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Risk Factors for Persistent Anal Incontinence After Restorative Proctectomy in Rectal Cancer Patients with Anal Incontinence: Prospective Cohort Study

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Abstract
Background This study evaluated the notion that preoperative anal incontinence might be a potent predictive factor for anal incontinence (AI) after restorative proctectomy in rectal cancer patients. The principal objective of this study was to determine the risk factors for persistent anal incontinence following restorative proctectomy.
Methods This study was designed as a single-center, prospective cohort study of a single group of 93 patients who had AI before restorative proctectomy for rectal cancer. The study group was re-evaluated for the presence of AI 12 months after restorative proctectomy or ileostomy takedown. Incontinence severity was determined using the Fecal Incontinence Severity Index (FISI). Logistic regression analysis was performed to identify the clinicopathologic factors associated with persistent AI.
Results Fifteen patients were excluded from analysis due to death within the 12 months after surgery ($n = 7$), no ileostomy repair ($n = 5$), loss to follow-up ($n = 2$), or previous treatment for anal incontinence ($n = 1$). At 12 months, 53 of 78 patients (67.9%) had persistent AI and 25 patients (32.1 %) had recovered. Multivariate analysis demonstrated that preoperative FISI scores higher than 30 (OR = 11.61, 95% CI 1.43-94.01, $p = 0.022$) and lower tumor location 5 cm or less from the anal verge (OR = 84.46, 95% CI 3.91-1822.85, $p = 0.005$) were independent factors for persistent AI.
Conclusions Anal incontinence may persist after restorative proctectomy in rectal cancer patients with high preoperative incontinence scores and lower tumor location. Therefore, this information should be provided when restorative proctectomy is offered for rectal cancer patients.

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Introduction

Sphincter preservation has been the primary concern in the treatment of rectal cancer because the quality of life in patients who underwent abdominoperineal resection (APR) tends to be poorer than in patients who had sphincter preservation [1], although the evidence gleaned thus far from comparative studies has been a matter of some controversy [2, 3]. However, the rate of newly developed anal incontinence after restorative proctectomy has been reported to be approximately 21–78% [4–7]. Unexpectedly, several studies regarding quality of life after rectal cancer surgery have shown that stoma patients evidenced superior social functioning and better quality-of-life outcomes than sphincter-preserved patients [3, 8]. Restorative proctectomy may reflect suboptimal treatment if their anorectal function is poor despite an adequate oncological outcome, and a subgroup of patients with permanent stoma may enjoy better outcomes in comparison with anal dysfunction [3].

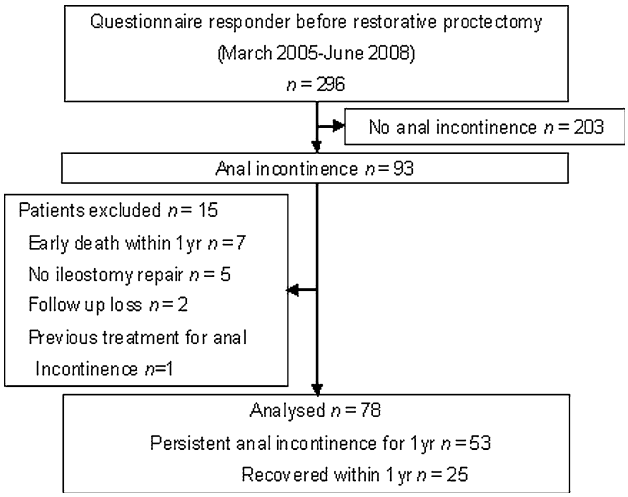

Fig. 1 Study design

Restorative proctectomy may involve dysfunction of the internal anal sphincter and the deterioration of reservoir function, and it may induce low anterior resection syndrome [7, 9], which is characterized by urgent defecation, frequency, loss of discrimination between gas and solid, and even anal incontinence. In certain patients, these anorectal dysfunctions may persist over the long-term. Postoperative anal incontinence is multifactorially related to age [10], reconstructive methods with colonic J pouch or straight anastomosis [11], tumor height [12], anastomotic height [13], anastomotic leakage [14], preoperative chemoradiotherapy (PCRT) [7, 15], excessive blood loss [12], presence of preoperative anal incontinence [16], and perioperative damage to pelvic floor innervation [16]. However, there is no consensus in previous studies regarding risk factors associated with postoperative anal incontinence.

In an effort to identify risk factors for anal incontinence after restorative proctectomy, this study evaluated the notion that preoperative anal incontinence might be a potent predictive factor for postoperative anal incontinence. The principal objective of this study was to determine the risk factors for persistent anal incontinence following restorative proctectomy in rectal cancer patients with preoperative anal incontinence.

Patients and methods

Patients

This study was designed as a single-center, prospective cohort study of a single patient group who had anal incontinence before undergoing restorative proctectomy for rectal cancer from March 2005 to June 2008. Preoperatively, all patients completed questionnaires via individual interviews and were assessed for the presence of anal incontinence. Rectal cancer patients with preoperative anal incontinence were re-evaluated for the presence of anal incontinence 12 months after restorative proctectomy, or ileostomy takedown in patients who had undergone ileostomies. This study was approved by the Institutional Review Board of the Seoul National University Bundang Hospital (B-0910-086-109).

Rectal cancer was defined as a tumor located within 15 cm from the anal verge, as measured by the use of a rigid rectoscope: ≤5 cm from the anal verge is low rectum, >5 cm but ≤10 cm is mid rectum, and >10 cm but ≤15 cm is high rectum. Twenty-one rectal adenocarcinomas that were 9 cm or less from the anal verge, which were clinically diagnosed as cT3, N0–2 lesions without distant metastasis based on pelvic computed tomography, transanal ultrasonography, and magnetic resonance imaging (MRI), were treated with PCRT. In accordance with our protocols, the patients were treated with a dose of 5,040 cGy of radiotherapy over 5 weeks (28 fractions), coupled with chemotherapy with 5-fluorouracil/leucovorin or capecitabine. The surgical procedure was conducted 6–8 weeks after the completion of PCRT. Our operative procedure has been described previously [17, 18].

Questionnaire and anorectal manometry

Anal incontinence is defined as the uncontrolled passage of flatus, liquid, or solid stool. An anal incontinence severity score was determined using the Korean version of FISI (Fecal Incontinence Severity Index) [19] via patient ratings. Serial tests of anorectal function via manometry were conducted preoperatively and 12 months after restorative proctectomy or

Table 1 Frequency according to types of incontinence

Type of incontinence	Frequency of incontinence during past month					
	≥2/day	1/day	≥2/week	1/week	1–3/month	Never[a]
Gas	41 (52.6%)	4 (5.1%)	3 (3.8%)	2 (2.6%)	5 (6.4%)	23 (29.5%)
Mucus	10 (12.8%)	3 (3.8%)	0 (0.0%)	2 (2.6%)	9 (11.5%)	54 (69.2%)
Liquid stool	18 (23.1%)	5 (6.4%)	7 (9.0%)	5 (6.4%)	10 (12.8%)	33 (42.3%)
Solid stool	7 (9.0%)	4 (5.1%)	8 (10.3%)	2 (2.6%)	8 (10.3%)	49 (62.8%)

[a] Defined as "never" if it occurred less than once per month

Table 2 Univariate analysis for persistent anal incontinence

	Persistent AI ($n = 53$)	Recovered AI (n = 25)	p
Age (years)	59.7 ± 11.0	64.6 ± 9.2	0.059
Gender			
Male	32 (60.4)	16 (64.0)	0.759
Female	21 (39.6)	9 (36.0)	
Body mass index (kg/m^2)	23.7 ± 3.0	24.2 ± 3.8	0.514
History of anal surgery			
No	48 (90.6)	22 (88.0)	0.706
Yes	5 (9.4)	3 (12.0)	
Preoperative CEA level	16.0 ± 33.1	5.9 ± 9.3	0.463
PCRT			
No	35 (66.0)	22 (88.0)	0.041
Yes	18 (34.0)	3 (12.0)	
Tumor height			
Low rectum	19 (35.8)	1 (4.0)	0.003
Mid rectum	25 (47.2)	13 (52.0)	
High rectum	9 (17.0)	11 (44.0)	
Preoperative FISI group			
≤30	30 (56.6)	22 (88.0)	0.006
>30	23 (43.4)	3 (12.0)	
Approach methods			
Open	31 (58.5)	11 (44.0)	0.231
Laparoscopy	22 (41.5)	14 (56.0)	
Anastomotic technique			
Handsewn	7 (13.2)	2 (8.0)	0.710
Double stapling	46 (86.8)	23 (92.0)	
Operative methods			
Low anterior resection	50 (94.3)	25 (100.0)	0.547
Intersphincteric resection	3 (5.7)	0 (0.0)	
Anastomotic height (cm)	4.1 ± 3.0	7.3 ± 3.0	<0.001
Estimated blood loss (ml)	317.0 ± 296.5	223.2 ± 189.6	0.207
Diverting ileostomy			
No	25 (47.2)	20 (80.0)	0.006
Yes	28 (52.8)	5 (20.0)	
Tumor gross type			
Polypoid	6 (11.3)	3 (12.0)	0.183
Ulcerofungating	28 (52.8)	18 (72.0)	
Ulceroinfiltrative	19 (35.8)	4 (16.0)	
Tumor differentiation			
Well	3 (5.7)	1 (4.0)	0.071
Moderate	49 (92.5)	20 (80.0)	
Poorly	1 (1.9)	3 (12.0)	
Others[a]	0 (0.0)	1 (4.0)	
Tumor size (cm)[b]	5.1 ± 2.5	5.4 ± 1.7	0.262
TNM stage			
0 or I	15 (28.3)	3 (12.0)	0.197
II	10 (18.9)	8 (32.0)	
III	19 (35.8)	12 (48.0)	
IV	9 (17.0)	2 (8.0)	

Table 2 continued

	Persistent AI ($n = 53$)	Recovered AI (n = 25)	p
Anastomotic leak			
No	52 (98.1)	24 (96.0)	0.541
Yes	1 (1.9)	1 (4.0)	

Values in parentheses are percentage unless indicated otherwise

AI Anal incontinence; *PCRT* preoperative chemoradiotherapy; *FISI* Fecal Incontinence Severity Index; *CEA* carcinoembryonic serum antigen level; *TNM* Tumor (T), Node (N), Metastasis (M) system according to AJCC stage

[a] Others included mucinous and undifferentiated types

[b] Greatest tumor diameter

ileostomy takedown. For the patients who underwent PCRT, the initial questionnaire and manometric data obtained before PCRT were used as preoperative values. All anorectal manometries were conducted with the patient in the left-lateral position with the hip flexed at a right angle and were performed in accordance with the water-perfusion technique using an 8-channel Micro Tip catheter (Medtronic, Minneapolis, MN) connected to a perfusion pump. The measured parameters were as follows: mean resting pressure, maximal squeezing pressure, sphincter length, high pressure zone, rectoanal inhibitory reflex, rectal sensation minimal volume, desire to defecate, compliance, and coughing reflex. The anorectal sensation tests were not performed in our hospital after restorative proctectomy after 2007 because of increased risk of bowel perforation [20]. The length of the residual rectum was calculated by subtracting the height of the high-pressure zone from the anastomotic height, which was measured by the rigid rectoscope.

Statistical analysis

All data were analyzed using the SPSS software system version 15.0 (SPSS, Inc., Chicago, IL). Discrete data were expressed numerically (%) unless specified otherwise, and continuous data were expressed as the mean ± standard deviation. Nonparametric methods were utilized in the statistical analyses because the FISI scores and other clinical data were not normally distributed. Univariate analyses with the χ^2 test, Fisher's exact test, or the Mann–Whitney U test were utilized for comparison between persistent anal incontinence and recovered anal incontinence groups. We utilized logistic regression analysis to evaluate independent factors associated with persistent anal incontinence. All statistical tests were two-sided, and $p < 0.05$ was considered to indicate a significant difference.

Results

Among the 337 patients who underwent restorative proctectomy from March 2005 to June 2008, 296 (87.8%) responded to a questionnaire concerning anorectal function prior to restorative proctectomy. Ninety-three (31.4%) had anal incontinence preoperatively; 15 of those patients were excluded from the analysis due to death within 12 months after surgery, no ileostomy takedown, loss to follow-up, and previous treatment for anal incontinence, leaving 78 patients for the final analysis (Fig. 1). Of these, 53 patients (67.9%) had persistent anal incontinence, and 25 patients (32.1 %) had recovered from anal incontinence at 12 months after restorative proctectomy or ileostomy takedown. Frequency according to type of incontinence is presented in Table 1. Complete incontinence for solid stool was observed in 29 patients (37.1%).

Univariate analysis for persistent anal incontinence

General demographic characteristics, pathologic data, and operative data were compared in order to identify risk factors for persistent anal incontinence 12 months, as shown in Table 2. Age, gender, body mass index, preoperative carcinoembryonic antigen serum level, approach method, anastomotic technique, estimated blood loss, tumor gross type, tumor differentiation, tumor size, TNM stage, and anastomotic leak were not found to be associated with persistent anal incontinence. Eight patients had a history of hemorrhoidectomy and one had had a fistulotomy; this history of anal surgery was not associated with incontinence. The mean distance from the anal verge to the inferior margin of the tumor was significantly shorter in the persistent anal incontinence group than in the recovered anal incontinence group (7.4 ± 3.5 vs. 11.0 ± 3.2 cm, $p < 0.001$). Preoperative FISI scores were significantly higher in the persistent anal incontinence group than in the recovered anal incontinence group (25.4 ± 14.6 vs. 17.3 ± 10.1, $p = 0.014$). The majority of patients with FISI scores higher than 30 had not recovered from anal incontinence 12 months after restorative proctectomy or ileostomy takedown (Fig. 2). In the persistent anal incontinence group, FISI scores 12 months after restorative proctectomy or ileostomy takedown did not differ from the

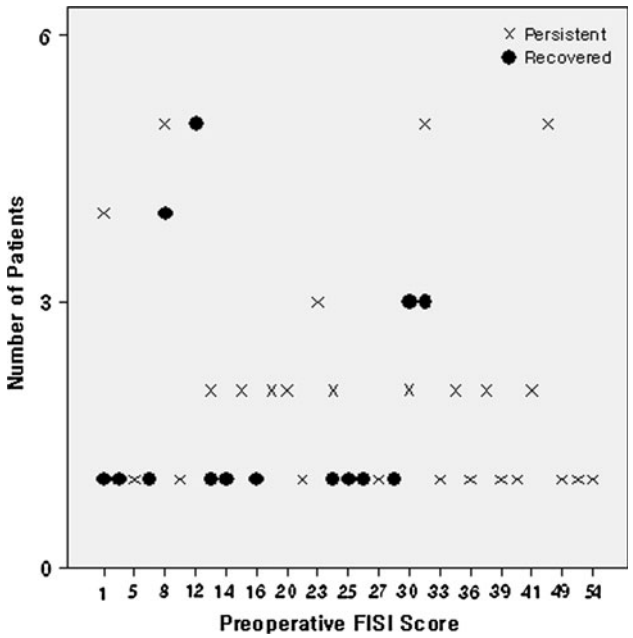

Fig. 2 Distribution of Fecal Incontinence Severity Index scores before restorative proctectomy in rectal cancer patients with preoperative anal incontinence. Persistent anal incontinence ($n = 53$) and recovered anal incontinence ($n = 25$) indicate the presence and disappearance of anal incontinence 12 months after restorative proctectomy, respectively. Most of the rectal cancer patients with preoperative anal incontinence and with a Fecal Incontinence Severity Index score of >30 had not recovered from anal incontinence 12 months after restorative proctectomy

preoperative scores (25.4 ± 14.5 vs. 21.97 ± 11.9, $p = 0.356$). PCRT, anastomotic height from the anal verge, and diverting ileostomy were significant factors for persistent anal incontinence.

Manometric analysis

Before restorative proctectomy, no differences in manometric variables were noted between the persistent anal incontinence and recovered anal incontinence groups (Table 3). However, 12 months after restorative proctectomy, the mean resting pressure was significantly lower in the persistent anal incontinence group than in the recovered anal incontinence group (26.8 ± 17.2 vs. 42.4 ± 20.7 mmHg, $p = 0.020$), although the other manometric variables did not differ between the groups. Residual rectal length was longer in the recovered anal incontinence group than in the persistent anal incontinence group (4.78 ± 2.57 vs. 1.71 ± 3.01 cm, $p = 0.002$).

Multivariate analysis for risk factors

Anastomotic height, anastomotic technique, operative method, and diverting ileostomy were not included in the multivariate analysis for risk factors because they were highly correlated with tumor height (correlation coefficient >0.6) (Table 4). In the rectal cancer patients with preoperative anal incontinence, preoperative incontinence scores higher than 30 (OR = 11.61, 95% CI 1.43-94.01, $p = 0.022$) and lower tumor location 5 cm or less from the anal verge (OR = 84.46, 95% CI 3.91-1822.85, $p = 0.005$) were independent factors for persistent anal incontinence.

Discussion

In the current study, it was noted that high preoperative FISI scores of over 30 and lower rectal cancer were

Table 3 Analysis of manometric variables according to presence of anal incontinence

	Preoperative			12 Months		
	Persistent AI ($n = 53$)	Recovered AI ($n = 25$)	p	Persistent AI ($n = 53$)	Recovered AI ($n = 25$)	p
Mean resting pressure (mmHg)	44.3 ± 16.6	41.8 ± 17.4	0.473	26.8 ± 17.2	42.4 ± 20.7	0.020
Maximal squeezing pressure (mmHg)	140.4 ± 72.0	144.5 ± 79.2	0.909	132.5 ± 68.7	144.5 ± 53.8	0.422
Sphincter length (cm)	3.6 ± 0.7	3.7 ± 0.6	0.569	3.4 ± 0.9	3.7 ± 0.8	0.268
High-pressure zone (cm)	2.2 ± 1.2	2.2 ± 0.5	0.315	2.1 ± 0.8	2.4 ± 0.5	0.178
Rectoanal inhibitory reflex[a]	23.7 ± 10.9	24.1 ± 9.1	0.729			
Rectal sensation minimal volume (ml)	27.8 ± 9.9	25.5 ± 9.1	0.332			
Desire to defecation volume (ml)	68.2 ± 19.3	68.2 ± 14.7	0.547			
Compliance (ml/mmHg)	1.1 ± 0.4	1.4 ± 0.5	0.052			
Coughing reflex (%)	127.5 ± 50.0	121.0 ± 81.5	0.158	131.2 ± 70.8	120.5 ± 40.9	0.720

AI Anal incontinence

[a] Minimal volume which induced rectoanal inhibitory reflex

Table 4 Multivariate analysis of risk factors for persistent anal incontinence

Variables	Exp(B)	95% CI for Exp(B)		*p*
		Lower	Upper	
Age (years)	0.97	0.90	1.04	0.322
Gender				
Male	1			0.269
Female	2.42	0.51	11.56	
History of anal surgery				
No	1			0.158
Yes	0.13	0.01	2.21	
Preoperative CEA level	1.03	1.00	1.07	0.093
PCRT				
No	1			0.710
Yes	0.65	0.07	6.25	
Tumor height (cm)				
Low rectum	84.46	3.91	1822.85	0.005
Mid rectum	12.59	1.58	100.58	0.017
High rectum	1			0.012
Preoperative FISI group				
≤30	1			0.022
>30	11.61	1.43	94.01	
Approach methods				
Open	1			0.463
Laparoscopy	0.57	0.13	2.57	
Tumor gross type				
Polypoid	1			0.068
Ulcerofungating	0.24	0.02	3.52	0.299
Ulceroinfiltrative	2.59	0.15	43.68	0.509
TNM stage				
0 or I	1			0.461
II	0.23	0.03	2.10	0.192
III	0.18	0.02	1.55	0.117
IV	0.18	0.01	3.83	0.273

AI Anal incontinence; *PCRT* preoperative chemoradiotherapy; *FISI* Fecal Incontinence Severity Index; *TNM* Tumor (T), Node (N), Metastasis (M) system according to AJCC stage

correlated with persistent anal incontinence following restorative proctectomy in rectal cancer patients with preoperative anal incontinence. In this study, about one third of rectal cancer patients had preoperative anal incontinence, which is comparable to the 41.4% noted in a previous study [16]. Our study demonstrated that pre- and postrestorative proctectomy FISI scores did not differ in the persistent anal incontinence group, which indicates that preoperative FISI may represent a strong predictor for the persistence of anal incontinence. A high preoperative FISI score as an indicator of baseline anorectal dysfunction was associated with anal incontinence that could not be resolved with surgery. This study confirmed the conclusion of a recent report conducted by Wallner et al. [16] which stated that functional results after total mesorectal excision for rectal cancer are altered by preoperative incontinence.

We found that tumor height was an incontinence-related risk factor, which is consistent with the results of other studies [12, 15]. Residual rectal length was shorter in the persistent anal incontinence group than in the recovered patients. In this study, anastomotic technique was highly correlated with tumor height. Previous investigators found that the stapled anastomotic technique or reconstruction with a colonic J pouch has superior functional reserve than hand-sewn anastomosis or straight anastomosis [11, 21], although this remains a matter of controversy. In the current study, the impact of reconstruction with a colonic J pouch was not analyzed because a colonic J pouch was performed in less than 10% of the patients. This study showed that baseline anorectal dysfunction was potentiated by intersphincteric resection [7, 10], which was performed in the extreme low rectal cancer patients, as compared to patients without preoperative anal incontinence. In the present study, the patients with persistent anal incontinence had a low mean resting pressure after restorative proctectomy, but there was no difference in pre- and postoperative resting pressure in the recovered anal incontinence patients. This finding is similar to previous studies, showing that anal function after proctectomy may be affected by maximal resting pressure related to the internal anal sphincter [22, 23].

In this study, about one third of preoperative anal incontinence patients improved after restorative proctectomy. We consider that anal incontinence may be improved in some patients after proctectomy for rectal cancer although the recovery mechanism is unknown. Preoperative rectal reservoir function is altered by the existence of a tumor [22], and tumor infiltration may induce loss of compliance, consistent with the previous finding that the ulceroinfiltrative type was correlated with intramural distal spread [24].

A policy of avoiding APR on the grounds of quality of life may not be justified [3]. Until recently, two systematic meta-analyses of quality of life did not permit definitive conclusions as to whether quality of life after anterior resection was superior to that of individuals after APR [2, 25]. Quality of life in patients who had rectal cancer with preoperative anal incontinence was influenced principally by anal dysfunction. APR may be a preferable option to restorative proctectomy in selected patients. Our study provides updated information regarding the risk factors of persistent anal incontinence after restorative proctectomy.

This study is the only one that uses a preoperative baseline assessment for the prediction of postoperative anal dysfunction. We identified the factors associated with high risk of persistent anal incontinence after restorative

proctectomy for rectal cancer patients with preoperative anal incontinence, although the majority of previous studies have focused on the risk factors associated with newly developed anal incontinence after operation. When deciding which operative method to use, predictive factors related to persistent anal incontinence can assist in deciding whether sphincter preservation is a better option than APR in cases of rectal cancer.

In conclusion, preoperative anal incontinence persists after restorative proctectomy in rectal cancer patients with high preoperative FISI scores and lower tumor location. This information should be provided to patients when they are offered a choice of treatment between APR or restorative proctectomy. This is important when making individualized decisions together with a patient prior to surgery.

Conflict of interest The authors have no conflicts of interest or financial ties to disclose.

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