*Original Article (Clinical Original)*

**Title**

# Preoperative incremental maximum squeeze pressure as a predictor of fecal incontinence after very low anterior resection for low rectal cancer


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**Key words:** low rectal cancer, very low anterior resection, fecal incontinence, anorectal manometry

**Abstract**

**Purpose:** Very low anterior resection (VLAR) is performed widely, but some patients are left with fecal incontinence (FI), which compromises their quality of life (QOL) severely. This study sought to identify the predictive factors of postoperative FI after VLAR, which remain unclear.

**Methods:** We evaluated the anorectal manometry data of patients who underwent VLAR to identify the risk factors for postoperative FI among the various clinicopathological factors and manometric characteristics. FI and QOL were analyzed using the Wexner score and EORTC QLQ-C30, respectively.

**Results:** The subjects of this study were 40 patients who underwent VLAR for low rectal cancer between April, 2015 and May, 2018. There were 11 (27%) patients in the major-FI group and 29 (73%) in the minor-FI group. Multivariate analysis revealed that low preoperative incremental maximum squeeze pressure (iMSP) was an independent risk factor for postoperative major-FI. Postoperative QOL tended to be worse in the major-FI group.

**Conclusions:** Preoperative low iMSP increases the risk of major-FI and impaired QOL after VLAR**.** This highlights the importance of performing preoperative anorectal manometry to evaluate the patient's anal function as well as to select the most appropriate operative procedure and early multifaceted treatment such as medication, rehabilitation, and biofeedback for postoperative FI.

## Introduction

Very low anterior resection (VLAR) with total mesorectal excision (TME) is the most common anus-preserving surgical procedure performed for low rectal cancer to avoid permanent colostomy. While VLAR is becoming popular based on an improved understanding of the pelvic anatomy, better endoscopic devices, and increased use of robotic surgery, some patients are left with severe postoperative fecal incontinence (FI) and uncontrollable flatus, urgency for defecation, and frequent bowel movements. The combination of these symptoms after LAR has recently been termed “LAR syndrome” (LARS). LARS is associated with impairment of quality of life (QOL), more hospital admissions, and an increased requirement for stoma formation surgery [1-4]. The FI in LARS is a serious complication, often necessitating the patient to wear diapers and emit an unpleasant smell, which may reduce social interaction and impose a psychological burden.

We occasionally encounter patients who suffer postoperative FI. These patients are treated mainly with antidiarrheal medication, sphincter exercises, and biofeedback, but their management is difficult. Sacral nerve stimulation has been performed for patients resistant to medical therapy, with a high response rate, but this treatment can also cause complications such as implant site pain, paresthesia, and infection requiring device removal [5, 6]. Therefore, predicting postoperative FI before surgery is important for its prevention or early treatment. Although several studies have analyzed the functional mechanisms and predictive factors of postoperative FI after LAR, the results have been inconsistent, and the unified view is inadequate. To resolve this issue, we conducted a single-center prospective observational study of patients with low rectal cancer to analyze the predictive factors of postoperative FI.

Anorectal manometry is a non-invasive test that involves measuring the pressure in the rectal bulb and anal canal, using a pressure transducer [7]. It is particularly useful for obtaining information on the function of the continence mechanism, as it can identify functional sphincter weakness and poor rectal compliance [2, 8, 9]. The differences between the two subgroups of major and minor-FI after anorectal manometry are useful for functional elucidation and identification of predictive risk factors. The aim of this study was to evaluate perioperative anorectal manometry data from patients who underwent VLAR, to identify the predictive risk factors of postoperative FI, which would enable clinicians to consider optimal prevention and treatment strategies.

## Materials and Methods

### *Participants*

Data were collected from the medical records of consecutive patients referred to Hiroshima University Hospital between April, 2015 and May, 2018 for treatment of histologically confirmed low rectal adenocarcinoma. Only those patients scheduled to undergo VLAR based on preoperative examinations were included in this study. The operation was defined as VLAR if the anastomosis was subjectively judged by the surgeons to be just below the upper edge of the puborectal muscle. The exclusion criteria were as follows: patients with a very low or advanced tumor requiring intersphincteric resection or abdominoperineal resection, the presence of known disseminated or local recurrence, a diverting loop ileostomy that was not closed, and age of <20 years. The patients were staged based on total body computed tomography, magnetic resonance imaging of the pelvis, and rectal echo-endoscopy.

Patients with clinical stage T3/4 cancer underwent neoadjuvant chemoradiotherapy, with a median radiation dose of 50.4 Gy, and all patients received concurrent chemotherapy; TS-1).

We collected clinicopathological data on the clinical risk factors of postoperative FI and measured anal function by anorectal manometry before surgery and ≥6 months after stoma closure. Questionnaires to evaluate FI and QOL were given when anorectal manometry was performed. The study protocol was approved by the ethics committee of Hiroshima University Hospital, and all patients gave informed consent for the procedures and use of their data in this study. The approval date was November 27, 2014 (No. 1090).

*Surgical techniques and assessments*

All patients enrolled in this study underwent VLAR with TME under general anesthesia. To maintain blood flow, the sigmoid colon and rectum were removed with low ligation of the inferior mesenteric artery. The autonomic nerves were preserved. The descending colon or sigmoid colon was anastomosed end-to-end to the anal canal using the double-stapling technique (DST) (Proximate ILS [Ethicon Endo-Surgery, Cincinnati, OH, USA] with an outer diameter of 29 mm). Diverting loop ileostomy was performed routinely at a site that had been marked previously by the stoma nurse, and it was closed 3 months or more after surgery.

*Anorectal manometry*

Each patient was placed in the left lateral position for a perianal inspection was performed, after which the high-resolution manometry (HRM) examination was explained. A solid-state manometric assembly with 12

longitudinal sensors placed at 0.6 cm intervals (4.7 mm outer diameter) aligned for pressure recording and a computerized system, Starlet ano (STARMEDICAL, Inc., Tokyo, Japan), were used for data analysis (Fig. 1). First, the basal pressure, such as the anal high-pressure zone length (HPZ), maximum resting anal pressure (MRAP), and mean resting rectal pressure (MRRP), were recorded. Next, the patient was asked to squeeze his or her perianal muscles as hard as possible and hold the contraction for 5 seconds. The incremental maximum squeeze pressure (iMSP) is the increased pressure above the resting pressure when patients voluntarily perform the maximum squeeze of the external anal sphincter (EAS). This was recorded as the average of five consecutive measurements.

*Wexner score and EORTC QLQ-C30*

The Wexner score examines the frequency of three types of fecal incontinence (solid, liquid, and gas) and their consequences; namely, the need to wear pads and the resulting impact on lifestyle. For each item, the five frequency options range from never (score 0) to always (meaning at least once per day; score 4). The total score is the sum of the item scores and ranges from 0 (complete continence) to 20 (complete incontinence). Regarding functional outcomes, a Wexner score ≥11 was defined as “major-FI”, whereas a score <11 was “minor-FI” [10].

The EORTC QLQ-C30 consists of a global health status/quality of life score, five functional scales; namely, physical, role, emotional, cognitive, and social functioning; and nine symptom scales/items; namely, fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties. Scores for the EORTC questionnaires were transformed linearly to give a score of 0–100. A high score for the

global health status and functional scales indicates good QOL and healthy functioning, whereas a high score for the symptoms scales/items represents a higher level of symptom distress.

*Statistical analyses*

Continuous variables are presented as the mean (standard deviation [SD]). The Mann-Whitney U test was used to compare the medians of two groups of variables. Categorical variables are presented as the number and percentage and compared using Pearson's Chi-squared test to analyze each clinical characteristic to identify the factors associated with postoperative FI. These variables were dichotomized using the median value in the analysis. Factors with a P-value of <0.10 in univariate analysis were subjected to multivariate analysis using a logistic regression model. The results of multivariate logistic regression analysis are presented as the odds ratio (OR) and 95% confidence interval (CI) with the corresponding P-value. All analyses were performed using the JMP software program (version 12; SAS Institute, Cary, NC, USA).

**Results**

*Participants*

Of the 87 consecutive patients with low rectal cancer, 71 met the criteria for this study. After informed consent, 69 patients enrolled and underwent preoperative anorectal manometry. Of these, 40 patients who underwent VLAR were included in the analysis (Fig. 2).

*Patient characteristics*

A total of 40 patients who underwent VLAR (32 men [80%], mean age 61.3 years, mean body mass index 21.8 kg/m$^2$) were studied. A pathological complete response was diagnosed in three patients who received preoperative CRT. All patients underwent laparoscopic surgery with every effort made to preserve pelvic autonomic innervation. End-to-end anastomosis with a circular stapler and diverting ileostomy was performed. All patients underwent stoma closure 3–7 months after surgery. No patient had a history of preoperative major-FI. Based on their continence graded by the Wexner score, patients were divided into a major-FI group (≥11) and a minor-FI group (<11). There were 11 (27%) patients in the major-FI group and 29 (73%) patients in the minor-FI group . The mean Wexner score (SD) of all the patients was 7.5 (4.5), and in the major and minor-FI groups it was 13.4 (1.6) and 5.1 (2.8), respectively. Table 1 summarizes the demographic and clinical data of the patients.

*Preoperative anorectal manometry in the major and minor-FI groups*

The HPZ, MRAP, and MRRP were similar in the major-FI and minor-FI groups, at 3.4 ± 0.4 cm vs. 3.6 ± 0.4 cm (P = 0.25); 64.0 ± 18.9 mmHg vs. 68.4 ± 17.8 mmHg (P = 0.62); and 18.3 ± 7.8 mmHg vs. 19.9 ± 7.0 mmHg (P = 0.54), respectively. However, the iMSP was significantly lower in the major-FI group than in the minor-FI group (147.9 ± 72.7 mmHg vs. 225.2 ± 74.3 mmHg, respectively (P = 0.004; Fig. 3).

*Univariate and multivariate analyses of risk factors for postoperative FI*

We analyzed the correlation between postoperative major-FI and clinical risk factors, such as clinicopathological factors and manometric characteristics, in the 40 patients who underwent VLAR for low rectal cancer. In the univariate analysis, the major-FI group tended to have preoperative CRT and advanced stage cancer and significantly lower preoperative iMSP values than the minor-FI group. Multivariate analysis revealed that the preoperative iMSP (OR 6.7, 95% CI 1.1–59.2, P = 0.03) was an independent risk factor for postoperative major-FI (Table 2). Other clinicopathological factors and manometric characteristics showed no significant difference between the groups.

*Comparison of EORTC QLQ-C30 scores in the major and minor-FI groups*

The global health status and two symptom scales of pain and appetite loss tended to be worse in the major-FI group ($P < 0.10$). The role and social functioning and one symptom scale (financial difficulties) were also worse in the major-FI group ($P < 0.05$). No other scale was remarkably different between the two groups (Fig. 4).

*Comparison of EORTC QLQ-C30 scores in the high and low-iMSP groups*

The global health status, two functional scales (role and cognitive), and one symptom scale (fatigue) tended to be worse in the low-iMSP group than in the high-iMSP group ($P < 0.10$). No other scale was remarkably different between the two groups (Fig. 5).

*Perioperative anorectal manometry*

The values of HPZ and MRAP decreased significantly after the operation, the preoperative vs. postoperative values being 3.5 ± 0.4 cm vs. 3.1 ± 0.5 cm, respectively (P = 0.001) and 67.2 ± 18.0 mmHg vs. 55.5 ± 16.9 mmHg, respectively (P = 0.005). In contrast, the values of MRRP and iMSP did not change significantly, the respective pre- and postoperative values being 19.4 ± 7.2 mmHg vs. 18.5 ± 7.4 mmHg (P = 0.45) and 204 ± 81 mmHg vs. 210 ± 95 mmHg (P = 0.82; Fig. 6).

**Discussion**

Previous studies suggest that LARS is correlated with a lower level of anastomosis, radiotherapy, advanced age, surgical technique, and postoperative complications [8, 11, 12]. LARS has been attributed to dysfunction of the anal sphincter, alteration of rectal sensitivity, impaired fecal capacity, and compliance of the new rectum, and pelvic innervation damage [8, 13, 14]. Moreover, in examining the relationship between anorectal manometry and FI, it has been reported that squeeze pressure and resting pressure are reduced in FI [15, 16]. In anorectal manometry, dysfunction of the anal sphincter is expressed as a reduction in the resting pressure because of dysfunction of the internal anal sphincter and a reduction in the squeeze pressure caused by dysfunction mainly of the external anal sphincter [17].

There are several reports on the factors predictive of postoperative FI. Matsushita et al. reported significant correlations between the length of the remaining rectum and the ratio of the decrease in maximum resting pressure, and believe that it is possible to predict postoperative FI using preoperative resting pressure

measurements and then to determine the length of the remaining rectum [16]. Morgado et al. reported that the resting pressure decreased significantly after surgery and improved after loop ileostomy closure, but it did not become a predictor of postoperative FI [18]. Yamana et al. reported that a preoperative high pressure zone, maximum tolerable volume, and anal mucosal electrosensitivity are predictors of postoperative defecatory function [19]. However, most previous studies attempting to identify predictors of postoperative anal function examined patients only after LAR, whereas few studies have focused on VLAR. Therefore, the factors predictive of postoperative FI after VLAR remain unclear, which is why the present study focuses on VLAR.

We compared the clinicopathological factors and preoperative anorectal manometric characteristics between patients with major FI and those with minor-FI after VLAR, and evaluated the preoperative iMSP as an independent risk factor for postoperative major-FI. We also found that the squeeze pressure did not change after VLAR, but that the resting pressure was significantly reduced (Fig. 6). The internal sphincter is injured during rectal resection because of the dilation of the anus, which is necessary to introduce the stapling device; however, this causes postoperative reduction in the resting pressure [2, 18]. Furthermore, the pelvic nerves can be damaged during mobilization of the rectum or following surgery when inflammation and fibrosis occur. Such perioperative procedures can reduce the resting pressure significantly. In contrast, the squeezing pressure did not decrease significantly after surgery because the motor supply of the external anal sphincter is through the somatic nerves, which are not injured in the operation [2]. Although the mechanism by which preoperative iMSP is a predictor of postoperative major-FI is unclear, we hypothesize that when the resting pressure is reduced after VLAR, the squeeze pressure contributes to the remaining anal function.

Although no correlation between postoperative FI and resting pressure was identified in this study, it is important to select an insertion device suitable for the anal size to prevent damage to the internal sphincter and to preserve the autonomic nerves during the operation in order to maintain postoperative anal function. In this study, DST using a device with an outer diameter of 29 mm was performed for all patients, but further studies are underway to select 25 mm and 29 mm according to the size of the anus. Furthermore, in patients with low preoperative iMSP, FI may be prevented by pelvic floor muscle training in the preoperative and early postoperative period, before stoma closure. Moreover, as it is likely that the postoperative QOL of patients with a very low iMSP will be impaired after surgery, we are actively selecting options for abdominoperineal resection with a permanent stoma.

In the present study, 27% of the patients had poor improvement in anal function and were suffering persistent postoperative FI a median of 380 days after stoma closure; however, several other studies have reported functional improvement 1 or 2 years after surgery [2, 8, 14, 20]. Therefore, even if the patient is left with FI postoperatively, it may improve over several years, so we should follow up with a sufficient inquiry and non-invasive treatment such as medication, sphincter exercises, and biofeedback before surgery is considered.

This study had some limitations. First, the number of patients enrolled was relatively small, which was unavoidable because the study was limited to a specific surgical procedure. Second, we examined FI using the Wexner score, but did not examine other symptoms of LARS, such as urgency, fragmentation, and difficulty evacuating. Further studies on a larger number of patients are needed to identify the optimum cutoff value of

preoperative iMSP and examine other symptoms of LARS using the LARS score, which is a better scale for evaluating functional problems in patients with LARS [3].

In conclusion, patients with a low preoperative iMSP are at a high risk of major FI and therefore, compromised QOL, after VLAR. It is important to perform preoperative anorectal manometry to evaluate the patient's anal function and select the most appropriate operative procedure with early multifaceted treatment such as medication, rehabilitation, and biofeedback to prevent and treat postoperative FI.

Conflict of interest statement: Masatoshi Kochi and his co-authors have no conflicts of interest to declare.

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**Figure legends**

Fig. 1. The high-resolution manometry (HRM) catheter with 12 longitudinal sensors used in this study.

Fig. 2. Flow chart of the patients included in the final analysis.

*APR*: abdominoperineal resection, *ISR*: intersphincteric resection, *LAR*: low anterior resection

Fig. 3. Preoperative anorectal manometry in the major-fecal incontinence (FI) and minor-FI groups

*HPZ*: Anal high-pressure zone length, *MRRP*: Mean resting rectal pressure, *MRAP*: Maximum resting anal pressure, *iMSP*: incremental maximum squeeze pressure. *: $P < 0.05$.

Fig. 4. Comparison of EORTC QLQ-C30 scores in the major-FI and minor-FI groups

The mean score ± SD in the major and minor-FI group. *: $P < 0.10$, **$P < 0.05$.

Fig. 5. Comparison of EORTC QLQ-C30 scores in the high and low- incremental maximum squeeze pressure (iMSP) groups

The mean score ± SD in the major and minor-FI group. *: $P < 0.10$, **$P < 0.05$.

Fig. 6. Perioperative anorectal manometry

*HPZ*: Anal high-pressure zone length, *MRRP*: Mean resting rectal pressure, *MRAP*: Maximum resting anal pressure, *iMSP*: incremental maximum squeeze pressure. *: $P < 0.05$.

Fig. 1

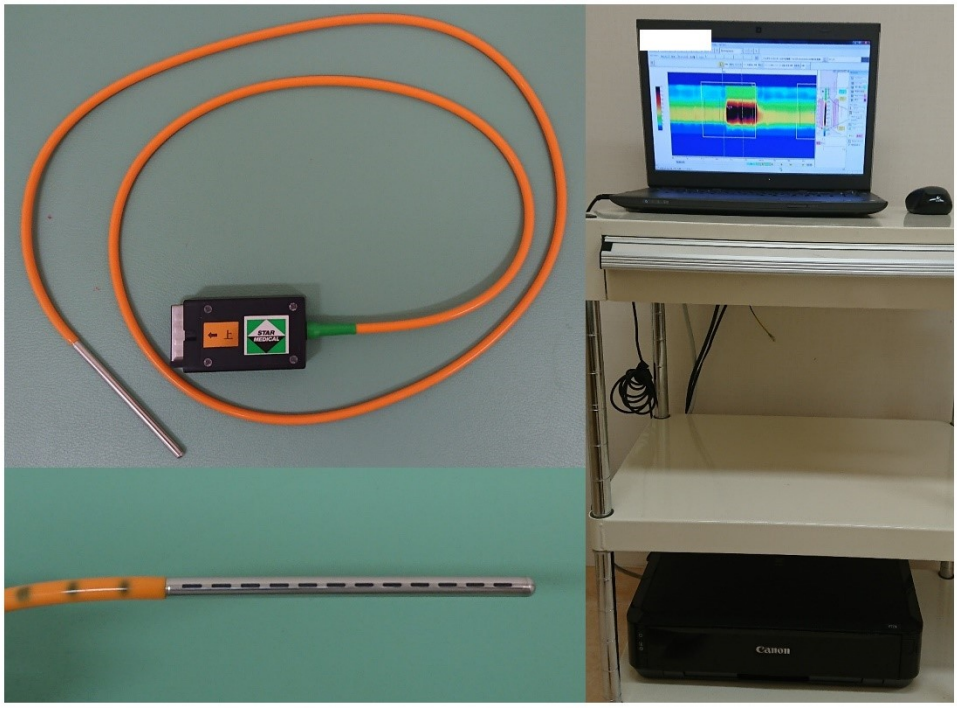


Fig. 2

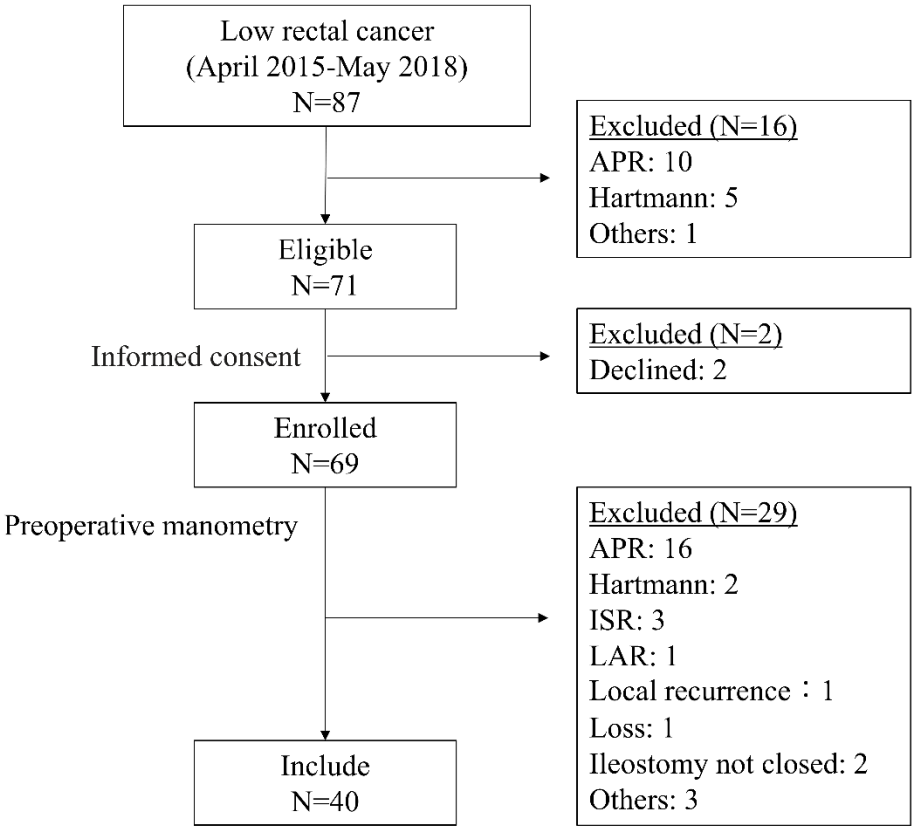

Low rectal cancer
(April 2015-May 2018)
N=87
Excluded (N=16)
APR: 10
Hartmann: 5
Others: 1
Eligible
N=71
Informed consent
Excluded (N=2)
Declined: 2
Enrolled
N=69
Preoperative manometry
Excluded (N=29)
APR: 16
Hartmann: 2
ISR: 3
LAR: 1
Local recurrence：1
Loss: 1
Ileostomy not closed: 2
Others: 3
Include
N=40

Fig. 3

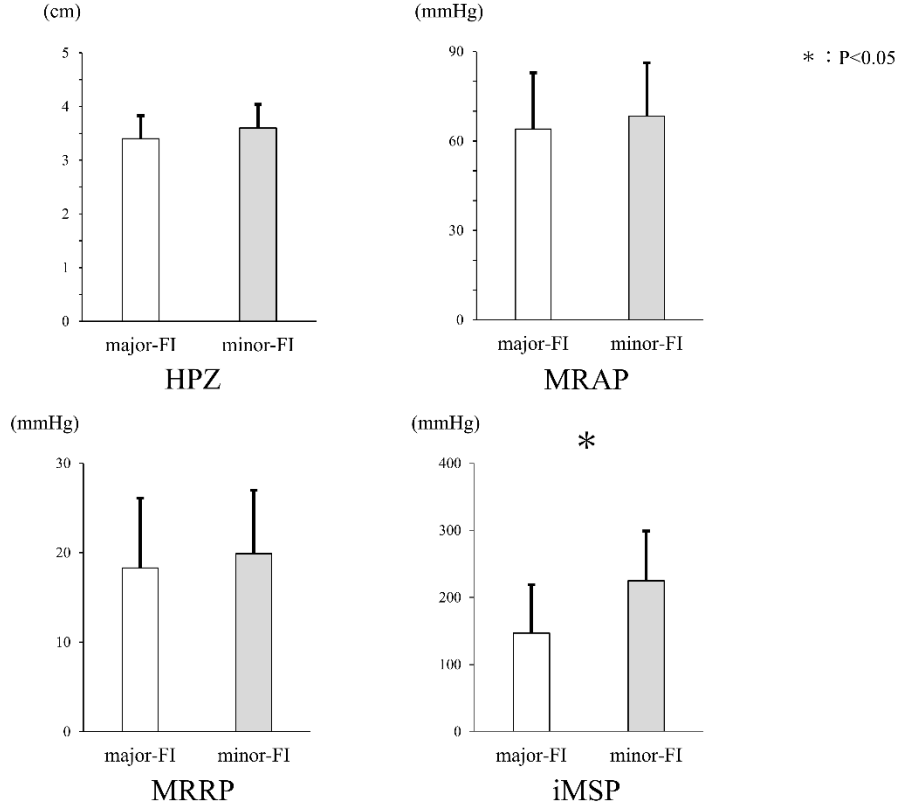
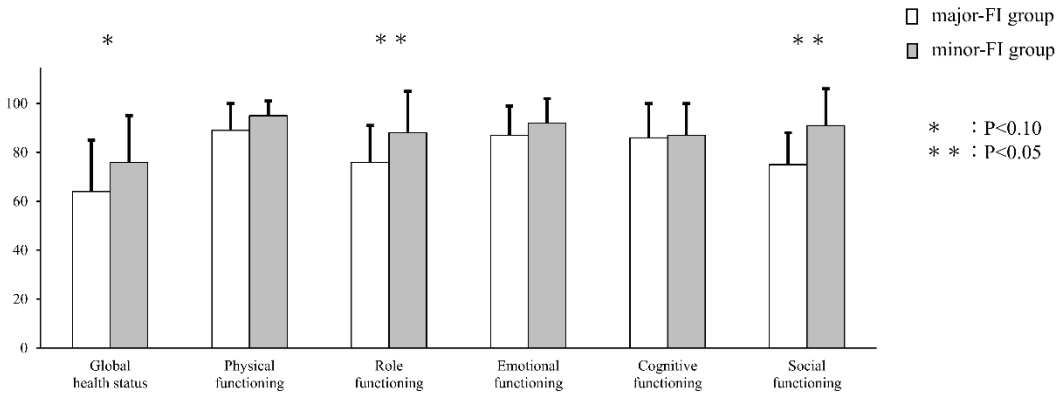

(cm)
5
4
3
2
1
0
major-FI
minor-FI
HPZ
(mmHg)
90
60
30
0
major-FI
minor-FI
MRAP
＊：P<0.05
(mmHg)
30
20
10
0
major-FI
minor-FI
MRRP
(mmHg)
＊
400
300
200
100
0
major-FI
minor-FI
iMSP

Fig. 4

a. QOL and function score




b. Symptom score

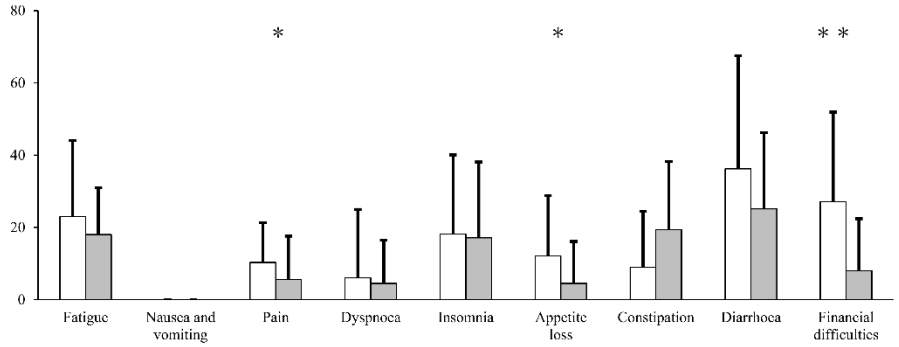
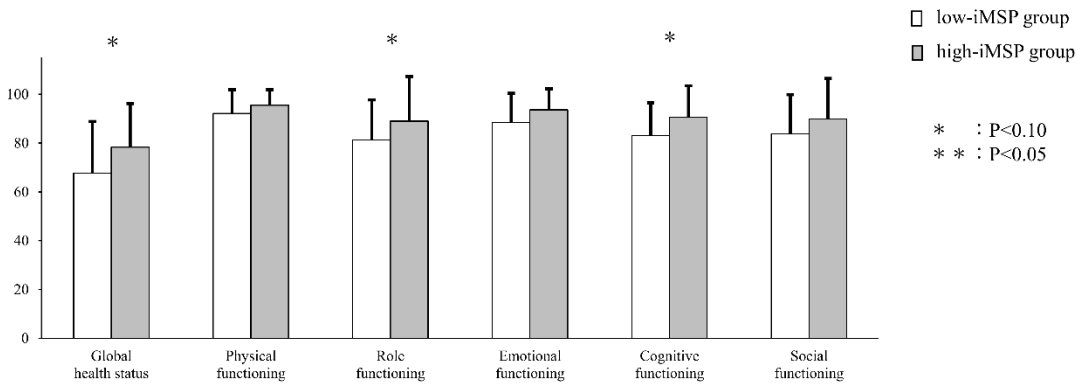


Fig. 5

a. QOL and function score




b. Symptom score

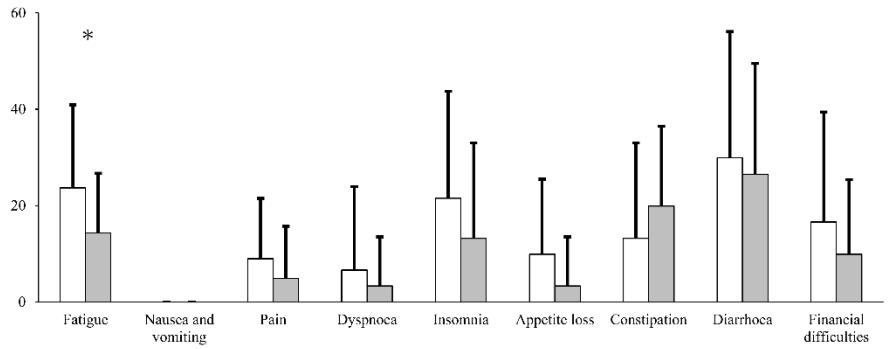
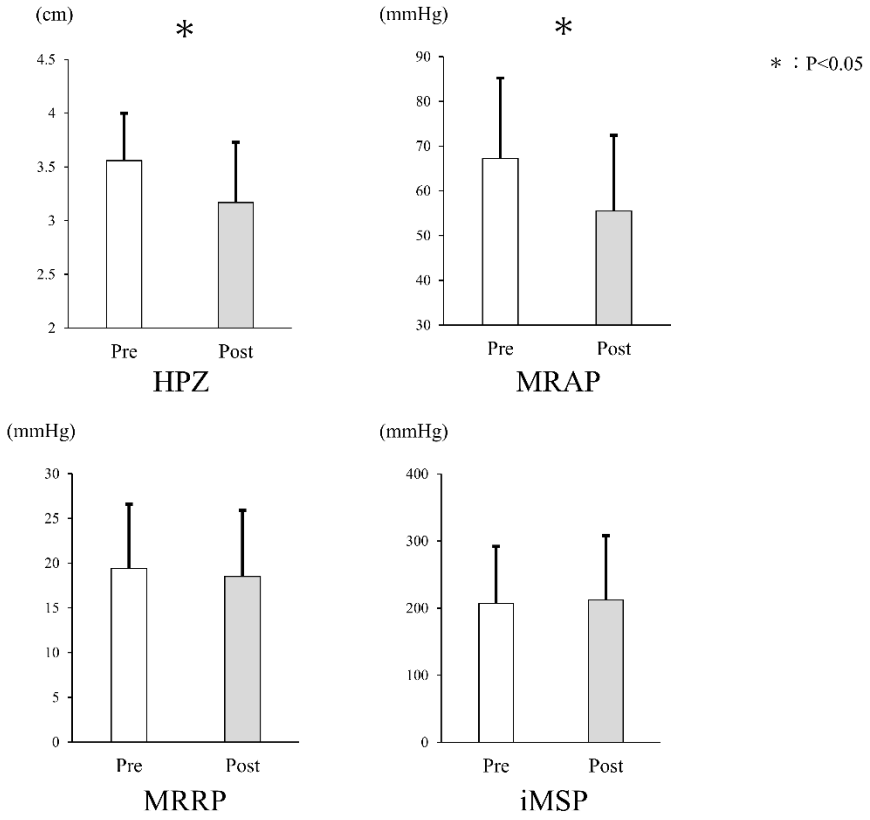


Fig. 6


(cm)
*
4.5
4
3.5
3
2.5
2
Pre
Post
HPZ
(mmHg)
*
90
80
70
60
50
40
30
Pre
Post
MRAP
＊：P<0.05
(mmHg)
30
25
20
15
10
5
0
Pre
Post
MRRP
(mmHg)
400
300
200
100
0
Pre
Post
iMSP

| Table 1. Patients' characteristics | |
|---|---|
| Characteristic | No. (%)<br>n=40 |
| Age, mean (SD) | 61.3 (9.6) |
| Sex, Male | 32 (80%) |
| BMI (kg/m2), mean (SD) | 21.8 (2.3) |
| ASA PS | |
| 1 | 13 (33%) |
| 2-3 | 27 (67%) |
| AV tumor distance (cm), mean (SD) | 6.8 (2.0) |
| Preoperative CRT | 13 (33%) |
| Invasion depth (T-factor) | |
| pT0-2 | 33 (82%) |
| pT3-4 | 7 (18%) |
| UICC-TNM | |
| pStage 0-II | 35 (87%) |
| pStage III-IV | 5 (13%) |
| Type of surgery | |
| Laparoscopic surgery | 40 (100%) |
| Lateral lymph node dissection | 2 (5%) |
| Diverting ileostomy | 40 (100%) |
| Postoperative complications (CD≧3)) | 2 (5%) |
| Adjuvant chemotherapy | 11 (27%) |
| Observation period (from stoma closure /day), mean (SD) | 432.6 (234.1) |
| Wexner score | |
| major-FI group (≧11) | 11 (27%) |
| minor-FI group (<11) | 29 (73%) |

*BMI*: body mass index, *AV*: anal verge, *CRT*: chemoradiotherapy, *FI*: fecal incontinence
*SD*: standard deviation

Table 2. Risk factors for postoperative fecal incontinence

| Characteristic | | FI | | Univariate | Multivariate | | |
|---|---|---|---|---|---|---|---|
| | | major (n=11) | minor (n=29) | *P-value* | Odds ratio | 95% CI | *P-value* |
| Age | ≧63 | 5 | 15 | 0.72 | | | |
| | ＜63 | 6 | 14 | | | | |
| Sex | Male | 8 | 24 | 0.47 | | | |
| | Female | 3 | 5 | | | | |
| BMI | ≧22.5 | 6 | 14 | 0.72 | | | |
| | ＜22.5 | 5 | 15 | | | | |
| ASA-PS | 1 | 4 | 9 | 0.74 | | | |
| | 2-4 | 7 | 20 | | | | |
| AV tumor distance | ≧6.5 | 5 | 12 | 0.69 | | | |
| | ＜6.5 | 4 | 13 | | | | |
| Preoperative CRT | Yes | 6 | 7 | 0.06 | 4.4 | 0.8-26.9 | 0.07 |
| | No | 5 | 22 | | | | |
| Invasion depth (T-factor) | 0-2 | 10 | 23 | 0.38 | | | |
| | 3-4 | 1 | 6 | | | | |
| UICC-TNM | 0-2 | 8 | 27 | 0.08 | 2.2 | 0.2-23.9 | 0.46 |
| | 3-4 | 3 | 2 | | | | |
| LLND | Yes | 0 | 2 | 0.37 | | | |
| | No | 11 | 27 | | | | |
| Postoperative complications (CD≧3) | Yes | 1 | 1 | 0.46 | | | |
| | No | 10 | 28 | | | | |
| Adjuvant chemotherapy | Yes | 5 | 6 | 0.11 | | | |
| | No | 6 | 23 | | | | |
| Observation period | ≧380 | 4 | 16 | 0.28 | | | |
| (from stoma closure /day) | ＜380 | 7 | 13 | | | | |
| Preoperative anal manometry | | | | | | | |
| Anal high-pressure zone length (cm) | ≧3.6 | 4 | 17 | 0.20 | | | |
| | ＜3.6 | 7 | 12 | | | | |
| Maximum resting anal pressure (mmHg) | ≧68.9 | 6 | 15 | 0.87 | | | |
| | ＜68.9 | 5 | 14 | | | | |
| Mean resting rectal pressure (mmHg) | ≧20.1 | 4 | 15 | 0.38 | | | |
| | ＜20.1 | 7 | 14 | | | | |
| incremental maximum squeeze pressure | ≧211 | 2 | 18 | 0.01 | 6.7 | 1.1-59.2 | 0.03 |
| (mmHg) | ＜211 | 9 | 11 | | | | |

*BMI*: body mass index, *CRT*: chemoradiotherapy, *FI*: fecal incontinence