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ORIGINAL ARTICLE

Usefulness of sennoside as an agent for mechanical bowel preparation prior to elective colon cancer surgery

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Summary *Objective:* We retrospectively evaluated the usefulness of sennoside as an agent for mechanical bowel preparation prior to elective colon cancer surgery.
Methods: A total of 86 patients were given 12 mg of sennoside on the evening prior to resective surgery for colon cancer, followed by intravenous antimicrobial prophylaxis used on the day of surgery or until postoperative day 2.
Results: The incidence of surgical site infection in the study group was 4.7%, which was comparable to that in the historical control patients (3.5%, $p > 0.99$), who had received polyethylene glycol for mechanical bowel preparation prior to colon surgery. On multivariate logistic regression analysis, only body mass index ($p = 0.04$) was an independent significant factor affecting the surgical site infection. The intraoperative spillage was not influenced by the presence of stenosis, although the amount of fecal matter was higher in the upstream colon segment ($p < 0.01$) and downstream segment ($p = 0.07$) in patients with a stenotic lesion occupying more than two-thirds of the lumen ($n = 29$) than in those without such severe stenosis ($n = 57$).
Conclusion: Sennoside seems to be an acceptable agent for mechanical bowel preparation even in patients with stenosis.

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1. Introduction

Several recent meta-analyses[1–3] have suggested that routine use of mechanical bowel preparation prior to elective colorectal surgery should be omitted, since mechanical bowel preparation did not seem to reduce the incidence of anastomotic leakage or wound infection. Despite the results of the meta-analyses, various types of mechanical bowel preparation, including with the use of polyethylene glycol (PEG), the standard agent used most frequently for mechanical bowel preparation, seem to have been undertaken prior to colon surgery, at least until recently, not only in Japan,[4,5] but also in Western countries.[6–8] In addition, some investigators[9] claimed that different mechanical preparation methods, as compared with no preparation, should be reconsidered in stratified studies. The evidence derived from the meta-analyses do not seem to be applicable to specific situations such as laparoscopic colorectal surgery or colorectal resection requiring intraoperative colonoscopy to identify the lesions.

It has been reported that PEG is not tolerated well in some patients. Discomfort was reported as an adverse effect in 20.7% to 25% of the patients and vomiting in 2.7% to 11% of the patients given PEG prior to colonoscopy or elective colorectal surgery.[10–13] Sennoside, an extract of senna, is used widely as a stimulant laxative, and its safety and efficacy have been established.[14] However, little is known about the usefulness of sennoside for mechanical cleansing prior to elective colon surgery.

The above prompted us to evaluate the usefulness of sennoside in terms of the incidence of surgical site infection, tolerance, and degree of colonic cleanness obtained. We present our data and discuss the potential usefulness of sennoside in colorectal surgery.

2. Patients and methods

2.1. Patients

The study group were 86 patients who were given sennnoside (Pursennid, Novartis Pharma, Tokyo, Japan) for mechanical bowel preparation prior to elective colon cancer surgery between July 2007 and December 2008 at our department. The patients who were not scheduled to undergo any bowel preparation because of complete or incomplete obstruction were excluded from the study. Written informed consent for use of sennoside as the agent for preoperative mechanical bowel preparation was obtained from each patient.

2.2. Bowel preparation and intravenous antibiotic use

All the eligible patients received 3 g of kanamycin and 2.4 g of erythromycin administered orally in three divided doses within 24 hours of the surgery. They were also given 12 mg sennnoside diluted in a glass of water the evening before the surgery (about 8–12 hours before the surgery). They did not receive any additional bowel preparations, such as enema. After induction of anesthesia, 1 g of cefmetazole was administered intravenously. An additional dose was administered if the duration of surgery exceeded 3 hours. In addition, the patients received one additional dose of cefmetazole 1 hour after the completion of the surgery or four additional doses over next 2 consecutive days after the surgery, according to the preference of the surgeons.

2.3. Procedures for the prevention of surgical site infection

Surgical wounds more than 7 cm long were covered with surgical towels, while those of minilaparotomy ($\leq$ 7 cm long),[15–18] an alternative to the usual laparoscopic approach, were covered with a wound protector (Applied Medical, Rancho Santa Margaria, CA, USA). Stapled anastomoses were performed to achieve bowel continuity in all patients. The abdominal cavity was washed with copious amounts (2–3 L) of saline before the wounds were closed. All gloves were changed after washing the abdominal cavity. After the fascia was approximated using absorbable sutures, the incisional site was washed with 200 mL of saline before closure of the skin, which was accomplished with a skin stapler. The incision site was covered with a sterile dressing, which was removed within 48 hours.

2.4. Factors evaluated

The main outcome measure was the incidence of surgical site infections, which was recorded according to the Centers for Disease Control and Prevention (CDC) definition.[19] Remote infection was defined as infection occurring at a site other than the surgical site, such as pneumonia, urinary tract infection, enteritis, or blood stream (catheter-related) infection. The incidences of surgical site infection, remote infection, re-operation and length of postoperative hospital stay were compared between the patients given sennoside for the bowel preparation (study group) and the historical control patients (control group, $n = 86$). The historical control patients were selected by matching them with the study patients for the type of surgery and duration of intravenous antimicrobial prophylaxis (use of cefmetazole or cefotiam on the day of surgery or until postoperative day 2), from among patients who had undergone mechanical cleansing with 2 L of PEG combined with chemical preparation using kanamycin and erythromycin prior to elective colon cancer surgery. The control patients had been enrolled in a randomized clinical trial performed between January 2003 and June 2007.[20] For the univariate and multivariate logistic regression analyses to determine factors affecting surgical site infection, 12 nominal variables including sex, age ($<$ 70 years vs. $\geq$ 70 years), BMI ($<$ 25 kg/m^2 vs. $\geq$ 25 kg/m^2), ASA score (I/II vs. III), location of the primary tumor (cecum/ascending/transverse vs. descending/sigmoid), length of skin incision (7 cm or less vs. $>$ 7 cm), stenosis ($<$ 2/3 normal caliber, $\geq$ 2/3 normal caliber), level of lymph node dissection (D0/D1/D2 vs. D3), duration of surgery ($<$ 135 min, $\geq$ 135min), blood loss ($<$ 100 mL, $\geq$ 100 mL), duration of intravenous antibiotic use (limited to the day of surgery vs. until

postoperative day 2), and type of mechanical cleansing (sennna vs. PEG) were selected.

Tolerance to bowel preparation using sennoside was evaluated by the presence of vomiting, abdominal pain, distention, or the need to discontinue the bowel preparation. The operating surgeon recorded the fecal matter consistency and intraoperative spillage of the bowel contents according to the method described by Hollender et al.[21] The fecal matter consistency was classified into four categories: solid; soft; fluid; or none. Intraoperative spillage was also classified into four categories: nil; minimal; moderate; or large. The fecal matter consistency and degree of intraoperative soiling were compared between patients with stenosis and those without stenosis. Stenosis was defined as a narrowing of the lumen by more than two-thirds of the normal caliber in the resected specimen.

2.5. Statistics

Continuous variables were expressed as medians with the range. For the statistical analyses, a statistical software package (Statview version 5.0, Abacus Concepts, Inc., Berkeley, CA, USA) running on a Windows personal computer was used. For comparison of the nominal variables, the Fisher exact probability test was used. Applied to a comparison of continuous variables, the Mann—Whitney U-test was used. Logistic regression analyses were used to identify independent risk factors for the surgical site infection. Variables with $p < 0.01$ determined by univariate analysis were entered into the multivariate analysis with stepwise selection. p values of less than 0.05 were considered to denote statistical significance.

3. Results

3.1. Patient characteristics

The characteristics of the patients are shown in Table 1. The median age of the patients was 70 years (range, 32—91 years). The male/ female ratio was 62/24. The median BMI was 22.9 kg/m^2 (range, 15.9—43.1 kg/m^2). The patients were classified according to the American Society of Anesthesiologists Physical Status (ASA) classification as class I ($n = 17$), class II ($n = 51$) or class III ($n = 18$). The locations of the primary tumor were the cecum ($n = 6$), ascending colon ($n = 14$), transverse colon ($n = 15$), descending colon ($n = 8$) or sigmoid colon ($n = 43$). The length of the abdominal incision was 7 cm or less in 51 patients (59%), and longer than 7 cm in 35 patients (41%). Stenosis, defined as a narrowing of the lumen by more than two-thirds as compared to the normal caliber of the bowel, was found in 29 patients (34%). The types of surgery included ileocecal resection ($n = 5$), right (hemi) colectomy ($n = 20$), transverse colectomy ($n = 8$), left (hemi) colectomy ($n = 8$), sigmoidectomy ($n = 35$), and other segmental colectomy ($n = 10$). Combined resection of other organ(s) was also performed in 13 patients (15%). The median duration of surgery was 140 minutes (range; 70—440 minutes) and the median blood loss was 105 mL (range; 10—2410 mL). The level of lymph node dissection, according to the Japanese classification of colorectal carcinoma,[11] was D1 ($n = 12$), D2 ($n = 17$) or D3 ($n = 57$). The distribution of the pTNM stage in the patients was as follows: stage 0 ($n = 7$), stage I ($n = 18$), stage II ($n = 17$), stage III ($n = 30$), and stage IV ($n = 14$). The duration of intravenous use of cefmetazole was limited to the day of surgery in 76 patients (88%) and until postoperative day 2 in 10 patients (12%). The two groups showed no significant differences in terms of the age, sex, BMI, ASA, location, length of incision, stenosis, type of surgery, combined resection, duration of surgery, blood loss, lymph node dissection pTNM stage or duration of intravenous antibiotic use.

3.2. Tolerance

After administration of sennoside, vomiting developed in two patients, abdominal pain in two patients, and abdominal distention in two patients. Including these 6 patients, discontinuation of bowel preparation was not necessitated in any of the patients.

3.3. Surgical site and remote infection

In the study group, three patients developed incisional site infection, and one patient developed organ/space infection; however, none of the patients developed anastomotic leakage. In the control group, three patients developed incisional site infection, and one patient developed organ/space infection in addition to incisional site infection. Therefore, the overall incidence of surgical site infection was not significantly different between the two groups (4.7% vs. 3.5%, $p > 0.99$). In the study group, one patient developed remote infection. There were no complications suggestive of enteritis caused by methicillin-resistant *Staplylococcus aureus* or *Clostlidium difficile*. The incidence of remote infection was also not significantly different between the two groups (1.2% vs. 3.5%, $p = 0.62$). The incidence of re-operation was also not significantly different between the two groups (0% vs. 1.2%, $p > 0.99$). The median length of postoperative hospital stay was 2 days longer in the control group than in the study group ($p < 0.01$) (Table 2).

3.4. Univariate and multivariate logistic regression analyses

On univariate logistic regression analysis, the BMI ($p = 0.03$) and location ($p = 0.06$) were selected as factors affecting the surgical site infection. On multivariate logistic regression analysis, only body mass index ($p = 0.04$) was an independent significant factor affecting the surgical site infection (Table 3).

3.5. Consistency of fecal matter and degree of intraoperative spillage

The distribution of the presence/absence of fecal matter and of the fecal matter consistency in the study group is shown in Table 4. In the proximal (upstream) bowel segment, there was no fecal matter in 39 patients (45%), the fecal matter was solid in 3 patients (3%), soft in 10 patients (12%), and fluid in 34 patients (40%); on the other

Table 1 Patient characteristics.

		Study group (Sennoside, n = 86)	Control group (PEG, n = 86)	*p*-value
Age (years)[a]		70 (32-91)	67 (29-87)	0.33
Sex (male: female)		62: 24	53: 33	0.14
Body mass index (kg/m^2)[a]		22.9 (15.9-43.1)	22.9 (15.0-32.2)	0.76
ASA[b]	I	17	28	
	II	51	43	
	III	18	15	0.16
Location	Cecum	6	6	
	Ascending colon	14	19	
	Transverse colon	15	14	
	Descending colon	8	7	
	Sigmoid colon	43	40	0.91
Length of incision	7cm or less	51	49	
	Longer than 7 cm	35	37	0.76
Stenosis	> 2/3 normal caliber	29	28	
	< 2/3 normal caliber	57	58	0.87
Type of surgery	Ileocecal resection	5	4	
	Right (hemi) colectomy	20	28	
	Transverse colectomy	8	7	
	Left hemicolectomy	8	7	
	Sigmoidectomy	35	30	
	Other segmental colectomy	10	10	0.85
Combined resection		13	10	0.5
	Liver	3	4	
	Duodenum	1	1	
	Small intestine or colorectum	3	2	
	Urinary bladder	1	0	
	Others	5	3	
Duration of surgery (min)[a]		140 (70-440)	130 (64-715)	0.13
Blood loss (ml)[a]		105 (10-2410)	90 (10-1920)	0.23
Lymph node dissection[c]	D1	12	9	
	D2	17	28	
	D3	57	49	0.16
pTNM stage	Stage 0	7	14	
	Stage I	18	22	
	Stage II	17	14	
	Stage III	30	17	
	Stage IV	14	19	0.12
Duration of intravenous antibiotic use	Limited to the day of surgery	76	69	
	Until POD[d] 2	10	17	0.14

[a] Median (range).
[b] American society of anesthesiologists physical status.
[c] According to Japanese classification of colorectal carcinoma.
[d] Postoprative day.

hand, in the distal (downstream) bowel segment, there was no fecal matter in 39 patients (45%), the fecal matter was solid in 1 patient (1%), soft in 11 patients (13%), and fluid in 35 patients (41%). In the proximal bowel segment, solid, soft or fluid matter was present in a significantly higher percentage of patients with a stenotic lesion ($n = 29$) than in the patients without a stenotic lesion ($n = 57$) (76% vs. 44%, $p < 0.01$). Also, in the downstream bowel segment, solid, soft or fluid matter tended to be present in a higher percentage of patients with a stenotic lesion than in those without a stenotic lesion (69% vs. 47%, $p = 0.07$). No intraoperative spillage of the bowel matter was observed in 72 patients (84%). Minimal ($n = 10$) or moderate spillage ($n = 4$) was noted in the remaining 14 patients. Large spillage was not noted in any of the patients. The incidence of intraoperative spillage did not differ significantly between the patients with a stenotic lesion and those without a stenotic lesion (21% vs. 14%, $p = 0.54$).

4. Discussion

The results of this study suggest that the use of sennoside as an agent for mechanical bowel preparation prior to elective colon cancer surgery may be acceptable in terms of the incidence of surgical site infection, tolerance, and

Table 2 Surgical site infection and remote infection compared between the study group and the control group.

	Study group (Sennoside, $n = 86$)	Control group (PEG, $n = 86$)	p value
Overall surgical site incision	4 (4.7%)	3 (3.5%)	> 0.99
Incisional site infection	3 (3.5%)	3 (3.5%)	> 0.99
Organ/space infection	1 (1.2%)	1 (1.2%)	> 0.99
Anastomotic dehiscence	0 (0%)	0 (0%)	> 0.99
Remote infection	1 (1.2%)	3 (3.5%)	0.62
Pneumonia	1 (1.2%)	1 (1.2%)	
Urinary tract infection	0 (0%)	1 (1.2%)	
Blood stream (catheter-related) infection	0 (0%)	1 (1.2%)	
Re-operation	0 (0%)	1 (1.2%)	> 0.99
Length of postoperative hospital stay	11 (7—29)	13 (6—37)	< 0.01

feasibility of bowel resection and anastomosis, even in patients with stenosis, but free of obstruction.

Although this was not a prospective randomized study, the overall incidence of surgical site infection in the study group (4.7%) was identical to that in the historical control group (3.5%) in which the mechanical cleansing had been performed with PEG. In addition, the incidence of surgical site infection in this series seems to be within an acceptable limit and superior to the recently reported incidences of surgical site infection following colon cancer surgery in Japan, ranging from 6.3% to 13%.[4,22,23]

On multivariate analysis, overweight (BMI $> 25.0\ kg/m^2$) was the only risk factor identified to be independently associated with surgical site infection. Obesity is generally recognized as a risk factor for the development of surgical site infection following various types of surgeries. Since the

Table 3 Factors affecting surgical site infection by the unvariant and multivariate regression analyses.

Factor		Univariant regression analysis			Multivariate regression analysis		
		Odds ratio	95% confidence interval	p-value	Odds ratio	95% confidence interval	p-value
Sex	male	1					
	female	0.973	0.234-4.032	0.97			
Age	<70	1					
	>70	2.231	0.540-9.223	0.27			
Body mass Index	$<25\ kg/m^2$	1			1		
	$>25\ kg/m^2$	4.410	1.125-17.285	0.03	4.409	1.095-17.753	0.04
ASA[a] score	I/II	1					
	III	1.143	0.227-5.747	0.87			
Location	right colon	1			1		
	left colon	7.353	0.898-58.824	0.06	7.519	0.907-62.500	0.06
Length of skin incision	7 cm or less	1					
	>7 cm	2.924	0.707-12.048	0.14			
Stenosis	<2/3 normal caliber	1					
	>2/3 normal caliber	1.000	0.241-4.151	>0.99			
Lymph node dissection[b]	D0/D1/D2	1					
	D3	2.273	0.458-11.236	0.31			
Duration of surgery[c]	<135 min	1					
	>135 min	1.952	0.472-8.070	0.36			
Blood loss[d]	<100 ml	1					
	>100 ml	5.526	0.675-45.226	0.11			
Duration of intravenous antibiotic use	limited to the day of surgery	1					
	until POD[e] 2	1.513	0.362-6.329	0.57			
Mechanical cleansing	Sennoside	1					
	PEG	0.988	0.239-4.082	0.99			

[a] American society of anesthesiologists physical status.
[b] According to Japanese classification of colorectal carcinoma.
[c] Median duration of surgery was 135 min.
[d] Median blood loss was 100 ml.
[e] Postoperative day.

Table 4 Fecal matter consistency and intraoperative spillage in the study group.

		Present of stenosis (n = 29)		Absent of stenosis (n = 57)		*p*-value
Proximal bowel segment	None	7	22 (76%)	32	25 (44%)	<0.01
	Solid	1		2		
	Soft	5		5		
	Fluid	16		18		
Distal bowel segment	None	9	20 (69%)	30	27 (47%)	0.07
	Solid	1		0		
	Soft	5		6		
	Fluid	14		21		
Intraoperative spillage	Nil	23	6 (21%)	49	8 (14%)	0.54
	Minimal	4		6		
	Moderate	2		2		
	Large	0		0		

incidence of obesity (BMI $> 30.0\ kg/m^2$) is lower in Japan than in Western countries, we evaluate the impact of BMI using the cut-off value of $25.0\ kg/m^2$, which discriminates non-overweight from overweight individuals. Our results concur with previous reports demonstrating overweight as a risk factor for the development of surgical site infection following colorectal surgery.[24,25] In addition, left-sided colon surgery also tended to be a risk factor for surgical site infection. To the best of our knowledge, there have been no similar reports. The reasons are unclear and further investigation is warranted. In any case, adoption of mechanical cleansing had little impact on the risk of development of surgical site infection.

This study also showed that the incidence of remote infection was not significantly different between the two groups. The incidence of re-operation was not evaluated as there were no cases requiring re-operation in the sennnoside group, while one patient in the historical control group required re-operation. This is probably because the clinical pathway for elective colon cancer surgery was introduced in the majority of patients of the sennnoside group. There may be a criticism that the postoperative length of hospital stay was relatively long in both the groups. Japanese patients usually demand longer hospital stays than recommended by their surgeons, which consequently results in longer hospitalizations than required for recovery to their preoperative status. Moreover, patients' family members tend to strongly support a longer stay.

The tolerance to sennoside was considered acceptable in this series, because discontinuation of bowel preparation before surgery was not necessitated in any of the patients. We have often encountered cases in clinical practice in Japan, especially from the geriatric age group, where mechanical bowel cleansing using 2 L of PEG needed to be discontinued, because of the occurrence of nausea, vomiting, abdominal fullness, or intolerable abdominal pain. According to the literature, the reported incidence of discontinuation of bowel preparation among Japanese patients in whom 2 L of PEG was used for mechanical bowel cleansing prior to colorectal resection was 2.2% to 3.1%.[26,27] To the best of our knowledge, there have been no prospective randomized trials comparing senna (sennoside) with PEG for mechanical bowel preparation prior to elective colorectal surgery, except for the report by Valverde et al.[12] In their study, all patients received 2 L of 5% povidone iodine enema twice before colorectal surgery. They reported that senna was better tolerated in the presence of stenosis, even though their definition of stenosis was not documented. Radaelli et al[28] compared senna with PEG as agents for bowel preparation prior to elective colonoscopy, and reported that senna was significantly superior to PEG in terms of the tolerance. The results of the present study seem to be consistent with the results of these studies mentioned above[12,28] in terms of tolerance, although we did not compare sennoside with PEG.

It is noteworthy that the colonic cleanness was significantly worse in the proximal bowel segment and tended to be worse in the distal bowel segment in patients with stenosis than in those without stenosis. The similar tendency noted between the proximal and distal segments in our study participants can be assumed to be a direct reflection of sennnoside use and the degree of stenosis, because we did not undertake any additional mechanical bowel preparation measures, such as enema. The presence of stenosis did not affect the rate of intraoperative spillage. In addition, the overall incidence of surgical site infection was limited to 4.7% and none of the patients in this series developed anastomotic leakage. Thus, the greater amounts of bowel matter remaining in both the proximal and distal bowel segments could be cleaned easily by the operating surgeon, leading to a favorable postoperative course regardless of the presence or absence of stenosis. Senna, as compared with PEG, has been reported to have the advantage of keeping the residual contents of the colon less fluid, therefore, the risk of spillage into the operative field is lower.[12]

The optimal antibiotic choice, timing and route of administration in elective colorectal surgery remain undetermined. Nelson et al[29] suggested from their meta-analysis that combined oral and intravenous prophylaxis would yield favorable results, but were still uncertain about the timing of the oral dosing. Since two meta-analyses[1,29] have challenged the necessity for mechanical bowel preparation, establishing the timing for oral dosing has become even more problematic, especially as it is not known whether oral antibiotics would still be effective when the colon is not empty. Based on our previous experience and in agreement with the guidelines of the CDC,[19] we selected

a short-term (< 24 hour) chemical preparation combined with mechanical cleansing by sennoside in this study. The intravenous antibiotic use was limited to the day of surgery in 88% of the patients and was continued until postoperative day 2 in the remaining 12%, in agreement with the recommendation of the guidelines of the CDC in the majority of cases, even though most Japanese surgeons usually use intravenous antibiotics for 3 to 4 days after elective colorectal surgery.

Considering that recent meta-analyses[1–3] have shown no benefits of mechanical bowel preparation in elective conventional open colorectal surgery, the opportunity for applying our results to clinical practice might be limited. Nonetheless, sennoside (senna) is easy to administer and relatively inexpensive. In addition, this study revealed that sennoside might be acceptable as an agent for mechanical bowel preparation prior to elective colon cancer surgery in terms of the tolerance and incidence of surgical site infection, even in patients with stenosis. Thus, sennoside (senna) may be worth evaluating in specific situations such as laparoscopic colorectal surgery or colorectal resection requiring intraoperative colonoscopy within the framework of a prospective randomized study comparing sennoside (senna) and PEG or no preparation.

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