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ORIGINAL SCIENTIFIC REPORT

Mechanical Bowel Preparation Does Not Affect Clinical Severity of Anastomotic Leakage in Rectal Cancer Surgery

Woong Bae Ji[1] · Koo Yong Hahn[2] · Jung Myun Kwak[3] · Dong Woo Kang[3] · Se Jin Baek[3] · Jin Kim[3] · Seon Hahn Kim[3]

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Abstract

Background Previous multicenter randomized trials demonstrated that omitting mechanical bowel preparation (MBP) did not increase anastomotic leakage rates or other infectious complications. However, the most serious concern regarding the omission of MBP is ongoing fecal peritonitis after anastomotic leakage occurs. The aim of this study was to compare the clinical manifestations and severity of anastomotic leakage between patients who underwent MBP and those who did not.

Methods This study was a single-center retrospective review of a prospectively maintained database. From January 2006 to September 2013, 1369 patients who underwent elective rectal cancer resection with primary anastomosis were identified and analyzed.

Results Anastomotic leakage rates were not significantly different between patients who did not undergo MBP (77/831, 9.27%) and those who did (42/538, 7.81%). However, a significantly lower rate of clinical leakage requiring surgical exploration was observed in the leakage without MBP group (30/77, 39.0%) compared with the leakage with MBP group (30/42, 71.4%) ($P = 0.001$). There were no significant differences in the clinical severity of anastomotic leakage as assessed by the length of hospital stay, time to resuming a normal diet, length of antibiotic use, ileus rate, transfusion rate, ICU admission rate, and mortality rate between the leakage without MBP and leakage with MBP groups.

Conclusion MBP was not found to affect the clinical severity of anastomotic leakage in elective rectal cancer surgery.

Woong Bae Ji and Koo Yong Hahn contributed equally as the first authors of this study.

✉ Jung Myun Kwak
jmkwak@korea.ac.kr

[1] Division of Colorectal Surgery, Department of Surgery, Korea University Ansan Hospital, Korea University College of Medicine, Ansan-si, Republic of Korea

[2] Division of Colorectal Surgery, Department of Surgery, Chungju Hospital, Konkuk University, Chungju-si, Republic of Korea

[3] Division of Colorectal Surgery, Department of Surgery, Korea University Anam Hospital, Korea University College of Medicine, Seoul, Republic of Korea

Introduction

In order to prevent postoperative infectious complications and their associated mortality, preparation with mechanical cleaning has long been considered to be the standard practice for elective colorectal surgery [1, 2]. However, there has been a paucity of scientific evidence demonstrating the efficacy of this practice. Indeed, over the past decade, a number of randomized controlled trials have demonstrated that patients undergoing colorectal surgery without mechanical bowel preparation (MBP) were not at increased risk of postoperative complications [3–12].

While most colorectal surgeons accept these results, many are still reluctant to omit MBP, particularly in cases of rectal surgery [13, 14]. Regardless of the average rates of anastomotic leakage or other postoperative infectious complications, the most serious concern regarding the omission of MBP is severe fecal peritonitis, which can cause sepsis after anastomotic leakage has occurred. Therefore, the value of MBP should be reconsidered based on the clinical severity of anastomotic leakage rather than the overall leakage rate [15].

Another major concern regarding the use of MBP is the mixed study population included in previous trials. Most trials included a large number of patients undergoing ileocolostomy, colocolostomy, and various other procedures [3–11]. We cannot confirm the safety of rectal surgery without MBP based on these previous studies because the incidence, clinical presentation, and treatment strategy for anastomotic leakages in intra- and extra-peritoneal anastomoses differ.

No study has specifically addressed the effect of MBP on the clinical severity of anastomotic leakage after rectal cancer surgery. The aim of this study was to evaluate the impact of MBP on the clinical manifestation and severity of anastomotic leakage after rectal cancer surgery.

Materials and methods

Patients and study design

Patients undergoing elective rectal cancer surgery with primary anastomosis between January 2006 and September 2013 were identified and analyzed. Data were obtained from a colorectal cancer database prospectively maintained by surgeons and retrospective review of medical records and radiological findings. Rectal cancer was defined as pathologically proven adenocarcinoma located within 15 cm from the anal verge on a rigid proctoscope. Low anterior resection was defined as anastomosis below the peritoneal reflexion. Preoperative long-course chemoradiation was used when the circumferential margin was threatened or when lymph nodes beyond the dissecting plane were detected on abdominopelvic computed tomography (CT) or pelvic magnetic resonance imaging. Exclusion criteria were as follows: rectal resection without anastomosis (abdominoperineal resection (APR) or Hartmann's procedure), emergency operation, or cancer arising from familial adenomatous polyposis or inflammatory bowel disease.

Laparoscopic- or robotic-assisted surgery was considered first in all patients. The indications were the same between the two procedures, and the exclusion criteria were previous major pelvic surgery or T4 or large, low-lying tumors with a high risk of circumferential margin involvement and that were technically challenging. Diverting stoma was indicated in limited cases with a positive air leak test, incomplete doughnuts, preoperative radiation, extremely difficult pelvic dissection, or coloanal hand-sewn anastomosis.

The institutional review board of Korea University Medical Center approved this study (AN14133-002).

Bowel preparation

The bowel preparation method was selected based on surgeon preference. MBP was carried out with polyethylene glycol (Tae Joon Pharm, Seoul, Korea) or sodium phosphate (Tae Joon Pharm) 24 h before surgery. Patients who did not undergo MBP received 133 ml of Fleet enema (Unimed Pharmaceutical INC. Seoul, Korea) the evening before and early in the morning before surgery to avoid extrusion of stool during stapling. After MBP, patients were allowed only clear fluids all day. Patients who did not undergo MBP had no preoperative dietary restrictions up to the evening before surgery. Fasting from midnight onward was used in all patients. Antibiotic prophylaxis consisted of intravenous administration of 1 g of cefotetan with the induction of anesthesia and every 8 h postoperatively on the day of surgery.

Assessment of outcomes

The primary endpoint for the assessment of outcomes was the incidence of surgical intervention for the management of anastomotic leakage. Secondary endpoints were the clinical severity of anastomotic leakage assessed by the intensive care unit (ICU) admission rate, hemodynamic instability, need for ventilator care, and duration of therapeutic antibiotic use. Anastomotic leakage was defined as in previous studies including abscess near anastomotic site and was diagnosed based on endoscopic and radiologic findings together with clinical symptoms and signs such as a change in drainage color or signs of peritonitis that required operative procedure [16]. All suspected cases underwent CT scan, which was helpful for evaluating the extent of pelvic or peritoneal abscess. Management of anastomotic leakage was performed according to surgeon preference; however, the principle was the same, in that locally limited abscesses were treated with non-operative drainage and antibiotics. If there was clinical deterioration or the patient had generalized symptoms, surgical procedures were performed for the management of anastomotic leakage. Subclinical leakage that had an asymptomatic phlegmon or that was locally contained by peritoneal defense mechanisms was excluded ($n = 5$).

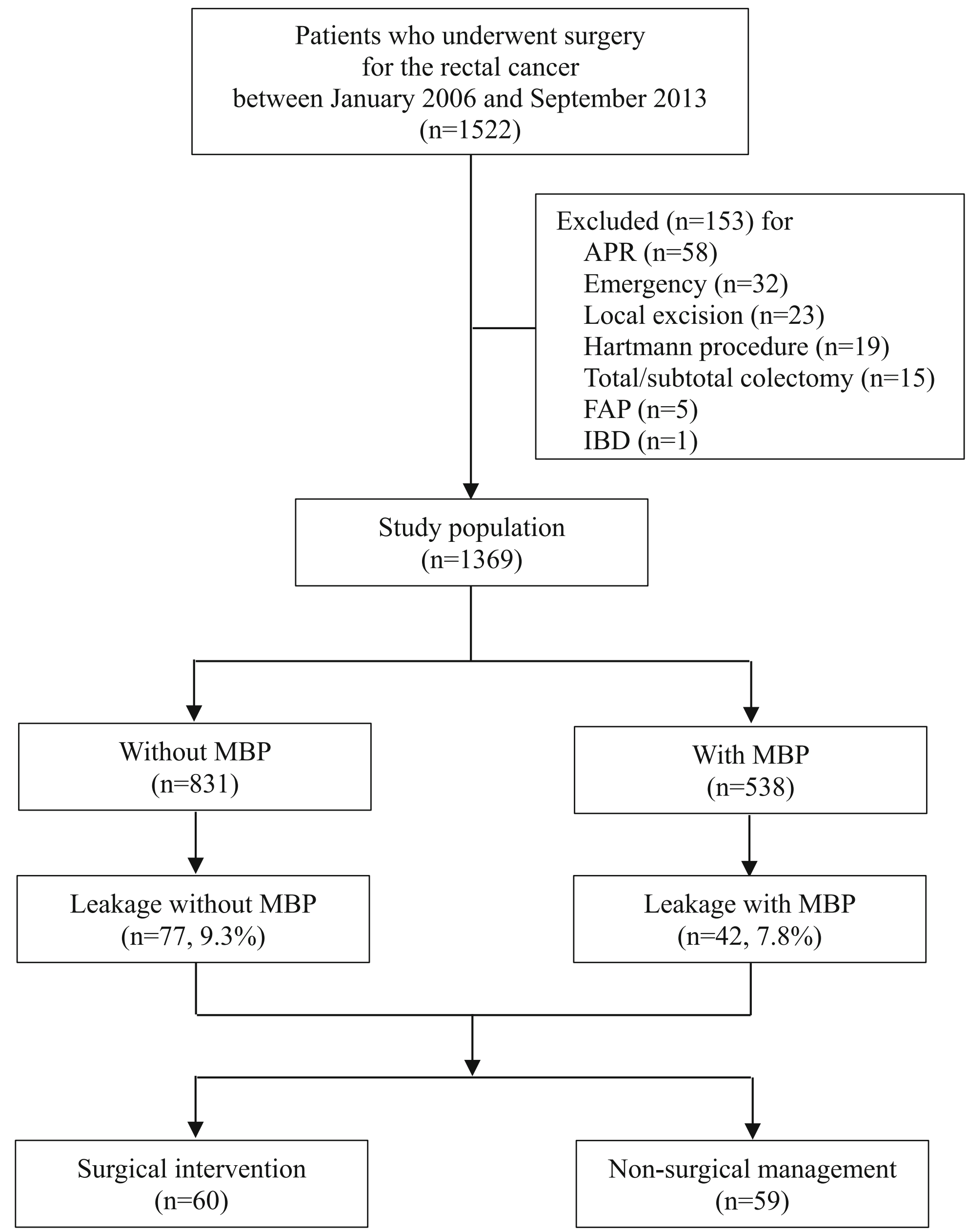

Fig. 1 Study flow diagram. *APR* abdominoperineal resection, *FAP* familial adenomatous polyposis, *IBD* inflammatory bowel disease, *MBP* mechanical bowel preparation

Statistical analysis

For descriptive purposes, data are presented as means with standard deviations for quantitative variables. Discrete variables are expressed as counts and percentages. The Student's *t* test was used to compare the differences in continuous variables between the two groups. The comparison of variables that had skewed distributions was made using the Mann–Whitney *U* test, a nonparametric alternative of the independent *t* test. Differences in categorical and binary variables between the two groups were tested by a two-tailed Pearson Chi-square test or Fisher's exact test. Multivariate analysis was performed using a logistic regression test, which included univariate associations that were significant at a P value <0.1. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics 20.

Results

Among 1522 patients who underwent surgery for rectal cancer, 153 patients were excluded due to APR ($n = 58$), emergency operation ($n = 32$), local excision of the tumor ($n = 23$), Hartmann procedure ($n = 19$), total abdominal colectomy followed by ileorectal anastomosis ($n = 15$),

Table 1 Clinical characteristics of the two groups

	Leakage without MBP ($n = 77$)	Leakage with MBP ($n = 42$)	P
Age (year), mean ± SD	61.8 ± 11.3	57.6 ± 11.32	0.054
Gender, male, n (%)	56 (72.7)	33 (78.6)	0.410
Body mass index, mean ± SD	24.1 ± 3.5	23.9 ± 2.2	0.483
ASA, n (%)			0.561
I	35 (45.5)	15 (35.7)	
II	38 (49.4)	25 (59.5)	
III	4 (5.2)	2 (4.8)	
Tumor height from AV (cm), mean ± SD	9.1 ± 4.9	10.6 ± 7.4	0.253
Neoadjuvant chemoradiation, n (%)			0.225
Yes	16 (20.8)	5 (11.9)	
No	61 (79.2)	37 (88.1)	
Type of operation, n (%)			0.068
Open	4 (5.2)	5 (11.9)	
Laparoscopic	47 (61.0)	32 (76.2)	
Robotic	26 (33.8)	5 (11.9)	
Operation name, n (%)			0.473
HAR with double stapling	11 (14.3)	9 (21.4)	
LAR with double stapling	52 (67.5)	28 (66.7)	
ISR with coloanal anastomosis	14 (18.2)	5 (11.9)	
Temporary diverting ileostomy, n (%)[a]			0.189
Yes	39 (50.6)	16 (38.1)	
No	38 (49.4)	26 (61.9)	

SD standard deviation, *ASA* American Society of Anesthesiologists, *AV* anal verge, *HAR* high anterior resection, *LAR* low anterior resection, *ISR* intersphincteric resection

[a] The diversion rate for patients with rectal cancer was 39.44%

familial adenomatous polyposis ($n = 5$), or inflammatory bowel disease ($n = 1$). A total of 1369 patients were identified and divided into two groups, the without MBP group ($n = 831$) and the with MBP group ($n = 538$) according to bowel preparation method (Fig. 1). The anastomotic leakage rate was similar between the two groups: 77 patients (9.3%) in the without MBP group versus 42 (7.8%) in the with MBP group ($P = 0.349$).

Demographic data and clinical characteristics between the leakage without MBP group and the leakage with MBP group showed no significant differences in age, sex, tumor location, preoperative chemoradiation, type of operation, or diverting ileostomy formation (Table 1).

As shown in Table 2, the initial clinical presentation of anastomotic leakage was significantly different. Over half of the patients in the leakage without MBP group presented with localized pelvic, intra-abdominal, or peri-anastomotic abscess, which is most successfully managed by antibiotic treatment or percutaneous/transanal drainage. On the other hand, 29 patients (69%) in the leakage with MBP group required immediate surgical exploration for generalized peritonitis. The median hospital stay after initial operation tended to be longer in the leakage with MBP group (17 days in the leakage without MBP group versus 27 days in the leakage with MBP group, $P = 0.076$), although this was not statistically significant. Other postoperative outcomes including the duration of antibiotic usage, time until resuming a normal diet after leakage, postoperative ileus rate, need for transfusion, and intensive care unit (ICU) admission rate did not vary between the two groups. There were two cases of mortality in each group.

The initial decision making for management of anastomotic leakage failed in 19 patients with leakage without MBP and in 10 patients with leakage without MBP. Ultimately, 30 patients in each group underwent surgical exploration. The severity of the clinical course of those 30 patients was not significantly different in terms of hemodynamic instability, rate of bacteremia, ICU admission rate, need for ventilator care, transfusion rate, or mortality rate between the two groups (Table 3).

The patients were divided into two groups according to whether they were treated with surgical intervention or

Table 2 Clinical outcomes in patients with anastomotic leak

	Leakage without MBP (*n* = 77)	Leakage with MBP (*n* = 42)	*P*
Leakage date (days), mean ± SD	4.3 ± 2.8	5.1 ± 2.8	0.152
Initial treatment, *n* (%)			0.000
Conservative management	36 (46.8)	6 (14.3)	
Percutaneous/transanal drainage	19 (24.7)	7 (16.7)	
Surgical exploration	22 (28.6)	29 (69.0)	
Needs for additional intervention, *n* (%)	19 (24.7)	10 (23.8)	0.916
Final treatment, *n* (%)			0.001
Conservative management	32 (41.6)	5 (17.9)	
Percutaneous/transanal drainage	15 (19.5)	7 (16.7)	
Surgical exploration	30 (39.0)	30 (71.4)	
Hospital stay (days), mean ± SD	25.3 ± 22.4	41.2 ± 54.2	0.076
Hospital stay (days), median (IQR)	17 (13–34)	27 (15–40)	
Resume diet (days), mean ± SD	6.4 ± 6.0	6.8 ± 6.5	0.700
Use of antibiotics (days), mean ± SD	17.5 ± 12.3	18.8 ± 15.6	0.612
Ileus, *n* (%)	7 (9.1)	6 (14.3)	0.385
Transfusion, *n* (%)	17 (22.1)	11 (26.2)	0.613
ICU admission, *n* (%)	10 (13.0)	9 (21.4)	0.230
MOF, *n* (%)	8 (10.4)	5 (11.9)	0.800
Mortality, *n* (%)	2 (2.6)	2 (4.8)	0.613[a]

SD standard deviation, *IQR* interquartile range, *ICU* intensive care unit, *MOF* multiple organ failure

[a] Fisher's exact test

non-surgical management only. There was a statistically significant difference between the two groups in terms of neoadjuvant chemoradiation, MBP, and temporary diverting ileostomy (Table 4). Multivariate analysis showed that MBP was associated with increased risk of surgical intervention (OR 4.287; 95% CI 1.546–11.893; $P = 0.005$), and temporary diverting ileostomy decreased the risk of surgical intervention (OR 0.105; 95% CI 0.029–0.374; $P = 0.001$) (Table 5).

Discussion

An increasing number of studies have shown that the use of MBP is unnecessary in colorectal surgery and have even shown its negative effects on anastomotic leakage and infectious complications. However, in a 2003 survey, the American Society of Colon and Rectal Surgeons estimated that 99% of its members still prescribed some type of MBP as part of their standard preoperative protocol for elective

Table 3 Severity of clinical course in leaked patients who underwent surgical exploration

	Leakage without MBP (*n* = 30)	Leakage with MBP (*n* = 30)	*P*
Shock, *n* (%)	5 (16.7)	6 (20.0)	0.739
Length of vasopressors support (day), mean ± SD	2.0 ± 1.7	2.5 ± 1.8	0.648
Bacteremia, *n* (%)	6 (20.0)	3 (10.0)	0.472*
ICU admission, *n* (%)	10 (33.3)	8 (26.7)	0.573
Length of ICU stay (day), mean ± SD	9.5 ± 7.8	10.4 ± 14.5	0.872
Ventilator support, *n* (%)	9 (30.0)	7 (23.3)	0.559
Length of ventilator support (day), mean ± SD	6.9 ± 7.9	8.0 ± 15.0	0.844
Transfusion, *n* (%)	16 (53.3)	14 (46.7)	0.606
MOF, *n* (%)	8 (26.7)	5 (16.7)	0.347
Mortality, *n* (%)	2 (6.7)	2 (6.7)	1.000[a]

SD standard deviation, *ICU* intensive care unit, *MOF* multiple organ failure

[a] Fisher's exact test

Table 4 Univariate analysis of differences between the conservative management group and surgical intervention groups ($n = 119$)

	Non-surgical management ($n = 59$)	Surgical intervention ($n = 60$)	OR	95% CI		P
				Lower	Upper	
Age, median	63.25	60				0.180
>65	27 (45.8)	20 (33.3)	0.707	0.326	1.536	0.434
Gender						
Male	42 (71.2)	47 (78.3)	1.138	0.483	2.684	0.767
BMI, mean, n (%)	24.47	23.27				0.053
ASA score, n (%)						
I	24	26				
II/III	35	34	0.824	0.380	1.786	0.623
Tumor height, median (centimeters from AV)	7	8				0.085
Neoadjuvant chemoradition, n (%)	17 (28.8)	4 (6.7)	0.199	0.062	0.643	0.007
Mechanical bowel preparation, n (%)						
Yes	12 (20.3)	30 (50.0)	3.776	1.595	8.938	0.003
No	47 (79.7)	30 (50.0)				
Operation method, n (%)						0.334
Conventional laparotomy	1 (1.7)	4 (6.7)				
Laparoscopy	37 (62.7)	42 (70.0)				
Robot	19 (32.2)	12 (20.0)				
Conversion	2 (3.4)	2 (3.3)				
Operation time, mean (min)	274.07	248.84				0.111
Temporary diverting ileostomy, n (%)	41 (69.5)	13 (21.7)	0.129	0.054	0.305	<0.001
Leakage date (days)	4.96	4.32				0.254

CI confident interval, *OR* odds ratio, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *AV* anal verge

colorectal surgery [13]. This discrepancy between evidence and practice is also observed in a survey of the members of the Korean Society of Coloproctology. Most of the colorectal surgeons (97%) in a Korean national survey routinely performed preoperative MBP for elective colorectal surgery, and 73% of the respondents believed that MBP is an essential step in elective colorectal surgery [14].

Despite the fact that many clinical trials and meta-analyses have voiced caution about the potential disadvantages of MBP [3–12, 17, 18], there may be anecdotal reasons for colorectal surgeons to believe that MBP still has an important role in clinical practice, as shown in two surveys. Proponents for MBP primarily argue that although it cannot reduce the leakage rate, it mitigates the clinical severity of anastomotic leakage by reducing the fecal and bacterial load. Second, they have voiced doubts on whether omitting MBP is safe even in rectal surgery because the collective evidence from the literature is intended for colonic surgery. Third, there is no consensus on the optimal bowel preparation for minimally invasive colorectal surgery.

Many studies have investigated the effects of MBP on the rate of anastomotic leakage, but few studies have focused on the clinical sequelae and consequences of these events [19, 20]. However, the results of those studies did not show any benefit of MBP regarding the clinical severity of anastomotic leakage. In their randomized trial on colorectal surgery with or without MBP, van't Sant et al. [19] analyzed 63 patients with leakage (28 with MBP vs. 35 patients without MBP) among 1433 total patients. These investigators found that the mortality rate, the initial need

Table 5 Multivariate analysis of the non-surgical management group and surgical intervention groups including variables selected on univariate analysis

	OR	95% CI		P
		Lower	Upper	
MBP	4.287	1.546	11.893	0.005
Temporary diverting ileostomy	0.105	0.029	0.374	0.001
BMI	0.908	0.773	1.066	0.238
Tumor height from AV	0.937	0.799	1.099	0.423
Neoadjuvant chemoradiation	0.792	0.189	3.311	0.749

CI confident interval, *OR* odds ratio, *MBP* mechanical bowel preparation, *BMI* body mass index, *AV* anal verge for surgical intervention, and the extent of bowel contamination did not differ between the two groups. They concluded that there was no benefit of MBP on morbidity and mortality after anastomotic leakage in elective colorectal surgery. In another trial, Gubler et al. [20] recently reached a similar conclusion. They assessed more than 700 patients and found no appreciable difference in mortality, length of ICU stay, or hospital stay between 26 and 17 patients with leakage who did or did not undergo MBP, respectively. Our results also showed that there was no significant difference in parameters indicating the clinical severity of anastomotic leakage in rectal cancer resection with or without MBP.

These results refute the hypothesis that MBP can mitigate the clinical severity of anastomotic leakage by reducing the fecal and bacterial load. This might be explained by the fact that MBP frequently provides an incomplete clean bowel, resulting in liquid bowel contents [21]. Even though MBP reduces the amount of stool in the colon and the number of intestinal bacteria, it does not significantly alter the concentration of fecal organisms in liquid bowel contents [22]. Early feeding according to early recovery after surgery program makes the diverting effect of MBP more temporary.

Second, fact that MBP in elective colonic resection does not reduce anastomotic leakage or infectious complications is no longer in question. There is a large body of clinical evidence suggesting that primary ileocolic or colocolic anastomoses are safe in those with unprepared or even obstructed bowels [23, 24]. On the contrary, the incidence of anastomotic leakage after rectal resection is higher than it is after colonic resection. A study specifically devoted to the value of MBP in rectal surgery is lacking. Only one randomized study conducted by a French study group is available on the role of MBP in rectal resection [12]. Although that study demonstrates a higher overall and infectious morbidity rate in rectal cancer surgery without MBP, further study is needed to confirm this conclusion.

The last issue concerns the optimal bowel preparation for minimally invasive colorectal surgery. There are several potential advantages of MBP for minimally invasive colorectal surgery [25]. An empty colon may be easier to manipulate than a colon full of stool. The surgeon can visualize the location of the tumor in an empty colon and rectum [26]. MBP is deemed to offer better surgical exposure by reducing the volume in the small bowel. However, although more than 90% of the patients underwent laparoscopic or robotic rectal resection in this study, we did not find any advantage of MBP in terms of operative time, conversion rate, or intra-operative complications. All patients in the without MBP group received a preoperative enema; therefore, there was little difficulty locating the tumor. Evidence from the literature has also found no benefit to MBP for surgical field exposure [27]. The comfort of surgeons with a mechanically prepared bowel is highly subjective, but no evidence in this study suggests that MBP has clinical benefits.

It is very interesting that the clinical manifestation of anastomotic leakage was different between the two groups. In the leakage without MBP group, more than 60% of patients could be managed without surgical exploration because their symptoms, signs, and radiologic findings suggested localized pelvic abscess rather than pan-peritonitis. A similar result was observed by Bretagnol et al. [12] where isolated pelvic abscesses occurred more frequently in the non-MBP group (8%, 7/89) as compared with the MBP group (1%, 1/89).

We postulated that the varied presentation of leakage with or without MBP is derived from different stool consistencies. Mahajna et al. [21] indicated that MBP causes a significantly higher incidence of liquid bowel contents, which led to peritoneal spillage three times more frequently than did semisolid bowel contents, with spillage rarely occurring with solid bowel contents. Although we could not determine the exact stool consistency in this study because of the retrospective design, colons prepared with MBP are expected to more frequently have liquid contents. If there is a small anastomotic dehiscence, liquid contents may be able to spill out into the abdominal cavity and cause generalized peritonitis, which requires immediate surgical exploration. On the other hand, unprepared colons may contain formed or even hardened stool. This kind of stool is not likely to spill through a small anastomotic dehiscence, but instead can lead to peri-anastomotic abscess. This hypothesis is supported by a variety of clinical manifestations of colonic diverticulitis with perforation, ranging from a small abscess to full-blown fecal peritonitis, which depends on the size of the perforation and the level of extracolonic contamination [28, 29].

Recently, a study from large-scale database showed that surgical site infection (SSI) of the patients who underwent colorectal surgery was related to the oral antibiotic bowel preparation [30]. However, in terms of anastomotic leakage, despite some studies on the relationship of anastomotic leakage with oral antibiotic preparation, the results have not been uniform [31], and only a few studies have included rectal cancer patients only. Further well-designed large-scale studies should be followed to find out the relationship between SSI/anastomotic leakage and oral antibiotic bowel preparation in the rectal cancer patients.

The present study has some limitations. These findings are limited by the retrospective nature of the analyses, the single-center design, and selection bias from the non-randomized study design. MBP was mainly performed based on surgeon preference. In addition, the management strategy for anastomotic leakage differed according to individual surgeon preference. The anastomotic level was not homogeneous; this study included all colorectal anastomoses above and below the peritoneal reflection. Although most of the data were provided by a prospectively maintained cancer database, some critical parameters including the degree of bowel cleansing and the grade of contamination in leakage-related peritonitis could not be investigated.

Despite these limitations, this is the first report to assess the clinical severity of anastomotic leakage focusing on rectal resection. Compared with other studies [12, 19, 20], the considerable number of patients in our study with leakage strengthened the statistical power of this study and allowed for a more detailed analysis of the influence of MBP.

Compliance with ethical standards

Conflict of interest This study was supported by a Korea University Grant. The authors have no conflicts of interest to declare.

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