameter	Pretreatment	Posttreatment	P
Stool frequency per 24h	18.77±8.51	7.83±4.27	<.001*
Urgency	30 (93.8)	25 (78.1)	.063
Stool fragmentation	31 (96.9)	24 (75.0)	.016*
Nocturnal defecation	9 (28.1)	6 (18.8)	.125
Pad wearing	29 (90.6)	28 (87.5)	>.999
Antidiarrheal medications	27 (84.4)	9 (28.1)	<.001*
Wexner score	17.74±3.03	12.93±4.73	<.001*

NOTE. Values are mean ± SD, n (%), or as otherwise indicated. Stool frequency per 24 hours and Wexner score were compared with paired *t* tests. Urgency, stool fragmentation, nocturnal defecation, pad wearing, and antidiarrheal medications were compared with exact McNemar tests.

\*  $P < .05$ ; significant difference of functional outcomes and the quality of life before and after rehabilitation training.

85% of the resting pressure is contributed by the internal anal sphincter.<sup>36</sup> Partial or complete resection of the internal anal sphincter during operation may explain why we found no statistical difference in resting pressure for patients after NMES and BF training.

This study showed no significant improvements in resting and squeeze electromyography. Electromyography, which is used to measure the electrical activity of the skeletal muscle, may represent the result of voluntary pelvic floor contraction. Bø and Sherburn recommended that clinicians must be cautious about using electromyography data as an absolute measurement of muscle strength because there is no linear correlation between electromyography and muscle strength.<sup>22</sup> In general, numbers and the activating amplitude of motor units increase in correlation with the increase of muscle strength. Nevertheless, Bø and Sherburn concluded that the amplitude of motor units vary within and between individuals, which indicates that electromyography data does not totally represent muscle strength. Moreover, the Ammann et al<sup>37</sup> study concluded that fibrosis of the anal sphincter and the pudendal nerves as a result of pelvic irradiation may contribute to the diminished and inconsistent firing characteristics of the pelvic floor muscle. Furthermore, surface electromyography could be influenced by either cross-talk from other pelvic floor muscles or inability to track other pelvic floor muscles.

In our study, the mean stool frequency was 18.77 per 24 hours before the rehabilitation program and 7.8 per 24 hours after NMES and BF training. In a previously published series, the mean stool frequency ranged from 2.2 to 3.7 per 24 hours.<sup>38</sup> The difference may be caused by whether or not neoadjuvant CRT was performed and the distribution of various patients. Yamada et al<sup>39</sup> reported that neither preoperative radiotherapy nor chemotherapy was performed for a series of 107 patients after ISR. In a report by Chamlou et al,<sup>12</sup> more than half of the patients had a T1 or T2 tumor. Saito et al<sup>40</sup> reported a series of 228 patients with very low rectal cancer receiving ISR; only one fourth of the patients received preoperative CRT. In the present study, 78.1% of patients received preoperative CRT. Although CRT improves local control for rectal cancer treatment, patients have been reported to have significantly more incontinence symptoms and worse anorectal function than patients treated with surgery alone. Canda et al<sup>41</sup> observed significant reductions in anal canal resting pressures and squeeze pressures, Wexner score, and fecal incontinence QOL score immediately after the completion of preoperative CRT. The Ito et al study<sup>42</sup> demonstrated that preoperative CRT was the only independent factor associated with poor anal function after ISR. In a recent meta-analysis study of the effect of preoperative CRT on long-term functional outcome in patients with rectal cancer, Loos et al<sup>43</sup> stated that stool incontinence occurred more often in irradiated patients, and mean resting pressures and maximum squeeze pressures were significantly worse after CRT. These effects may contribute to the morphologic alterations in the irradiated anal sphincter and neurologic damage of the anorectum. Nishizawa et al<sup>44</sup> suggested that chemoradiation induces marked neural degeneration around the rectal tumor, which may induce severe anal dysfunction after surgery. Da Silva et al<sup>45</sup> concluded that pelvic irradiation damages the nerve plexus and increases collagen deposition, which may interfere with anorectal function and reduce rectal capacity. Ammann<sup>37</sup> pointed out that pelvic irradiation induces anal sphincter and pudendal nerves fibrosis, which may partially explain the decrease of resting pressure and maximum squeeze pressure, the increase in the number of

defecations and the frequency of tenesmus, and the impairment of anorectal function and increase of gastrointestinal symptoms.

Another important issue is the time at which a pelvic rehabilitation program should start. In a report by Pucciani et al,<sup>25</sup> the authors concluded that patients had significant improvements in rehabilitation of fecal incontinence after 22.4 months from sphincter-saving surgery. Laforest et al<sup>7</sup> showed significant effects of rehabilitation programs for laparoscopic sphincter-saving total mesorectal excision cases after 21.2 months. Kim et al<sup>46</sup> concluded that patients who begin BF therapy  $\geq 18$  months after surgery have greater improvement in fecal incontinence than patients who start BF therapy  $< 18$  months after surgery. Nevertheless, it has been reported that the symptoms of anterior resection syndrome (eg, changes in bowel habits), ranging from increased bowel frequency to fecal incontinence, or evacuatory dysfunction, improve gradually during the first 2 years after operation, indicating that patients who have undergone sphincter-saving procedures need sufficient time for natural adaptation of the irradiated pelvis and the neorectum. So far, there is no definite timing for clinicians to decide when the patients should join the rehabilitation programs, therefore making it difficult to distinguish natural recovery and training effects. Our prior experience revealed that patients may have several anorectal disorders after ISR procedures (eg, swelling and painful hemorrhoid tissue, frequent stool passage-induced excoriated, weeping perianal skin). Clinical observation showed that these disorders improved an average of 3 months after surgery. Furthermore, patients with primary tumor, regional lymph nodes, and distant metastasis stage II or stage III tumors received postoperative adjuvant systemic chemotherapy for  $\geq 6$  months. In the present study, the median time interval between surgery and the pelvic rehabilitation programs was  $246 \pm 394$  days. Therefore, it is suggested that the optimal waiting period after surgery should be 10 months before the pelvic rehabilitation programs start, and patients should participate in therapeutic programs longer than 2 to 3 months to achieve the most effective results. At the same time, we demonstrated that patients could shorten the period of functional impairment and get even earlier recovery if they receive timely rehabilitation interventions.

### Study limitations

This study was limited for its nonrandomized design and its small sample. The time between surgery and the start of rehabilitation varied greatly in this study.

### Conclusions

Our data show that NMES plus BF effectively improves both functional results and QOL for patients undergoing sphincter-saving rectal cancer resection. Large prospective randomized trials are needed to assess the long-term functional outcomes and clarify and standardize the result of pelvic rehabilitation programs.

### Suppliers

- a. Myomed 932; Enraf Nonius International.
- b. SAS version 9.3; SAS Institute.

### Keywords

Electric stimulation; Fecal incontinence; Rectal neoplasms; Rehabilitation

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