ORIGINAL ARTICLE

Is Mechanical Bowel Preparation Mandatory for Elective Colon Surgery?

A Prospective Randomized Study

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Background: Bowel preparation prior to colonic surgery usually includes antibiotic therapy together with mechanical bowel preparation (MBP). Mechanical bowel preparation may cause discomfort to the patient, prolonged hospitalization, and water and electrolyte imbalance. It was assumed that with the improvement in surgical technique together with the use of more effective prophylactic antibiotics, it was possible that MBP would no longer be necessary.

Hypothesis: There is no statistical difference in the postoperative results of patients who undergo elective colon resection with MBP as compared with those who have no MBP.

Design and Patients: The study includes all patients who had elective large bowel resection at Campus Golda between April 1, 1999, and March 31, 2002. Emergency operations were not included. The patients were randomly assigned to the 2 study groups (with or without MBP) according to identification numbers. All patients were treated with intravenous and oral antibiotics prior to surgery. The patients in the MBP group received Soffodex for bowel preparation.

Results: A total of 329 patients participated in the study, 165 without MBP and 164 with MBP. The 2 groups were similar in age, sex, and type of surgical procedure. Two hundred sixty-eight patients (81.5%) underwent surgery owing to colorectal cancer and 61 patients (18.5%) owing to benign disease. The hospitalization period was longer in the bowel-prepared group (mean ± SD, 8.2 ± 5.1 days) as compared with the nonprepared group (mean ± SD, 8.0 ± 2.7 days). However, this difference was not statistically significant. The time until the first bowel movement was similar between the 2 groups: a mean ± SD of 4.2 ± 1.3 days in the nonprepared group as compared with a mean ± SD of 4.3 ± 1.1 days in the prepared group (P = NS). Four patients (1.2%) died in the postoperative course owing to acute myocardial infarction and pulmonary embolism. Sixty-two patients (37.6%) of the non-MBP group suffered from postoperative complications as compared with 77 patients (46.9%) of the MBP group.

Conclusion: Our results suggest that no advantage is gained by preoperative MBP in elective colorectal surgery.

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THE VALUE OF MECHANICAL bowel preparation (MBP) for elective colorectal surgery is debatable. Mechanical bowel preparation aims to rid the colon and rectum of solid stool and fecal contents, to lower bacterial load, and to reduce the incidence of postoperative anastomotic and infectious complications. The majority of colorectal surgeons consider MBP a prerequisite for the prevention of complications of colorectal surgery.[1-4] Despite recent studies that contradict this view,[2,3,5-7] the majority of colorectal surgeons still continue to emphasize the importance of MBP.

This article describes the results of a prospective randomized clinical trial designed to compare MBP and non-MBP in patients undergoing elective colorectal surgery.

METHODS

The study population comprised adult patients admitted for elective colorectal surgery in the Division of General Surgery at the Rabin Medical Center, Tel Aviv, Israel, between April 1, 1999, and March 31, 2002. All patients gave their informed consent, and the study was approved by the hospital ethics committee. Patients were allocated to the 2 study groups according to their identification numbers. Patients with even numbers received MBP (group 1), and patients with odd numbers did not receive MBP (group 2).

STUDY PROTOCOL

Patients in both groups were excluded if they had taken antibiotics for the last 10 days before surgery or if there was evidence of infection. Patients undergoing emergency opera-

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Table 1. Surgical Procedures

Type of Operation	Mechanical Bowel Preparation (n = 164)	No Mechanical Bowel Preparation (n = 165)	Total No. (%) (N = 329)
Hemicolectomy, right	18	24	42 (12.8)
Hemicolectomy, left	38	36	74 (22.5)
Sigmoidectomy	40	46	86 (26.1)
Subtotal colectomy	7	4	11 (3.3)
Abdominoperineal resection	18	16	34 (10.3)
Transverse colectomy	1	2	3 (0.9)
Anterior resection	30	20	50 (15.3)
Low anterior resection	12	17	29 (8.8)

Table 2. Summary of General Parameters

	Mechanical Bowel Preparation (n = 164)	No Mechanical Bowel Preparation (n = 165)
Sex, M:F	99:65	102:63
Age, y, mean ± SD	68.17 ± 11.5	68.11 ± 9.5
Preoperative blood transfusion	17	10
Postoperative blood transfusion	41	21
Malignant to benign disease ratio	123:41	145:20
Surgeon: attending to resident ratio	60:104	53:112
Anastomosis: hand sew to stapler ratio	10:154	4:161
First defecation, d, mean ± SD	4.3 ± 1.1	4.2 ± 1.3
Hospital stay, d, mean ± SD	8.2 ± 5.1	8.0 ± 2.7

Table 3. Mortality and Morbidity*

Mortality and Morbidity	Mechanical Bowel Preparation (n = 164)	No Mechanical Bowel Preparation (n = 165)
Mortality	2 (1.2)	2 (1.2)
Wound dehiscence	3 (1.8)	2 (1.2)
Wound infection	16 (9.8)	10 (6.1)
Anastomotic breakdown	1 (0.6)	2 (1.2)
Anastomotic bleeding	NA	2 (1.2)
Abdominal/pelvic collection	1 (0.6)	1 (0.6)
Urinary tract infection	7 (4.3)	5 (3.0)
Pulmonary complications	16 (9.8)	9 (5.5)
Thrombophlebitis	15 (9.1)	16 (9.7)
Ileus	14 (8.5)	11 (6.7)
Relaparotomy	2 (1.2)	2 (1.2)

Abbreviation: NA, not available.
*Data are presented as number (percentage). *P* values were not significant.

tions were not included. Patients randomized to group 2 were excluded if they had bowel preparation for colonoscopy within 6 days prior to surgery. Patients undergoing proctectomy with low rectal anastomosis or surgery for polypoid lesion were also excluded.

All patients were admitted 1 day before surgery and received a low-residue diet. Parenteral hydration was given on the morning of surgery. For prophylaxis in all patients, 1 hour before induction we used 500 mg of metronidazole intravenously and 1 g of ceftriaxone. The same antibiotic prophylaxis was continued for 48 hours following the operation. One day before surgery, all patients in group 1 received Soffodex (2.4 g of monobasic sodium phosphate and 0.9 g of dibasic sodium phosphate) for MBP. Possible complications were registered daily after surgery, and patients were re-examined at the outpatient clinic 1, 3, and 6 weeks following surgery.

Wound infection was indicated by the presence of pus or discharge resulting in a culture positive for bacteria. Abdominal or pelvic infection comprised discharge or abscess, which was defined as a typical finding in ultrasonography or computed tomography, and a culture positive for bacteria from the puncture or drain. Wound rupture was defined as clinical evisceration. Anastomotic dehiscence was detected by radiologic imaging using water-soluble contrast. Investigation was undertaken in the presence of fever, tenesmus, abdominal pain, or clinical signs of peritonitis.

The operations were performed by a colorectal surgeon or by a resident surgeon assisted by a consultant. A midline incision was used in all patients.

STATISTICAL ANALYSIS

Unpaired *t* test was used to compare various parameters between the 2 groups, such as mean age, hospital stay, and time to first defecation, and χ^2 test or Fisher exact test was used to calculate the differences in various complications between the 2 groups. Significance tests were 2-tailed with 95% confidence intervals, and a *P* value $<.05$ was considered significant.

RESULTS

Between April 1, 1999, and March 31, 2002, 329 consecutive patients underwent elective colorectal procedures for nonobstructive large bowel pathologic features (**Table 1**). One hundred sixty-four patients (99 men, 65 women) underwent surgery with MBP, while 165 (102 men, 63 women) did not have MBP. **Table 2** summarizes general parameters. There were more men than women in both groups (no statistical difference between the 2 groups, $P=.79$). The patients in each group were similar in age. Preoperatively, 27 patients (MBP, 17; non-MBP, 10) who had hemoglobin levels lower than 9.5 g/dL received preoperative blood transfusion ($P=.15$). Sixty-two patients (MBP, 41; non-MBP, 21) received blood transfusion in the postoperative period ($P<.005$). The average hospital stay for patients in both groups was similar. Pathological examination of the resected specimens revealed that 268 patients (81.5%) had malignant disease, whereas 61 patients (18.5%) had benign disease such as irritable bowel disease or diverticulosis (no statistical differences between the 2 groups). The majority of operations were performed by residents. The majority of anastomoses were colocolonic, colorectal, or coloanal; in only 42 patients (12.8%) was the anastomosis ileocolic. No statistical difference was found between the 2 groups. In most cases, the anastomosis was performed by stapler technique. Time to first defecation was similar in both groups.

Postoperative complications are given in **Table 3**. The incidence of wound infection was higher in patients with MBP: 16 (9.8%) as compared with 10 (6.1%) in the non-

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MBP group. The incidence of wound dehiscence, abdominal/pelvic collection, urinary tract infection, thrombophlebitis, ileus, and anastomotic breakdown was not significantly different between the 2 groups.

Anastomotic bleeding occurred in 2 patients (1.2%), both in the non-MBP group. In one the bleeding stopped spontaneously, while the second required relaparotomy and suturing of the stapler line. Anastomotic breakdown occurred in 3 patients (1 with MPB and 2 without MBP) following anterior resection and was diagnosed on the basis of clinical findings that included signs of peritonitis or septicemia, fecal discharge from the surgical wound, worsening abdominal pain, fever, and diarrhea. Computed tomography and ultrasonography were used to confirm the anastomotic leak in all 3 patients.

Pulmonary complications occurred more frequently in the MBP group: 16 patients (9.8%) vs 9 patients (5.5%) in the non-MBP group. This difference was not statistically significant.

Mortality occurred in 2 patients (1.2%) from each group. One patient died of massive pulmonary embolism on the eighth postoperative day, 2 patients died of cardiorespiratory failure, and the fourth patient died of respiratory failure on the fourth day following relaparotomy owing to anastomotic failure.

Various secondary surgical procedures were carried out in 4 patients for anastomotic leak and bleeding in both groups. These included peritoneal lavage, abdominal drainage, defunctioning colostomy in 3 patients, and suturing of the stapler line in 1 patient with anastomotic bleeding.

All together, no statistical difference in the frequency of complications was observed between the 2 groups ($P = .64$). However, when the complications were categorized into a binary variable (yes/no complication), there was a tendency for fewer complications in the non-MBP group (36.4%) as compared with the MBP group (45.7%) ($P = .08$).

COMMENT

Most surgeons use MBP for elective colorectal surgery. However, the use of MBP in elective colorectal surgery is a controversial issue. The aim of MBP is to rid the colon of solid stool, thus reducing the bacterial load and minimizing the risk of infection and anastomotic complications. It also enables the surgeon to perform intraoperative colonoscopy and facilitates palpation of the entire colon during surgery. The disadvantages of MBP are electrolyte imbalance, dehydration, abdominal pain, bloating, fatigue, and the risk of perforation with enemas, especially in the elderly population.[8-12]

Mechanical bowel preparation has been justified by Smith et al[13] in their experimental model suggesting that the passage of a large fecal load can disrupt the healing anastomosis as compared with those individuals with an empty colon. On the other hand, Schein et al[2] failed to find a difference in anastomotic healing between groups of animals with or without bowel preparation. Various prospective randomized studies,[6,7,14-16] comparing patients with and without MBP, failed to show the benefit of MBP in reducing the rate of complications.

There is no doubt that prophylactic antibiotic therapy plays a very important role in colorectal surgery. Keighley et al[17] found that the combination of MBP and systemic antibiotics provided the most effective protection against wound infection. The role of MBP and prophylactic antibiotic therapy in preventing anastomotic dehiscence is unclear, despite some studies that describe a low incidence of anastomotic dehiscence.[6,18] LeVeen et al[19] and Cohen et al[20] have also shown the advantage of prophylactic antibiotics for colorectal anastomotic healing in the presence of fecal loading. Some studies[21,22] show that anastomotic dehiscence occurs mainly after low anterior resection; in our study also, the 3 cases of anastomotic leak occurred after this procedure.

Our study failed to show any increase in the rate of anastomotic breakdown in patients without MBP; only 2 patients (1.2%) from this group had anastomotic breakdown. However, the rate of wound infection was higher in the group that received MBP, but this was not statistically significant when compared with those who did not receive it. Despite these results, we strongly emphasize the need for MBP in 2 instances: patients who need low or very low anterior resection and when surgery is performed for polypoid lesion where palpatory and sometimes intra-operative colonoscopy is necessary. On the other hand, we recommend extreme caution regarding the use of MBP in patients with a tumor almost occluding the lumen. Mechanical bowel preparation in these patients may cause large bowel obstruction necessitating emergency operation that frequently requires stoma formation.

To our knowledge, this is the second prospective randomized study of its type that includes more than 300 patients. Both studies failed to show any superiority of MBP. This prospective randomized study suggests that MBP is unnecessary for safe elective colonic and colorectal surgery, although it is recommended in selected cases where palpation of the entire colon during surgery or intraoperative colonoscopy might be required.

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Announcement

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