ORIGINAL ARTICLE

Povidone-Iodine vs Sodium Hypochlorite Enema for Mechanical Preparation Before Elective Open Colonic or Rectal Resection With Primary Anastomosis

A Multicenter Randomized Controlled Trial

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Hypothesis: The anti-infective actions of povidone-iodine (PVI) and sodium hypochlorite enemas are different.

Design: Prospective, randomized, single-blind study.

Setting: Multicenter.

Patients: Five hundred seventeen consecutive patients with colorectal carcinoma or sigmoid diverticular disease undergoing elective open colorectal resection, followed by primary anastomosis.

Intervention: All patients received senna (1-2 packages diluted in a glass of water) at 6 PM the evening before surgery. Patients were administered two 2-L aqueous enemas of 5% PVI (n=277) or 0.3% sodium hypochlorite (n=240) at 9 PM the evening before surgery and at 3 hours before operation. Intravenous ceftriaxone sodium (1 g) and metronidazole (1 g) were administered at anesthetic induction.

Main Outcome Measure: Rate of patients with 1 infective parietoabdominal complication or more.

Results: The percentages of patients with 1 infective parietoabdominal complication or more did not differ between the 2 groups (13.7% in the PVI-treated group vs 15.0% in the sodium hypochlorite–treated group). Tolerance was better in the PVI-treated group than in the sodium hypochlorite–treated group (79.4% vs 67.9%), with fewer patients experiencing abdominal pain (13.0% vs 24.6%) or discontinuing their preparation (3.0% vs 9.0%) (P=.02 for all). There were more patients with malaise in the PVI-treated group than in the sodium hypochlorite–treated group (9.1% vs 4.9%, $P<.05$). Three patients in the sodium hypochlorite–treated group had necrotic ulcerative colitis.

Conclusion: When antiseptic enemas are chosen for mechanical preparation before colorectal surgery, PVI should be preferred over sodium hypochlorite because of better tolerance and avoidance of necrotic ulcerative colitis.

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SIMPLE MECHANICAL COLONIC preparation with laxatives such as senna,[1] polyethylene glycol,[1] and sodium phosphate[2] (with or without water or saline enemas[3]) improves colonic cleanliness.[1,4] However, a recent meta-analysis[3] shows that such preparation does not decrease the rate of infective postoperative complications, most likely

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because oral administration does not decrease the concentration of germs in the lumen or within the colonic or rectal mucosa.[5] The meta-analysis[3] only looked at controlled studies comparing oral (essentially polyethylene glycol and sodium phosphates) preparation. Senna is more efficient and better tolerated than mannitol[4] or laxatives (eg, polyethylene glycol[1]). To our knowledge, senna has not yet been compared with monosodium or bisodium phosphate. Two controlled clinical trials[6,7] showed that mechanical colonic enema preparations containing antiseptic solutions such as povidone-iodine (PVI) are bacteriologically efficient[5] and are clinically effective in reducing the number of patients with 1 or more infective complications. Sodium hypochlorite enema is also an active colonic and rectal antiseptic[8,9] and has been proposed as mechanical preparation for colorectal surgery.[9] A bacteriological study[9] comparing PVI enemas with sodium hypochlorite enemas showed that sodium hypochlorite was superior against rectal flora (*Escherichia coli* and *Bacteroides fragilis*), but we are aware of no clinical ran domized trials

to date comparing the 2 preparations. For these reasons, we conducted a prospective multicenter randomized trial to compare the rates of parietoabdominal infective complications and tolerance of PVI and sodium hypochlorite enemas before elective open colorectal surgery.

METHODS

PATIENTS, DISEASE, AND ELIGIBILITY CRITERIA

From January 2, 1997, to January 2, 2002 (60 months), 549 consecutive patients (280 men and 269 women; mean ± SD age, 65 ± 12 years [age range, 29-92 years]) were eligible for the study. Although all 20 centers (2 university hospitals, 13 teaching hospitals, and 5 private clinics) participating in the study did not start at the same time, they all finished by January 2002; a median of 25 patients (range, 11-79 patients) was enrolled per center. Twenty-eight surgeons performed or supervised all operations. Patient eligibility included a minimal age of 18 years (no upper age limit) and an elective resection, followed by primary anastomosis performed for carcinoma of the colon or the proximal or middle rectum (whether with palliative or curative intent) or for postremission acute sigmoid diverticular disease.

The degree of stenosis was defined clinically as narrowing of the colonic lumen. After opening the resected intestinal specimen, this was quantified grossly by the surgeon as mild (reduction of colonic diameter by less than one third), moderate (reduction between one third and two thirds), or tight (reduction of more than two thirds), which usually corresponded to the impassibility of an adult colonoscope through the stenosis.

NONELIGIBILITY CRITERIA

Patients were excluded if they were younger than 18 years; had specific or ulcerative colitis, benign tumor, or familial polyposis without carcinoma; did not undergo resection or underwent resection without immediate anastomosis (eg, Hartmann procedure, double-barreled colostomy, or abdominoperineal resection); or underwent emergency resection (for obstruction, hemorrhage, or peritonitis), reversal of the Hartmann procedure, or simple colostomy closure. Tight stenosis was not a reason for exclusion of the patient, nor was the presence of organ (heart, pulmonary, kidney, hepatic, or other) failure.

COLONIC AND RECTAL PREPARATION

At 6 PM the evening before surgery, all patients drank a senna solution (X-Prep; Viatris, Merignac, France, formerly Laboratoire Sarget) (a 5-g package [or 2 packages for obese patients] of flavored powder with 270 mg of senna diluted in a glass of water). Patients were then randomly allotted to administration of two 2-L enemas of aqueous solutions of 5% PVI or 0.3% sodium hypochlorite (Miltor; Rivadis Pharma, Thoars, France) at 9 PM the evening before surgery and at 3 hours before operation.[9] Single-dose ceftriaxone sodium (1 g) during 2 to 4 minutes and metronidazole (1 g) diluted in 125 mL of isotonic sodium chloride solution infused for 15 minutes were administered to all patients intravenously at anesthetic induction.[7] Patients with previously recognized allergies to any of these drugs or to iodine were excluded.

OPERATIVE TECHNIQUE

The type of skin preparation (disinfection and shaving) was left to the discretion of the surgeon. All patients underwent laparotomy. The following techniques were recommended to all surgeons participating in this study: midline incision, protection of the abdominal wound by textile or plastic towels, and mechanical or handsewn (single-layered extramucosal with 3-0 polyglactic acid or polyglactin) anastomoses. Ileocolonic, colocolonic, colorectal or ileorectal, and ileoanal or coloanal anastomoses were performed, with or without diverting stoma, omentoplasty, or abdominal drainage according to surgeon preference. The fascia was closed with caliber 1 polyglactic acid or polyglactin running sutures,[10] and the skin was closed with nonresorbable sutures or staples.[11]

OUTCOME MEASURES

The main outcome measure was the rate of patients with 1 infective parietoabdominal complication or more occurring during the postoperative hospital stay and 30 days following hospital discharge.[12] These included intra-abdominal abscess or generalized peritonitis, clinical or radiological anastomotic leakage, and fascial dehiscence or abdominal wound infection (defined as the presence of pus in the superficial or deep incisional surgical site). Routine diatrizoate sodium enema administration was recommended between days 8 and 10 to detect asymptomatic anastomotic leaks.

Subsidiary criteria included the following 4 outcome measures: (1) Rate of extra-abdominal complications (infective or not), defined as respiratory, heart, urinary tract, cerebral, or septic (including blood borne) complications. (2) Poor tolerance to the preparation as indicated by (*a*) distention, vomiting, malaise (including lipothymia), abdominal pain (irrespective of its type or intensity, whether measured by a visual analog scale or not), need to discontinue the preparation (during or after the first or second enema), or other disorders as evaluated by the nursing staff after randomization and before operation and (*b*) gross or histological alterations of the colonic wall as evaluated by the surgeon and the pathologist. (3) Mechanical effects of the preparation as judged by colonic cleanliness, intraoperative fecal soiling, and consistency of fecal matter. The degree of colonic and rectal cleanliness was judged by the operating surgeon in the proximal and distal intestinal segments and was defined[13] as follows: 0, no fecal matter; 1+, small amounts of fecal matter not bothersome to the surgeon; and 2+, fecal matter bothersome to the surgeon. A 0 or 1+ in the proximal or distal segment was considered satisfactory, while a 2+ in 1 segment or both was considered unsatisfactory. The magnitude of intraoperative fecal soiling was subjectively classified by the surgeon as nil, minimal, moderate, or massive. Consistency of fecal matter (solid, soft, or fluid), even if not bothersome, was assessed in the proximal and distal segments through the end segments in the manual anastomosis or through the opening made in the intestine to introduce the mechanical stapling devices for side-to-end or end-to-end anastomosis or after confection of the purse string in circular mechanical anastomosis. In the double-stapling technique, the endoluminal contents were assessed when the anvil was inserted (or retrieved) through the anus. (4) The severity of complications was judged by the duration of hospitalization, the rate of overall postoperative mortality, and the rate of second operations (wound exploration, percutaneous drainage, or relaparotomy).

Table 1. Preoperative Risk Factors*

Variable	Povidone-Iodine–Treated Group (n = 277)	Sodium Hypochlorite–Treated Group (n = 240)
Male-female ratio	142:135	128:112
Age, mean ± SD [range], y	67 ± 12 [32-92]	65 ± 13 [29-90]
Obesity >20% of theoretical weight	82 (29.6)	79 (32.9)
Weight loss >10% of usual weight	69 (24.9)	72 (30.0)
Anemia <120 g/dL	57 (20.6)	62 (25.8)
Mechanical ventilation >24 h	16 (5.8)	15 (6.3)
Ascites	**17** (6.1)	**14** (5.8)
Cirrhosis	12 (4.3)	8 (3.3)
Carcinomatosis	5 (1.8)	6 (2.5)
Other risk factors†	98 (35.4)	75 (31.3)

*Data are given as number (percentage) unless otherwise indicated.
†Diabetes mellitus, kidney failure, corticosteroid therapy, radiotherapy, and chemotherapy.

Table 2. Intraoperative Risk Factors

Variable	No. (%)	
	Povidone-Iodine–Treated Group (n = 277)	Sodium Hypochlorite–Treated Group (n = 240)
Disease		
Cancer	213 (76.9)	179 (74.6)
Sigmoid diverticulitis	64 (23.1)	61 (25.4)
Resection		
Right hemicolectomy	48 (17.3)	41 (17.1)
Left hemicolectomy	91 (32.9)	83 (34.6)
Segmental left colectomy	119 (43.0)	101 (42.1)
Total colectomy	7 (2.5)	5 (2.1)
Coloproctectomy	12 (4.3)	10 (4.2)
Anastomosis		
Ileocolonic	55 (19.9)	46 (19.2)
Colocolonic	36 (13.0)	28 (11.7)
Colorectal	174 (62.8)	156 (65.0)
Proximal	127 (45.8)	111 (46.3)
Distal	47 (17.0)	45 (18.8)
Coloanal or ileoanal	12 (4.3)	10 (4.2)
Anastomotic technique		
Mechanical	107 (38.6)	86 (35.8)
Manual	170 (61.4)	154 (64.2)
Dukes C cancer	67 (24.2)	64 (26.7)
Palliative surgery*	37 (13.4)	23 (9.6)
Anastomosis protection		
Stoma	18 (6.5)	10 (4.2)
Omentoplasty	75 (27.1)	50 (20.8)
Stenosis	**163** (58.8)	**138** (57.5)
Moderate	**119** (43.0)	**97** (40.4)
Reduction of lumen less than ⅓ of normal	54 (19.5)	43 (17.9)
Reduction of lumen ⅓ to ⅔ of normal	65 (23.5)	54 (22.5)
Tight, reduction of lumen greater than ⅔ of normal	44 (15.9)	41 (17.1)
None	114 (41.2)	102 (42.5)

*Incomplete excision or presence of metastases.

The surgeon, patient, and attending nurse who administered the preparation were aware of the allotted colonic preparation because of color differences, whereas the physician and nurses who cared for the patient after surgery were not. Almost all patients who died before hospital discharge underwent an autopsy. Patient characteristics and preoperative and intraoperative risk factors are listed in **Table 1** and **Table 2**.

RANDOM ALLOTMENT

On the evening before surgery, patients were allotted to one or the other colonic preparation in 2 separate strata of patients (ie, those with carcinoma and those with sigmoid diverticular disease) by the surgeon, who unfolded the previously stapled upper corner of a questionnaire[14] under which PVI or sodium hypochlorite (as determined by random number tables) was written. Random assignment was balanced every 4 patients by center and by stratum.

NUMBER OF PATIENTS

According to 2-tailed explicative testing[15] and based on an expected 10% improvement in the rate of infective abdominal complications from 15%[1] to 5% (with α and β risks set to .05), the number of patients required was 219 per group (ie, 438 patients total). The validity of data was checked randomly (1 of 5 patients) by a control officer (surgical resident in applied sciences research). The ethical committee of the coordinating center approved the study, and informed consent was obtained from the patients.

STATISTICAL ANALYSIS

Categorical values were compared using χ^2 test, and continuous variables were compared using *t* test. Nonparametric values were compared using Mann-Whitney test. The center effect was evaluated.

RESULTS

Thirty-two patients were withdrawn after random allotment (15 in the PVI-treated group [hereafter referred to as the PVI group] and 17 in the sodium hypochlorite–treated group [hereafter referred to as the sodium hypochlorite group]) because of absence of resection or anastomosis (n=11), random allotment error (n=9), lack of colonic preparation (n=6), presence of inflammatory disease (n=4), or refusal of operation (n=2). Five hundred seventeen patients remained for final analysis, 277 in the PVI group and 240 in the sodium hypochlorite group. Both groups of patients were comparable for the degree of stenosis and preoperative and intraoperative risk factors (Table 1 and Table 2).

MAIN END POINT

The percentages of patients with 1 or more infective parietoabdominal complications did not differ significantly between the 2 groups (13.7% in the PVI group and 15.0% in the sodium hypochlorite group) ($P \leq .90$) (**Table 3**); likewise, the rates of overall morbidity (14.8% vs 15.4%) and postdischarge complications (1.8% vs 1.7%) were almost identical ($P \leq .90$). The anastomotic leakage rate was 9.7% in the PVI group and 7.9% in the sodium hypochlorite group ($P \leq .50$).

Table 3. Postoperative Outcomes*

Variable	Povidone-Iodine–Treated Group (n = 277)	Sodium Hypochlorite–Treated Group (n = 240)
Patients with ≥1 immediate parietoabdominal complications	38 (13.7)	36 (15.0)
Wound infection†	8 (2.9)	8 (3.3)
Wound fascial dehiscence	9 (3.2)	4 (1.7)
Intra-abdominal abscess	10 (3.6)	9 (3.8)
Generalized peritonitis	4 (1.4)	2 (0.8)
Anastomotic leakage	**27** (9.7)	**19** (7.9)
Clinical	16 (5.8)	8 (3.3)
Radiological alone	11 (4.0)	11 (4.6)
Second operation	24 (8.7)	**14** (5.8)
Wound exploration	7 (2.5)	4 (1.7)
Drainage of intra-abdominal abscess	10 (3.6)	2 (0.8)
Generalized peritonitis	4 (1.4)	2 (0.8)
Colostomy	5 (1.8)	2 (0.8)
Miscellaneous‡	3 (1.1)	4 (1.7)
Patients with ≥1 extra-abdominal complication, associated or not	60 (21.7)	51 (21.3)
Infective	**38** (13.7)	**35** (14.6)
Blood borne	8 (2.9)	4 (1.7)
Catheter related	3 (1.1)	6 (2.5)
Pulmonary	19 (6.9)	12 (5.0)
Urinary tract	8 (2.9)	13 (5.4)
Noninfective	**22** (7.9)	**16** (6.7)
Heart	9 (3.2)	5 (2.1)
Lung	9 (3.2)	7 (2.9)
Brain	3 (1.1)	3 (1.3)
Kidney	1 (0.4)	1 (0.4)
Mortality		
Overall	6 (2.2)	8 (3.3)
Associated with anastomotic leakage	0 (0.0)	1 (0.4)
Duration of postoperative hospital stay, median [range], d	11 [1-106]	13 [2-78]
Patients with ≥1 complication within 30 d after discharge	**5** (1.8)	**4** (1.7)
Wound infection	1 (0.4)	2 (0.8)
Intra-abdominal abscess	0 (0.0)	0 (0.0)
Incisional hernia	4 (1.4)	2 (0.8)

*Data are given as number (percentage) unless otherwise indicated.
†Superficial or deep incisional surgical site infection.
‡Splenectomy, cholecystectomy, intestinal obstruction, unnecessary laparotomy, ablation of drain, redo anastomosis for anastomotic hemorrhage, and acute necrotizing pancreatitis.

Table 4. Poor Tolerance and Results According to Degree of Stenosis

Variable	No. (%)	
	Povidone-Iodine–Treated Group (n = 277)	Sodium Hypochlorite–Treated Group (n = 240)
Patients with poor tolerance	57 (20.6)	77 (32.1)*
Poor tolerance*		
Abdominal pain	36 (13.0)†	59 (24.6)†
Distention	8 (2.9)	14 (5.8)
Malaise	24 (8.7)‡	9 (3.8)‡
Vomiting	12 (4.3)	8 (3.3)
Miscellaneous	6 (2.2)	19 (7.9)
Discontinuation of preparation	14 (5.1)	26 (10.8)*
Stenosis		
None or moderate (n = 432)	233	199
Infected patients	31 (13.3)	31 (15.6)
Patients with poor tolerance	51 (21.9)	63 (31.7)
Patients with malaise	20 (8.6)	7 (3.5)
Discontinuation of preparation	7 (3.0)†	18 (9.0)†
Satisfactory cleanliness	187 (80.3)	172 (86.4)
Fluid matter in both segments	56 (24.0)	57 (28.6)
Moderate to massive fecal soiling	12 (5.2)	21 (10.6)
Tight (n = 85)	44	41
Infected patients	7 (15.9)	5 (12.2)
Patients with poor tolerance	6 (13.6)§	14 (34.1)§
Patients with malaise	4 (9.1)	2 (4.9)
Discontinuation of preparation	7 (15.9)	8 (19.5)
Satisfactory cleanliness	23 (52.3)	20 (48.8)
Fluid matter in both segments	13 (29.5)	10 (24.4)
Moderate to massive fecal soiling	13 (29.5)	12 (29.3)

*$P<.01$.
†$P<.001$.
‡$P<.05$.
§$P<.02$.

SUBSIDIARY END POINTS

Extra-abdominal Complications

The overall rate of patients with 1 or more extra-abdominal complication (isolated or associated) was 21.4% (Table 3), including 14.1% with infective complications and 7.3% with noninfective complications. No statistically significant differences were noted between the 2 groups overall or by complication.

Tolerance

There were significantly fewer patients ($P<.01$) with poor tolerance in the PVI group (20.6%) compared with the sodium hypochlorite group (32.1%) (**Table 4**). Fewer patients in the PVI group had abdominal pain (13.0% vs 24.6%, $P=04$). More patients in the PVI group sustained malaise (8.7% vs 3.8%, $P<.02$). Fewer patients had to discontinue their colonic preparation in the PVI group (5.1%) than in the sodium hypochlorite group (10.8%) ($P<.01$). When the stenosis was tight, fewer patients in the PVI group reported poor tolerance (13.6% vs 34.1%, $P<.05$); tight stenosis did not affect the rate of patients with infective complications (15.9% vs 12.2%, $P=.40$). Three patients in the sodium hypochlorite group (2 with sigmoid diverticular disease and 1 with cancer) had gross mucosal erosive lesions discovered during surgery (the intestinal mucosa was edematous with longitudinal superficial ulcerations). Microscopically, inflammatory infiltration of the mucosa and submucosa associated with mucosal necrotic areas was found (2 nonspecific and 1 pseudomembranous). These patients had primary anastomosis without a protective stoma, followed by an uneventful recovery.

Table 5. Intraoperative Colorectal Cleanliness, Fecal Soiling, and Consistency of Fecal Matter

Variable	No. (%) Povidone-Iodine–Treated Group (n = 277)	No. (%) Sodium Hypochlorite–Treated Group (n = 240)
Cleanliness		
Satisfactory	210 (75.8)	192 (80.0)
Unsatisfactory	52 (18.8)	34 (14.2)
Unknown, clamped segments	5 (1.8)	8 (3.3)
Intraoperative fecal soiling		
Nil	143 (51.6)	120 (50.0)
Minimal	81 (29.2)	59 (24.6)
Moderate	21 (7.6)	21 (8.8)
Massive	4 (1.4)	12 (5.0)
Not stated	28 (10.1)	28 (11.7)
Consistency of fecal matter		
Proximal segment		
Nothing	140 (50.5)	110 (45.8)
Solid	7 (2.5)	3 (1.3)
Soft	42 (15.2)	46 (19.2)
Fluid	84 (30.3)	79 (32.9)
Unknown	4 (1.4)	2 (0.8)
Distal segment		
Nothing	120 (43.3)	99 (41.3)
Solid	4 (1.4)	2 (0.8)
Soft	53 (19.1)	46 (19.2)
Fluid	94 (33.9)	89 (37.1)
Unknown	6 (2.2)	6 (2.5)
Fluid matter		
In both segments	69 (24.9)	67 (27.9)
In proximal segment alone	15 (5.4)	12 (5.0)
In distal segment alone	25 (9.0)	22 (9.2)

Colorectal Cleanliness, Fecal Soiling, and Consistency of Matter

The groups were similar for colorectal cleanliness, fecal soiling, and consistency of matter. There were no statistically significant differences in the rates of satisfactory colonic and rectal cleanliness (75.8% in the PVI group vs 80.0% in the sodium hypochlorite group, $P<.20$), moderate to massive intraoperative fecal soiling (9.0% vs 13.8%, $P<.10$), and fluid consistency of fecal matter in at least 1 segment (39.4% vs 42.1%, $P=.80$) (**Table 5**).

Effect of Degree of Stenosis

Compared with patients with none or moderate stenosis, slightly fewer patients with tight stenosis had poor tolerance (20/85 [23.5%] vs 114/432 [26.4%], but not significantly so, $P=.68$). In the case of tight stenosis, PVI was better tolerated than sodium hypochlorite (38/4 [86.4%] vs 27/41 [65.9%], $P=.02$), with less abdominal pain and less discontinuation of preparation.

Severity of Complications

Mortality. Fourteen (2.7%) of 517 patients died (Table 3). Six deaths were in the PVI group, including 2 each of pneumonia and heart-related disease and 1 each secondary to catheter septicemia and kidney failure. Eight deaths were in the sodium hypochlorite group, including 3 of pneumonia, 2 of heart-related complications, and 1 each of stroke, anastomotic leakage with generalized peritonitis, and postoperative pancreatitis.

Second Operations. There were more patients undergoing 1 or more successive operations in the PVI group (n=24) than in the sodium hypochlorite group (n=14), but the difference was not statistically significant ($P=.30$) (Table 3). Twenty-nine procedures were performed in 24 patients in the PVI group, including splenectomy (n=1), wound exploration (n=7), drainage of intra-abdominal abscess (n=10), colostomy to treat anastomotic leakage (with or without abscess) (n=5), and operations for generalized peritonitis with anastomotic leakage (n=4), acute cholecystitis (n=1), and small-intestinal obstruction (n=1). Twenty-one procedures were performed in 14 patients in the sodium hypochlorite group, including wound exploration (n=4), drainage of intra-abdominal abscess (n=2), colostomy for anastomotic leakage (n=2), operation for generalized peritonitis with anastomotic leakage (n=2), unnecessary exploratory laparotomy (n=1), ablation of abdominal drain (n=1), redo anastomosis for anastomotic hemorrhage (n=1), and acute necrotizing pancreatitis (n=1).

Duration of Hospitalization. The median duration of hospitalization did not differ statistically between the 2 groups (11 days in the PVI group vs 13 days in the sodium hypochlorite group, $P=.02$) (Table 3). No center effect was found concerning patient demographics or results.

COMMENT

Our study shows that PVI and sodium hypochlorite enemas had similar effects on the rate or severity of infective complications (Table 3) and on cleanliness of the colon, intraoperative fecal soiling, and consistency of fecal matter (Table 5). On the other hand, clinical (except for malaise) and anatomopathologic tolerance was better in the PVI group (Table 4).

COMPLICATION RATE

The percentages of patients with 1 or more immediate or 30-day parietoabdominal complications were almost the same in the 2 groups (15.5% in the PVI group and 16.7% in the sodium hypochlorite group) (Table 3). This is comparable to the 15.1% rate among patients receiving PVI who were similarly analyzed and classified in a previous study.[1] The theoretical bacteriological advantages of sodium hypochlorite[9] were unassociated with any clinical outcome benefits.

TOLERANCE

The percentage of patients with poor tolerance to enemas associated with oral senna varies in the literature and is lower (8%) with water enemas[6] or saline enemas[7]

compared with PVI (15%-18%[6] and 21%[1]). In the present series, 20.6% of the PVI group and 32.1% of the sodium hypochlorite group had poor tolerance, with the sodium hypochlorite enemas significantly less well tolerated than the PVI enemas ($P=.004$) (Table 4), notably related to abdominal pain. Because all the other variables (volume, administration schedule of enema, and associated oral senna preparation) were similar in the present study and in the previous studies,[1,6,7] the variability of tolerance to antiseptic enemas might be explained by differences in the chemical compositions of the antiseptic solutions.

Antiseptic enemas are associated with more malaise (8.7% in the PVI group and 3.8% in the sodium hypochlorite group, $P<.04$) (Table 4) than saline (0.8%)[7] or water (1%)[6] enemas, probably because of their chemical composition. The percentages in 2 preceding studies were 9%[7] and 8.8%.[1] Possible explanations include unrecognized iodine allergy (although patients known to be allergic should have been excluded), iodine-related toxic effects (although no mucosal lesions were found on the specimens), or (most probably) individual susceptibility to iodine. Whatever the reasons for poorer tolerance to antiseptic compared with water or saline enema, the need to discontinue the enemas was rare and occurred significantly less often ($P<.01$) in the PVI group (5.1%) than in the sodium hypochlorite group (10.8%) (Table 4). Vomiting, distention, and pain occurred and affected discontinuation of colonic preparation more often than malaise.

Three patients in the sodium hypochlorite group had gross and histologically proven colonic lesions that could potentially impair the performance or affect the outcome of the anastomosis. To our knowledge, this type of complication due to sodium hypochlorite enemas has not been reported in humans. Sodium hypochlorite is often used as an antiseptic in dental surgery and has been shown to produce occasional cytotoxic lesions on soft tissues in humans,[16] but the concentrations used in dental surgery were higher (0.5%-5.25%),[16] with the upper limit being more than 10 times greater[16] than the concentrations used in the present study for enema (0.3%) or rectal washout.[9] Sodium hypochlorite has 2 potential effects, a significant antiseptic effect by the release of chloride and a dissolving action on the organic soft tissue as a result of oxidation. This last action has been shown to induce inflammatory colitis in rats.[17] The explanation most often cited for this aggressive effect in the odontology literature is individual susceptibility to sodium hypochlorite.[16,17] Because these complications due to sodium hypochlorite occurred rarely (3/240 [1.3%] in our series), they may have been ignored and unreported in the initial literature on sodium hypochlorite enemas.[9]

COLONIC CLEANLINESS

In our study, complete or almost complete cleanliness judged to be satisfactory (Table 5) was obtained in 75.8% of patients in the PVI group and in 80.0% of patients in the sodium hypochlorite group. The rate of colonic cleanliness obtained in the PVI group was close to the 69.5% rate in a previous study[1] on PVI enema and was superior to the 66% rate in another study[4] on water enema. This probably attests to the increased colonic motility due to mucosal irritation, secondary to the antiseptic action, and eventually manifested by abdominal pain.

FECAL SOILING

Moderate to massive intraoperative fecal soiling occurred in 9.0% of patients in the PVI group and in 13.8% of patients in the sodium hypochlorite group (Table 5). This is consistent with the mean values found in the literature of 8.8% to 15.5% for PVI enemas[1,7] and 18.7% for saline enemas.[7]

CONSISTENCY OF FECAL MATTER

In the proximal and distal segments, the consistency of fecal matter was fluid in 24.9% of patients receiving PVI and in 27.9% of patients receiving sodium hypochlorite (Table 5). This is almost identical to the 25.5% rate found in a previous study[1] using the same agents.

EFFECT OF DEGREE OF STENOSIS

Tight stenosis is associated with poor tolerance, discontinuation of preparations, diminished colonic cleanliness, and increased potential for intraoperative soiling.[1] In the case of tight stenosis, tolerance was significantly better ($P<.02$) in the PVI group compared with the sodium hypochlorite group (86.4% vs 65.9%) (Table 4). Sodium hypochlorite is more aggressive than PVI; once the product has passed the stenosis, it may stagnate longer and manifest clinical aggressivity.

SEVERITY OF COMPLICATIONS

There were no statistically significant differences found in the severity of complications as evaluated by mortality, second operations, and duration of hospital stay. Our overall mortality (2.6%) was lower than that reported by Birkmeyer et al[18] among specialized colorectal units (5.4%-7.4%), although their national study involved patients older than 65 years and included patients undergoing emergency and urgent surgery. In our series, only 1 patient died of anastomotic leakage, confirming that anastomotic leakage is no longer the principal cause of death in colorectal surgery.[19] The percentage of patients undergoing second operations (7.2%) was similar to that in a previous study[1] (6.7%); this rate was unaffected by the type of enema used (PVI vs sodium hypochlorite). Our median durations of hospital stay (11 days in the PVI group and 13 days in the sodium hypochlorite group) seem long, but hospital stay may reflect cultural and reimbursement systems rather than actual complication rates.[20]

CONCLUSIONS

Based on the results of our study and other studies[1,3-7] on colonic preparation, we conclude the following: (1) Antibiotic prophylaxis with ceftriaxone and imidazoles has been shown to be effective.[7] (2) If oral laxatives are

chosen, senna should be used rather than polyethylene glycol.[1] (3) If mechanical preparation by enema is chosen, antiseptic enemas are preferred because they are associated with fewer septic complications than water or saline enemas.[4,7] (4) If antiseptic enemas are used, PVI is better than sodium hypochlorite because of better tolerance, especially in the case of stenosis. (5) In the case of preoperative tight stenosis or intraoperative poor cleanliness, colonic lavage could be used.[21]

We recommend 4 future goals. (1) Identify the single best or 2 best antibiotic preparations at anesthetic induction and determine whether preoperative oral antibiotics add anything to the local action of PVI enema and the antibiotic preparations. (2) Confirm the clinically significant antiseptic action of PVI enema to decrease the rate of abdominal infective complications through large controlled trials. (3) Because laparoscopic colorectal surgery is common, find the ideal preparation to facilitate handling of the bowel and performing the anastomosis without spillage. (4) Improve tolerance by decreasing the volume administered from 2 L to 1 L, provided that this does not diminish the colonic cleanliness or the bactericidal action of the antiseptic enema.

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