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Preoperative Oral-Bowel Preparation Using Sodium Picosulfate and Magnesium Citrate Combination Powder for Left-Sided Colorectal Cancer: A Prospective Study

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Objective: This study aimed to determine if induction of sodium picosulfate and magnesium citrate (SPMC) preparation leads to adequate surgery for left-sided colorectal cancer (CRC).

Summary of Background Data: Adequate bowel cleansing is vital for safe and accurate colorectal surgery. Ingestion of laxatives for bowel cleansing may be associated with a broad spectrum of adverse effects during surgical intervention.

Methods: A single-center prospective study was conducted with hospitalized patients scheduled operation for left-sided CRC. All enrolled patients were instructed to consume normal diet until before preparation. Twenty-seven patients underwent preoperative SPMC preparation.

Results: The primary endpoint of this study was the 30-day postoperative morbidity rate, which was 23%, and no postoperative complication was higher than Clavien-Dindo grade 3. The primary anastomosis rate was 100%, and there was no anastomotic leakage. The colonic cleansing grades were 1 or 2 according to the bowel preparation scale for surgical assessment in 89% of the patients. The acceptability of the cleansing procedure by the

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patients assessed by a questionnaire was 85%, and the acceptability of the SPMC preparation by the medical staff was 93%. The surgical procedures included 18 laparoscopies, 6 robotic surgeries, and 3 laparotomies. The median operation time was 165 minutes, and the median blood loss was <50 cc. The median sodium serum concentration was significantly decreased after surgery.

Conclusion: Ingestion of an SPMC preparation as a cleansing procedure was judged to be adequate for curative surgery in patients with left-sided colorectal cancer.

Key words: Bowel preparation – Colorectal cancer – Surgery – SPMC – PICOPREP

Colorectal cancer (CRC) remains the leading cause of cancer-related deaths worldwide because many patients are initially diagnosed in advanced stages.[1] Screening colonoscopy is effective for preventing advanced CRC and has therefore gained importance over recent decades.[2] Adequate bowel cleansing is vital for safe and accurate colonoscopy.[3] To be successful, the cleansing preparation must be both acceptable to the patient and effective. Inadequate cleansing may result in missed lesions, increased procedure time, a need for repeat colonoscopy, and patient reluctance to undergo a repeat examination.[4,5]

Ingestion of laxatives for bowel cleansing has been reported to be a major barrier that discourages patients from participating in screening programs.[6,7] Polyethylene glycol (PEG) is a standard solution preparation used as a bowel-cleansing agent before colonoscopy.[8] Unfortunately, PEG intake may be associated with a broad spectrum of adverse effects, such as nausea, vomiting, bloating, or abdominal pain.[3] The consensus of the European Society of Gastrointestinal Endoscopy is that, compared with PEG, sodium picosulfate and magnesium citrate (SPMC) provided satisfactory colon cleansing in a similar proportion of patients, with less-frequent adverse events.[9] Similar SPMC effects also have been reported in patients who received PEG the day before surgical intervention.[10]

This study aimed to determine if ingestion of an SPMC preparation is acceptable to patients and provides sufficient colon cleansing before surgery for left-sided colorectal cancer.

Materials and Methods

Patients

A single-center prospective study was conducted in hospitalized patients older than 20 years who were scheduled to undergo surgical intervention for left-sided colorectal cancer of the descending colon, sigmoid colon, or rectum. We excluded patients who had risk factors, such as bleeding, occlusion, and symptoms of a nausea, vomiting, bloating, or abdominal pain, related to poor cleansing preparation. In addition, the exclusion criteria included planning of Hartmann's operation or abdominoperineal resection, previous colorectal surgery, presence of ascites, cognitive impairment, or an estimated glomerular filtration rate (eGFR) of <30 mL/min per 1.73 m^2.

Ethical approval was obtained from the Ethics Committee of Higashiosaka City Medical Center, and participants provided written informed consent before bowel preparation. CRC was diagnosed by clinical examination, radiography, endoscopy, endoscopic biopsy, and computed tomography. The operation was performed by using 1 of 3 approaches: well-planned laparotomy, laparoscopy, or robotic surgery, which include D3 lymph-node dissection and primary anastomosis using a double-stapling technique. The medical records of patients who underwent primary colorectal resection at Higashiosaka City Medical Center between January 2019 and March 2020 were reviewed.

Procedure of preparation

All enrolled patients were instructed to consume a normal diet until performing the cleansing procedure. The patients were prescribed preoperative SPMC powder (2 packs of PICOPREP Combination Powder; Nippon Chemiphar, Tokyo, Japan) and instructed to follow the "Day-Before Dosage Regimen," which requires twice ingesting 1 pack of SPMC powder with 150 mL water followed by drinking clear water: once 2 PM and once at 6 PM on the day before surgery (Figure 1). If necessary, the physicians also prescribed liquid sodium picosulfate to be included in the first SPMC preparation and sennoside calcium to be taken before bed the day before surgery. Patients were required to subse-

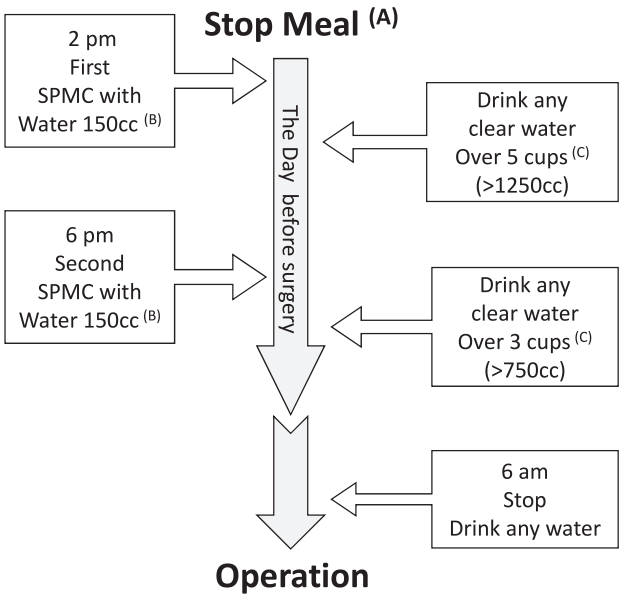

Fig. 1 Preoperative SPMC preparation protocol. (A) Intake of food and any fluid oral nutrition was stopped after 2 PM. (B) Bowel preparation using PICOPREP with water was ingested twice at 2 different times. (C) Mechanical bowel preparation was followed by chasing water.

quently drink more than 2 L of clear water, but any type of clear fluid water was acceptable (water, tea, coffee, sports drink, or juice).[11] The patients stopped drinking fluids at 6 AM on the day of surgery. All surgeries were scheduled to be performed before 5 PM on the same day. Patients were followed according to the Higashiosaka Medical Center clinical pathway protocol, which includes starting to drink on postoperative day 1 and eating a low-residue meal on postoperative day 3.

Histological findings

All specimens in this study were obtained according to the protocol guidelines set by Higashiosaka City Medical Center, and the protocol was approved by the institutional review board. Paraffin-embedded specimens were obtained from a cohort of patients diagnosed by the Union for International Cancer Control staging system.

Outcome measurement

The primary endpoint of this study was the 30-day postoperative morbidity rate. The secondary endpoint of this study was the efficacy of bowel cleansing assessed according to an in-house quality scale, acceptance of the procedure by patients, the presurgery preparation suitability by medical staff, surgical outcomes, and blood examination. We used our institution-specific preparation quality scale for surgery, which was named the Bowel Preparation Scale for surgical assessment at the time of use for this study.[12] This scale was modified for use in surgical interventions and is similar to the Japanese colon-cleansing scale for colonoscopy.[13] Surgeons perform diagnosis directly before anvil insertion into the colon during anastomosis. The quality of bowel cleaning was assessed by the surgeon for only 1 site of each oral side bowel (sigmoid colon or descending colon) according to the following scoring: Score 1, colon empty and clean; Score 2, presence of clear liquid in the bowel, but easy to remove; Score 3, presence of brown liquid or small amounts of semisolid residual liquid, allowing a complete visualization of the bowel mucosa; Score 4, presence of semisolid stool, only partially removable with a risk of incomplete visualization of bowel mucosa; and Score 5, presence of semisolid or solid stool causing incomplete observation. For patients with scores of 1 or 2, the bowel preparation was considered to be a success. For patients with a score of 3 to 5, the bowel preparation was considered to be a failure (Figure 2).

The Patient's Acceptance questionnaire included 7 sections: (1) Did you complete SPMC intake? (2) Was it easy to drink? (3) What was your impression of the powder? (4) How did it taste? (5) Was the quantity ingested acceptable? (6) Were you able to repeat the procedure? (7) Will you decline to perform this cleansing procedure in the future? Responses with all positive answers or 1 negative answer were considered to be acceptable. Responses with 2 negative answers were considered to be unacceptable.

The medical staff (nurses and doctors) acceptance questionnaire included 6 sections: (1) How well were you able to explain the procedure to your patient? (2) Did you complete the SPMC procedure? (3) Was the preparation easy for the patient to drink? (4) Did the patient have leftover of SPMC intake? (5) What is your impression of the powder? (6) Would you recommend the new powder for repeated use? The questions had 5 possible answers: 0, excellent; 1, good; 2, fair. 3, difficult; and 4, awful. Scores of 0 to 2 were considered to be acceptable, whereas scores of 3 or 4 were considered to be unacceptable. The patients' blood was tested for the eGFR and serum concentrations of creatinine, magnesium, sodium, and potassium.

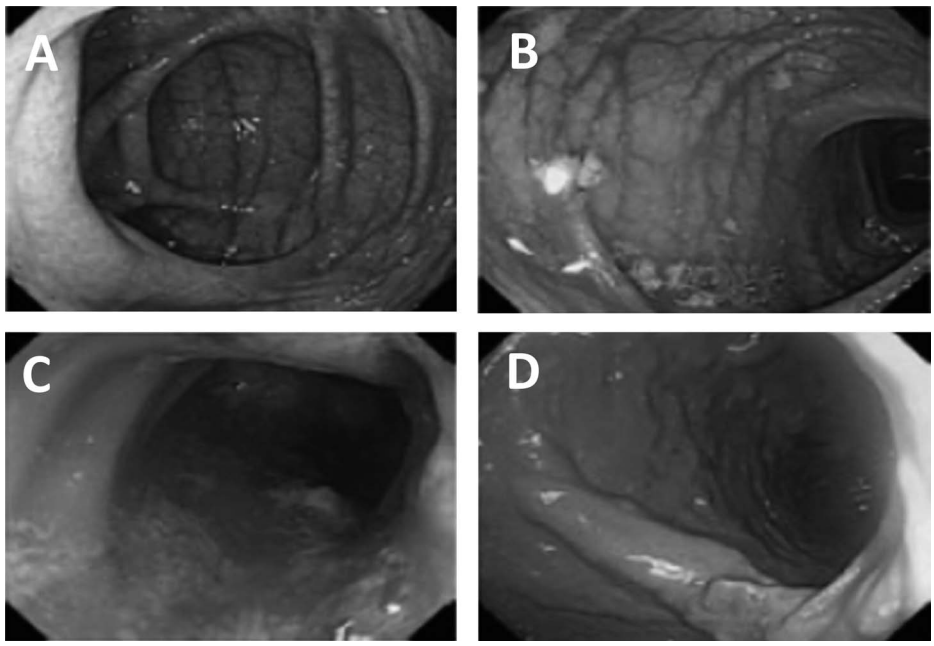

Fig. 2 The bowel preparation scale for surgical assessment. The quality of bowel cleaning was assessed by the surgeon for 1 site of each oral side bowel. (A) Score 1, colon empty and clean; (B) Score 2, presence of clear liquid in the bowel, but easy to remove; (C) Score 3, presence of brown liquid or small amounts of semisolid residual liquid, allowing a complete visualization of the bowel mucosa; (D) Score 4, presence of semisolid stool, only partially removable with a risk of incomplete visualization of bowel mucosa; and Score 5, presence of semisolid or solid stool causing incomplete observation.

Statistical analysis

Student's *t* test and the Wilcoxon test were performed for continuous variables, and the χ^2 and Fisher's exact tests were performed for categorical variables. All statistical analyses used JMP (version 8.01; SAS Institute, Cary, NC) or statistical scripting language R (http;//www.r-project.org/). *P* values $\leq$0.05 (2-sided) were considered to be indicative of statistical significance.

Results

Thirty patients had been enrolled in this protocol, but 3 patients were excluded. In total, 27 patients performed the SPMC cleansing procedure (PICOPREPP) before surgery. The technical success rate was 96% (26 patients); 1 patient experienced vomiting after ingesting the second PICOPREPP preparation. The median amount of clear water for chasing was 2.25 L, and the median number of stool discharges in a restroom to show nearly complete voiding of the ingested SPMC preparation was 7 (Table 1).

The colon-cleansing grades after using the bowel preparation scale for surgical assessment were scores of 1 or 2 in 89% of the patients, and a score of 3 in the remaining 11% of patients (Table 2). We found that 85% of the patients rated the SPMC preparation as acceptable. We also found that 93% of the medical staff scored the SPMC preparation as suitable for surgical assessment and that it decreased the degree of medical care needed relative to the care needed when using previous colon-cleansing preparations.

The tumor location, pathological finding, surgical procedure, and surgical outcome are shown in Table 3. The pathologic tissue accounted for 96% of differentiated types. The surgical approaches included 18 laparoscopies, 6 robotic surgeries, and 3 laparotomies. Open conversion from laparoscopy was performed for 1 patient, and 2 patients required creation of a covering stoma after low anterior resection. The median operation time was 165 minutes, the median blood loss was <50 cc, and there was no mortality after surgery. The 30-day postoperative morbidity rate was 23% and included 3 bowel obstructions, 1 surgical site infection, prostate hypertrophy, and dehydration. All postoperative complications were assessed as Clavien-Dindo grades <3, which were mostly acceptable results. The primary anastomosis rate was 100%,

Table 1 Patient demographics and outcomes of preoperative SPMC preparation

	n = 27
Gender	
Male	17
Female	10
Age, median (range)	74 (38–88)
BMI, median (range; kg/m^2)	21.4 (13.7–35.7)
eGFR, median (range; mL/min/1.73 m^2)	59.5 (42.0–89.8)
ASA-PS, mean ± SD	2.1 ± 0.4
Risk factor	
Overall	20 (74.1%)
Diabetes mellitus	8*
Hypertension	5*
Urologic	2*
Neurologic	2*
Others	5*
SPMC intake, complete	26 (96.3%)
Chasing clear water, mean ± SD (L)	2.25 ± 1.0
Stool after preparation, Median (range; times)	7 (1–24)

BMI, body mass index; eGFR, estimated glomerular filtration rate; SD, standard deviation; SPMC, sodium picosulfate and magnesium citrate.

* Overlapped.

Table 2 Overall bowel-cleansing grade before surgery and results of questionnaires for patients and medical staff

	n = 27, n (%)
Bowel preparation scale	
1	19 (70)
2	5 (19)
3	3 (11)
4	0
5	0
Patient's acceptance	
Symptom-free	26 (96)
Vomit	1 (4)
Acceptable	23 (85)
Not-accept	4 (15)
Medical staff acceptance	
0	14 (52)
1	7 (26)
2	4 (15)
3	2 (7)
4	0

and there was no anastomotic leakage. The median postoperative hospital stay was 10 days.

We examined the patients' eGFRs and serum concentrations of creatinine, magnesium, calcium, sodium, and potassium before ingesting the SPMC preparation and 3 days after surgery. Their eGFRs and serum concentrations of creatinine, magnesium, calcium, and potassium were not significantly different before and after preparation and surgery. The median serum sodium concentration was 140 mEq/L before preparation and significantly decreased to 137 mEq/L after surgery ($P = 0.004$, Table 4).

Discussion

This study demonstrated that oral SPMC provided good mechanical bowel cleansing before left-sided colorectal surgery, as assessed by patients and medical staff, and showed that it was reasonably safe, as assessed by the 30-day postoperative morbidity rate of 23% and Clavien-Dindo grades <3. We are not aware of previous reports that assessed safety and suitability. There was no anastomotic leakage and no severe morbidity after colorectal surgery with preoperative SPMC preparation. More patients reported that the taste was pleasant than did not and more of the medical staff reported that the preparation was acceptable before surgery than they had experienced with previous colon-cleansing preparations.

Our study simulated a setting described in previous studies that used the SPMC preparation and that cited its convenience and increased patient satisfaction for colonoscopy.[11] Previous studies have reported that inadequate preparation before colonoscopy occurred in 20% to 33% of patients.[14,15] Approximately 80% of patients achieved adequate bowel preparation using SPMC, which is a higher rate than that for screening using an ascorbic acid-enriched PEG solution.[16] This cleansing efficacy was similar to that found by 21 studies using PEG solutions and sodium picosulfate in 5443 patients.[17] Therefore, in the present study, we instructed the patients to perform preoperative colon cleansing using an SPMC combination powder 2 times by ingesting 1 pack with 150 mL water followed by drinking clear water each time. We observed no severe morbidity after the operations; however, there was a significant difference in serum sodium concentrations pre- and postoperatively. We are usually using infusion therapy for all patients until oral intake, thereby these infusions have potential to effect on the sodium reduction. In addition, bowel preparation using a hypertonic solution like SPMC, decreases in sodium and increases in hematocrit and hemoglobin as a sign of intravascular volume depletion have been reported.[18,19]

Mechanical bowel preparation has continued to be routinely performed throughout the world.[20] Many reports, especially in colorectal surgery, have recommended that aggressive intestinal cleansing

Table 3 Surgical intervention and their results

	n = 27
Location, n (%)	
Descending	4 (15)
Sigmoid	10 (37)
Rectum (RS)	5 (17)
Rectum (Ra)	6 (22)
Rectum (Rb)	2 (7)
pT factor	
T1	5
T2	3
T3	11
T4	8
pN factor	
N0	15
N1	5
N2	6
N3	1
Histological	
tub1	7
tub2	19
others	1
Surgical approach, n (%)	
Laparoscopy	18 (63)
Robotic surgery	6 (24)
Laparotomy	3 (13)
Open conversion	1 (4)
Surgical procedure, n (%)	
Colectomy	12 (44)
High anterior resection	8 (30)
Low anterior resection	7 (26)
Covering stoma creation	2 (7)
Operation time, median (range; min)	165 (98–357)
Blood loss, median (range; mL)	0 (0–642)
Morbidity, n (%)	
Overall	6 (23)
Bowel obstruction	3 (11)
Surgical site infection	1 (4)
Prostatic hypertrophy	1 (4)
Dehydration	1 (4)
Anastomotic leakage	0
Hospital stay, median (range; days)	10 (4–60)

reduced the bacteria in the gastrointestinal tract and would reduce the risk of postoperative infection or anastomotic leakage.[21–25] On the other hand, a meta-analysis of 23 randomized controlled trials and 13 observational studies compared mechanical bowel preparation with absolutely no bowel preparation or a single rectal enema and found no statistically significant difference in the incidences of anastomotic leakage, surgical site infection, intra-abdominal fluid collection, mortality, and reoperation.[26] These studies predominantly were in patients who underwent a mixture of colonic and rectal procedures.[27,28] The documentation was inadequate to differentiate results between the 2 procedures in those studies, which may be particularly important for assessing the value of using a single rectal enema as a bowel preparation.[26] Furthermore, there was poor documentation regarding the procedure of the anastomosis, which involved a mixture of ileocolic, colon-colon, and colorectal anastomoses, within the studies included. Other reports could not exclude the possibility of modest beneficial or harmful effects of oral mechanical bowel preparations when compared with no preparation or enema only.[29] Most studies included a predominance of colonic procedures, with some focusing entirely on colonic rather than rectal surgery. In rectal surgery, some reports have suggested that the incidence of anastomotic leakage was higher in nonmechanical bowel preparation than in mechanical bowel preparation.[30] Nonmechanical preparation was usually used for right-sided colon surgery.[31] Our study appears to be the first to report the use of SPMC for surgery to treat left-sided colorectal cancer and that it was safe and feasible. We plan to conduct a randomized controlled study in a larger number of patients in the future.

This study was designed as a pilot study to determine if the SPMC colon-cleansing preparation warranted testing in a subsequent a multicenter clinical study. However, these findings should be considered in light of several limitations. First, although this was a prospective study, it included a small number of patients from a single institution who were not randomized. Consequently, the heterogeneity of the surgical intervention may have affected the morbidity rate. Second, although validated preparation procedures were performed by

Table 4 Comparison of blood serum test results in patients before and after SPMC preparation and surgery

	Before	After	*P*
eGFR, median (range; mL/min/1.73 m^2)	63.5 (42.0–89.8)	65.3 (36.6–97.4)	0.489
Creatinine, median (range; mg/dL)	0.80 (0.61–1.28)	0.78 (0.60–1.13)	0.522
Magnesium, median (range; mg/dL)	2.4 (2.2–2.6)	2.5 (1.9–2.6)	0.471
Sodium, median (range; mEq/L)	140 (133–143)	137 (130–144)	0.004
Potassium, median (range; mg/dL)	4.2 (3.5–4.9)	4.2 (3.5–4.9)	0.917

eGFR, estimated glomerular filtration rate.

medical staff, the SPMC preparation used in this study used different concomitant drugs. Third, the scoring of the preparations used an institution-specific bowel preparation scale because there was no bowel preparation scale assessment available for surgical intervention. Comparable previous studies had used the Ottawa Bowel Preparation Quality Scale, Aronchick Scale, and Boston Bowel Preparation Scale. All of these scales were in settings intended to assess the quality of colonoscopy but were considered for assessments of colonoscopies in a future study.[11] These findings have to be considered when planning future clinical trials.

To investigate the long-term postoperative complications after SPMC preparation for colorectal surgery, a prospective, large-sample, randomized controlled trial in patients from multiple institutions is warranted to confirm the treatment safety and patients' acceptance shown in our small study.

In conclusion, the primary endpoint of this study was the 30-day postoperative morbidity rate after surgery, which was 23%, and all postoperative complications were assessed as Clavien-Dindo grades <3. We demonstrated that the morbidity rate and acceptance of the preoperative colon-cleansing SPMC preparation by patients and medical staff were acceptable. Our results support the use of the SPMC preparation for colon cleansing before curative surgery in patients with left-sided colorectal cancer.

Ethical Statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Committee and with the 1964 Helsinki Declaration and its later amendments or with comparable ethical standards. All subjects or their guardians have given their written informed consent and that the study protocol was approved by Higashiosaka City Medical Center Ethical Committee on human research; assignment number 02–0498

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Author contributions: KO: Protocol/project development, data collection, management, and manuscript writing/editing. MI: Protocol/project development, management, and manuscript writing/editing. MU, YT, SN, and TT: Protocol/project development, data collection, and management. JM and SE: Data collection and management. KI, TN, and TY: Data analysis and manuscript writing/editing.

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