

Effectiveness of Minimal Bowel Preparation With Oral Bisacodyl Before Laparoscopic Radical Proctectomy: Case-Control Comparison of Bisacodyl and Polyethylene Glycol as Oral Laxative Agents

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The aim of this study was to evaluate the usefulness of minimal mechanical bowel preparation (MBP) using oral bisacodyl before laparoscopic rectal cancer surgery. Preoperative MBP using conventional oral laxatives in laparoscopic proctectomy may detrimentally affect morbidity and surgical outcomes. Between March 2010 and December 2014, 272 rectal cancer patients who underwent laparoscopic proctectomy were included in the current study. A total of 85 patients undergoing bowel preparation with oral bisacodyl (bisacodyl group) were individually matched to patients receiving polyethylene glycol (PEG group) using propensity score matching. Operative outcomes, morbidity, and mortality were compared between the matched groups. The quality of bowel cleansing was much poorer in the bisacodyl group than in the PEG group (excellent, 43.5% versus 68.2%; fair, 41.2% versus 16.5%; and poor, 15.3% versus 15.3%; $P < 0.001$). The degree of small bowel distension (collapsed, 56.4% versus 52.9%; mildly distended, 41.2% versus 40.0%; and severely distended, 2.4% versus 7.1%; $P = 0.452$) and postoperative outcomes, including time to first flatus (3.0 versus 3.0 days, $P = 0.426$); hospital stay (16.0 versus 15.0 days, $P = 0.215$); anastomotic leakage rate (8.2% versus 5.9%, $P = 0.549$); and mortality (0 versus 1.2%, $P = 1.000$), were similar between the bisacodyl group and the PEG group, respectively. MBP using oral bisacodyl before laparoscopic proctectomy was feasible and safe with respect to morbidity and surgical outcomes.

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Minimal bowel preparation with bisacodyl seems to be a useful preparation method for laparoscopic proctectomy.

Key words: Bowel preparation – Bisacodyl – Rectal surgery – Laparoscopy – Polyethylene glycol

The use of laparoscopic proctectomy has steadily increased since 2000¹ due to better short-term outcomes than open proctectomy. Regarding long-term oncologic outcomes for laparoscopic radical proctectomy, the recent multicenter trial indicated that oncologic results for laparoscopic proctectomy were comparable to those for open proctectomy,² which will likely encourage the wider adoption of laparoscopic procedures in rectal cancer management.

Surgeons still favor the use of mechanical bowel preparation (MBP) before rectal surgery based on the traditional belief that MBP reduces postoperative anastomotic leakage and infectious complications.^{3–5} In contrast with this belief, a recent meta-analysis demonstrated no beneficial effect of MBP on overall morbidity or mortality following rectal surgery.⁶ In addition, conventional MBP using large volumes of oral laxatives causes considerable discomfort, including nausea, vomiting, and abdominal bloating.^{7,8} On the basis of these results, previous studies^{4,9} tried to overcome this shortcoming by bowel preparation without oral laxatives in rectal surgery. Oral laxative use had no significant effect on anastomotic leakage rate, while pelvic sepsis was more severe in patients without oral laxatives.^{9,10} Thus, several studies have investigated minimal bowel preparation regimens of improving cleansing quality and compliance in rectal surgery using small volumes of oral laxatives, such as Senna, sodium phosphate, and bisacodyl.^{11–13} Among these regimens, oral bisacodyl, an adjuvant colonic laxatives for colonic cleansing,¹⁴ may be practically preferred over other regimens in terms of compliance and tolerability.

Surgeons frequently perform bowel preparation to improve surgical field exposure, especially for laparoscopic proctectomy.¹⁵ However, the beneficial or detrimental effect of MBP on laparoscopic surgical view has not yet been reported based on surgical data. Therefore, we hypothesized that the method of MBP may influence the small bowel diameter and surgical field during laparoscopic proctectomy.

The aim of this study was to evaluate the usefulness of minimal preparation method using

oral bisacodyl compared with conventional preparation method using polyethylene glycol (PEG) solution for MBP before laparoscopic rectal cancer surgery.

Materials and Methods

Patient sample and data collection

Between March 2010 and December 2014, a total of 698 colorectal cancer patients underwent laparoscopic resection in the Department of Colorectal Surgery at Inje University, Haeundae Paik Hospital, Korea. Of the 698 patients, 310 patients with lesions with distal tumor margins <15 cm from the anal verge who underwent laparoscopic proctectomy were considered for this study using prospectively constructed databases. We excluded patients who had tumors with endoscopically obstructed lesion without clinical symptoms of obstruction (n = 9); patients who underwent Hartmann's proctectomy (n = 8) or abdominoperineal resection (n = 6); patients who underwent stoma creation (n = 7) or colonoscopic stent insertion (n = 6) before laparoscopic resection; and patients who had perforation (n = 2). Thus, we included 272 rectal cancer patients with primary anastomosis who underwent laparoscopic proctectomy (Fig. 1).

Patients underwent 1 of 2 MBP methods. Patients in the bisacodyl group (n = 85) underwent minimal preparation with 10 mg bisacodyl orally given twice on the day before surgery. Patients in the PEG group (n = 187) underwent MBP with 2 to 4 L PEG on the day before surgery. All operations were performed by 1 colorectal surgeon with experience with >1,000 cases of laparoscopic colorectal surgery. A total of 85 patients took 10 mg bisacodyl twice (first at 10:00 AM and then at 4:00 PM on the day before surgery). Additionally, 187 patients were administered 2 to 4 L of PEG beginning at 10:00 AM on the day before surgery. We administered 500 mg metronidazole orally twice on the day before surgery to all patients. Perioperative intravenous antibiotics (2.0 g cefotetan) were prophylactically administered to all patients within 30 minutes prior to surgery and discontinued 24 hours postoperatively.

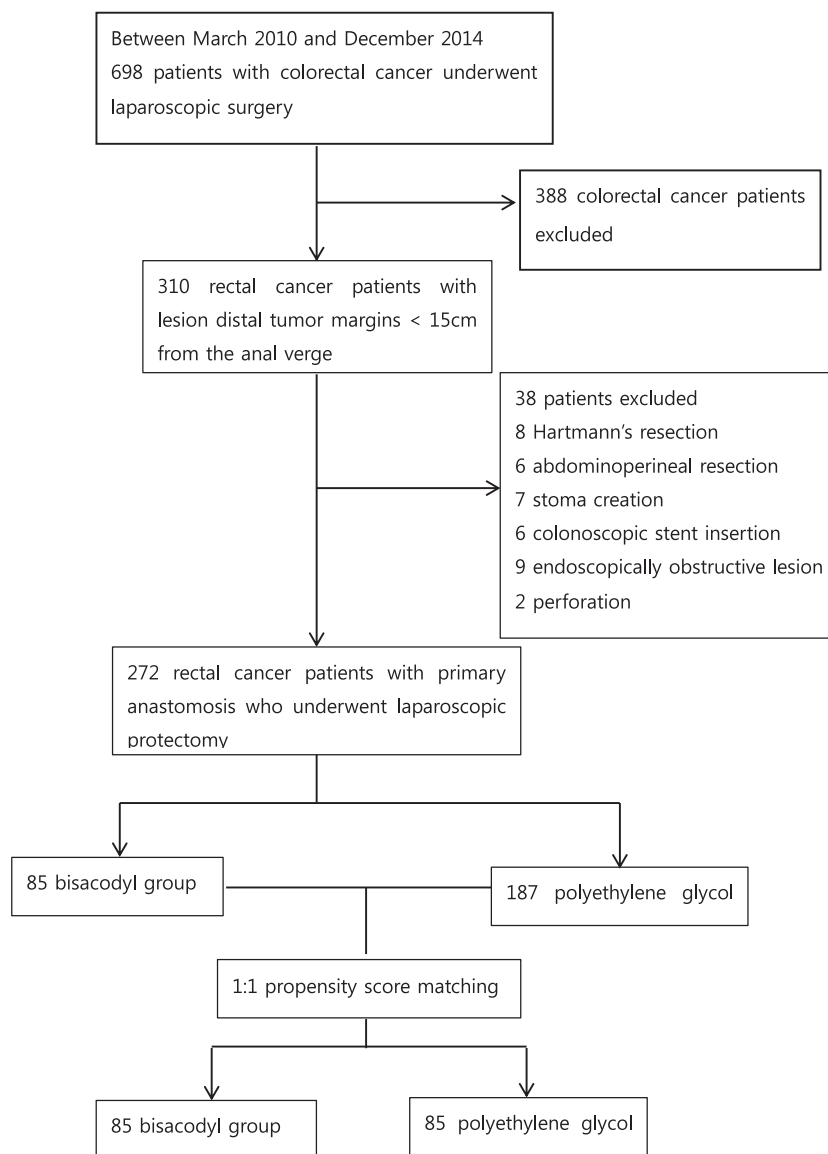


Fig. 1 Study design.

We evaluated bowel preparation quality in the proximal colonic segment to be anastomosed using the modified Ottawa bowel preparation categorical system¹⁶: excellent, mucosa of the colon segment with no residual stool; fair, mucosa of the colon segment with a small amount of solid stool; or poor, mucosa of the colon segment with a large amount of solid or liquid stool. Small bowel distension was classified in the laparoscopic view as collapsed, mildly distended, and severely distended. Laparoscopic proctectomy using a 4-port technique with (sub)-total mesorectal excision, defined as sharp dissection under direct vision with excision of the (sub)-total mesorectum, was performed according to tumor location. All anastomoses were constructed

using a double stapling technique. After colorectal or coloanal stapled anastomosis, 4 to 6 intracorporeal reinforcement sutures of stapled anastomosis were placed in most patients undergoing (low) anterior resection and in some patients with very low anterior resection. A diverting stoma was performed when the anastomosis was problematic, in such cases as a positive air-leak test, very low-lying anastomosis, difficult pelvic dissection, and for other factors suggesting a high risk for anastomotic failure. Operative time was calculated as the time between the first incision and wound closure, and intraoperative blood loss was measured by subtracting the volume of instilled fluids from the aspirated volume.

Table 1 Demographic and clinical characteristics

Variables	PEG group (n = 85)	Bisacodyl group (n = 85)	P value
Age, y (range)	65.0 (59.0–72.0)	65.0 (58.0–74.0)	0.903
Sex			0.259
Male, n (%)	26 (30.6)	33 (38.8)	
Female, n (%)	59 (69.4)	52 (61.2)	
BMI, kg/m ² (range)	23.6 (21.7–25.7)	23.3 (22.0–25.2)	0.870
ASA class			1.000
I and II, n (%)	74 (87.1)	74 (87.1)	
III, n (%)	11 (12.9)	11 (12.9)	
Stage			0.938
I, n (%)	14 (16.5)	17 (20.0)	
II, n (%)	27 (31.8)	26 (30.6)	
III, n (%)	38 (44.7)	37 (43.5)	
IV, n (%)	6 (7.0)	5 (5.9)	

BMI, body mass index; SD, standard deviation.

Postoperative morbidity within 30 days post-surgery was classified according to the Clavien-Dindo classification. Patients were classified with anastomotic leakage if anastomosis defects were identified upon rectal examination by the surgeon or in the contrast study, irrespective of clinical symptoms (fever, leukocytosis, and/or purulent or fecal discharge from the drain), or from fluid collection in the pelvic cavity on imaging. Wound infection was defined as pus discharge from the wound or a positive discharge culture. Mortality was defined as in-hospital death or death within 30 days after the operation. The ethics committee of Haeundae Paik Hospital approved this study.

Statistical analysis

Patients in the PEG and bisacodyl groups were matched using propensity scores, as described by D'Agostino.¹⁷ An individual's propensity score was calculated based on age; sex; body mass index; American Society of Anesthesiologists (ASA) score; and primary tumor, regional lymph nodes, and distant metastasis stage using a multivariable logistic regression model. The 85 patients in the bisacodyl group were matched to patients in the PEG group with the nearest available score without replacement using statistical software (SAS version 9.3, SAS Institute, Cary, NC). We compared short-term surgical outcomes in the 85 matched pairs of bisacodyl and PEG patients.

Demographic, clinical characteristics, and surgical outcomes for the matched data were compared using independent *t*-tests or Wilcoxon rank sum tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables. All data were analyzed using statistical software (SAS version 9.3,

SAS Institute, Cary, NC) and two-sided *P* values < 0.05 were considered statistically significant. Statistical analysis was done by Pusan National University Hospital Clinical Trial Center Biostatistics Office.

Results

Demographic and clinical characteristics did not differ between the groups (Table 1). Most patients underwent proctectomy with extraperitoneal colorectal or coloanal anastomosis (80%, bisacodyl group; 91%, PEG group). There were no significant differences between the groups for operation time, anastomosis level, splenic mobilization, or diverting stoma use (Table 2). Bowel cleansing quality was much poorer in the bisacodyl group compared to the PEG group (excellent, 43.5% versus 68.2%; fair, 41.2% versus 16.5%; and poor, 15.3% versus 15.3%, respectively, *P* < 0.001). Small bowel distension did not significantly differ between the bisacodyl group and the PEG group (collapsed, 56.4% versus 52.9%; mildly distended, 41.2% versus 40.0%; severely distended, 2.4% versus 7.1%, *P* = 0.452; Table 3). However, the proportion of poor bowel cleansing was lower in the bisacodyl group (6/26) than in the PEG group (9/17; *P* = 0.044) in a subgroup of 43 patients with circular tumors. The percentages of the collapse status of small bowel were 61.5% (16/26, bisacodyl group) and 52.9% (9/17, PEG group; *P* = 0.397) in the subgroup of 43 patients with circular tumor. There was no significant difference in the time to the first flatus and the hospital stay length between the bisacodyl and PEG groups (3.0 versus 3.0 days, and 16.0 versus 15.0 days, respectively). The overall morbidity rate was similar between the

Table 2 Details of operation

Variables	PEG group (n = 85)	Bisacodyl group (n = 85)	P value
Operation time, min (range)	290 (245–330)	260 (230–315)	0.089
Estimated blood loss, mL (range)	200 (100–300)	100 (50–100)	<0.001
Level of anastomosis			0.051
Intraperitoneal, n (%)	7 (8.2)	17 (20.0)	
Extraperitoneal, n (%)	62 (72.9)	49 (57.7)	
Coloanal, n (%)	16 (18.9)	19 (22.3)	
Mobilization of splenic flexure, n (%)	32 (37.7)	21 (24.7)	0.069
Diverting stoma, n (%)	34 (40.0)	46 (54.1)	0.065
Conversion to open or hand-assisted laparoscopic surgery, n (%)	0 (0.0)	2 ^a (2.4)	0.155

^aOne patient in the bisacodyl group was converted to hand-assisted laparoscopic surgery due to tumor invasion of sacrum, and other patient open surgery due to tumor invasion to urinary bladder.

2 groups, 29.4% (25/85, bisacodyl group) versus 30.6% (26/85, PEG group, $P = 0.426$). The number of grade I through II and III through IV abdominal complications were 8 versus 8 (9.4% versus 9.4%) and 2 versus 3 (2.4% versus 3.5%), respectively, between the bisacodyl and PEG groups. Anastomotic leakage rate was comparable between the bisacodyl and PEG groups (8.2% versus 5.9%, respectively; $P = 0.549$). Of 146 patients with extraperitoneal anastomosis (EPA), similar results were observed for anastomotic leakage (bisacodyl group, 8.8% versus PEG group, 6.4%; $P = 0.755$). There was no significant difference in abdominal complications requiring reoperation [bisacodyl group: 1 (1.2%) versus PEG group: 3 (3.5%); $P = 0.621$; Table 4]. Reoperation was required for anastomotic leakage (3 patients) in the PEG group and for peritonitis due to bile duct injury (1 patient) in the bisacodyl group. There was 1 case of hospital mortality from anastomotic leakage in the PEG group (1.2%) among the 7 patients who developed anastomotic leakage. None of the patients underwent reoperation related to anastomotic leakage in the bisacodyl group. In the bisacodyl group, 1 reoperation was performed to manage peritonitis from bile duct injury following adhesiolysis between the liver and T-colon resulting from a

previous gastric surgery. Bile leakage occurred 1 day after laparoscopic proctectomy and was managed with laparoscopic intraperitoneal irrigation and drain insertion into the subhepatic space. The patient recovered uneventfully and was discharged on postoperative day 12 (Table 5).

Discussion

Although MBP is believed to be essential for reducing surgical site infections following colorectal surgery, the most recent randomized controlled trials and meta-analyses concluded that MBP has little effect on reducing postoperative complications following colorectal surgery.^{18,19} Even among patients with extraperitoneal colorectal anastomosis, a role for MBP in preventing anastomotic leakage or septic complications was not shown.²⁰ In contrast, the French GRECCAR III trial¹⁰ demonstrated that rectal cancer surgery without MBP was associated with a higher risk of overall and infectious morbidity. The authors recommended that MBP continue to be performed before elective rectal cancer surgery.¹⁰ Therefore, until now, there is no consensus as to whether MBP should be used for patients with rectal cancer.

Table 3 Assessment of cleanliness and distension of bowel at operative finding

Variables	PEG group (n = 85)	Bisacodyl group (n = 85)	P value
Classification of LB cleanliness			<0.001
Excellent, n (%)	58 (68.2)	37 (43.5)	
Fair, n (%)	14 (16.5)	35 (41.2)	
Poor, n (%)	13 (15.3)	13 (15.3)	
Degree of SB distension			0.452
Collapsed, n (%)	45 (52.9)	48 (56.4)	
Mildly distended, n (%)	34 (40.0)	35 (41.2)	
Severely distended, n (%)	6 (7.1)	2 (2.4)	

LB, large bowel; SB, small bowel.

Table 4 Short-term surgical outcomes

Variables	PEG group (n = 85)	Bisacodyl group (n = 85)	P value
Time to first flatus, d (range)	3.0 (2.0–4.0)	3.0 (2.0–4.0)	0.426
Postoperative hospital stay, d (range)	15.0 (12.0–19.0)	16.0 (14.0–22.0)	0.215
Overall morbidity	26 (30.6)	25 (29.4)	0.426
Clavien-Dindo classification			0.816
I–II, n (%)	8 (9.4)	8 (9.4)	
III–IV, n (%)	3 (3.5)	2 (2.4)	
Wound infection, n (%)	1 (1.2)	1 (1.2)	1.000
Anastomotic leakage, n (%) ^a	5 (5.9)	7 (8.2)	0.549
Anastomotic leakage after EPA	5/78 (6.4)	6/68 (8.8)	0.755
Reoperation for abdominal complications	3 (3.5)	1 (1.2)	0.621
Mortality	1 (1.2)	0 (0.0)	1.000

^aAnastomotic leakage included patients with only anastomotic defect on rectal examination.

Although PEG solution has been the most commonly used oral laxative for MBP in colorectal surgery,²¹ PEG solution has several disadvantages, such as causing less safe bowel handling during surgery and requiring patients to intake large volumes of unpleasant-tasting solutions.^{7,19,21} However, in cases of patients without oral laxatives, endoluminal cleanliness was considered as inadequate for safe rectal surgery.^{9,10} Based on these results, the need for oral laxatives in MBP for rectal surgery appears to be still ongoing. Therefore, we evaluated the value of other oral laxatives by using bisacodyl instead of conventional MBP before laparoscopic radical proctectomy.

Previous studies evaluating the role of MBP included all patients undergoing laparoscopic and open surgery for rectal cancer.^{10,22} But, we focused on laparoscopic proctectomy, calling into question the effect of MBP on laparoscopic surgical field exposure. In laparoscopic surgery, radical proctectomy with a distended small bowel or poor surgical field is more challenging than that with an emptied small bowel or a good surgical field.

Therefore, bowel preparation procedures for laparoscopic proctectomy may need to be modified from those used in the past, because the large amount of oral solution often inadequately prepares the bowel and may lead to increased fluid in the small bowel. In the present study, the status of severely distended small bowels, which can hamper laparoscopic vision, was noted in 2.4% of the bisacodyl group compared to 7.1% of the PEG group. Our finding of a higher tendency toward poor exposure of surgical field in the conventional MBP group was in contrast to a previous article¹⁵ mentioning that the reason for MBP is to improve visualization during colorectal laparoscopic surgery.

In contrast to colonoscopy preparation, bowel preparation safety for patients undergoing rectal surgery without PEG solution has been previously demonstrated.^{6,10} It is presumed that a prepared proximal colon with fair status in our classification on the basis of the modified Ottawa bowel preparation categorical system¹⁶ may be safely anastomosed to the low rectum or anal canal. Thus, we found no differences with respect to abdominal complication rates, including anastomotic leakage, wound infection, and reoperation, between bisacodyl and PEG groups. In addition, especially in cases of EPA, the anastomotic leakage rate was comparable between 2 groups. Based on results derived from our abdominal complication rates, the present study indicates that MBP with bisacodyl for laparoscopic rectal surgery may be performed safely. Because there has been to date insufficient evidence to support a standard for MBP in laparoscopic rectal cancer surgery, our results obtained in this study may be used as background data when surgeons re-evaluate their MBP method.

Table 5 Extra-abdominal complications

Variables	PEG group (n = 85)	Bisacodyl group (n = 85)	P value
Urinary, n (%) ^a	11 (12.9)	13 (15.3)	
Pulmonary, n (%) ^b	2 (2.4)	0	
Cardiac, n (%) ^c	0	2 (2.4)	
Neurologic, n (%) ^d	2 (2.4)	0	
Total	15 (17.6)	15 (17.6)	1.000

^aUrinary complications included urinary retention and urinary tract infection.

^bPulmonary complications included pneumonia and pulmonary embolism.

^cCardiac complications included arrhythmia and atrial fibrillation.

^dNeurologic complication was postoperative delirium.

A trend toward a beneficial effect of oral bisacodyl on operative time shortening was observed in this study. In contrast, no beneficial effect of MBP without oral laxatives on operative time shortening in rectal cancer surgery was reported in the other multicenter randomized trial.¹⁰ As mentioned in previous studies,⁴ the colon is frequently not clean after MBP with large amounts of oral laxatives. Based on previous suggestions,^{4,18,19} the trend toward the shorter operative time of the bisacodyl group in our study is assumed to be related to the ease of handling the bowel as a result of reducing the liquid bowel content.

Some limitations of the present study should be considered. First, as this study was not prospective and included a relatively small number of patients, hidden bias was inevitable. Thus, we used propensity score matching for case-control comparisons to reduce selection bias and increase precision. Second, the categorized degree of bowel cleanliness and distension was subjective and was based on the operator's estimation during laparoscopic surgery. However, it is very difficult to objectify the degree of bowel cleanliness and distension. Third, this study did not use a questionnaire with a discomfort rating scale and tolerance rate following each MBP. However, patients who received minimal MBP using oral bisacodyl had relatively fewer complaints than did patients who received PEG solutions based on retrospective nursing records (data not shown).

We believe that this study could serve as background research for future clinical trials on alternative MBP for laparoscopic radical proctectomy. In conclusion, the present study showed that laparoscopic radical proctectomy may be performed safely with minimal preparation method using oral bisacodyl.

Acknowledgments

Each author certifies that they have no financial or personal relationships with other people or organizations that could inappropriately influence their work. This study was approved by the ethics committee of Inje University Haeundae Paik Hospital (institutional review board code: 129792-2015-044). Informed consent was obtained from all individual participants included in this study. We acknowledge assistance with statistical analysis from Pusan National University Hospital Clinical Trial Center Biostatistics Office.

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