Randomized clinical trial

Randomized clinical trial of mechanical bowel preparation *versus* no preparation before elective left-sided colorectal surgery

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Background: **Mechanical bowel preparation (MBP) is performed routinely before colorectal surgery to reduce the risk of postoperative infectious complications. The aim of this randomized clinical trial was to compare the outcome of patients who underwent elective left-sided colorectal surgery with or without MBP.**

Methods: **Patients scheduled for elective left-sided colorectal resection with primary anastomosis were randomized to preoperative MBP (3 litres of polyethylene glycol) (group 1) or surgery without MBP (group 2). Postoperative abdominal infectious complications and extra-abdominal morbidity were recorded prospectively.**

Results: **One hundred and fifty-three patients were included in the study, 78 in group 1 and 75 in group 2. Demographic, clinical and treatment characteristics did not differ significantly between the two groups. The overall rate of abdominal infectious complications (anastomotic leak, intra-abdominal abscess, peritonitis and wound infection) was 22 per cent in group 1 and 8 per cent in group 2 ($P = 0{\cdot}028$). Anastomotic leak occurred in five patients (6 per cent) in group 1 and one (1 per cent) in group 2 ($P = 0{\cdot}021$). Extra-abdominal morbidity rates were 24 and 11 per cent respectively ($P = 0{\cdot}034$). Hospital stay was longer for patients who had MBP (mean(s.d.) 14·9(13·1) *versus* 9·9(3·8) days; $P = 0{\cdot}024$).**

Conclusion: **Elective left-sided colorectal surgery without MBP is safe and is associated with reduced postoperative morbidity.**

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Introduction

The morbidity and mortality rates associated with colorectal surgery decreased substantially over the past century[1,2]. Since the first attempts at bowel surgery, a major aim has been to reduce the rate of postoperative infectious complications, especially of anastomotic dehiscence[3]. Efficient mechanical bowel preparation (MBP) is considered to be one of the critical factors in preventing infectious complications after colorectal procedures[4,5]. It is difficult to pinpoint when bowel preparation was introduced for patients undergoing colorectal surgery[6]. In 1966, Plumley described a new regimen[7] and MBP was subsequently accepted as a surgical dogma in the early 1970s[6,8–13].

Mechanical bowel cleansing has several theoretical advantages. It may decrease the intraluminal bacterial content, prevent disruption of the anastomosis by the passage of hard faeces, and decrease operating time by improving bowel handling during construction of an anastomosis. In practice, however, MBP does not alter the concentration and only slightly modifies the relative composition of the faecal flora[14–16].

Modern surgical techniques and improved perioperative care have significantly lowered the morbidity rates of colorectal surgery. However, even with the demonstration of the effectiveness of prophylactic antibiotic therapy[17,18], the routine practice of bowel preparation remains unchanged in most institutions.

Some authors have questioned the role of bowel cleansing[19] and retrospective studies have demonstrated a low rate of infectious complications after emergency

colonic surgery including primary anastomosis without bowel preparation[20,21]. The feasibility and safety of colorectal procedures without MPB has been confirmed in prospective studies[16,22–26]. However, these series included a large number of right colectomies with ileotransversostomy and various procedures without primary anastomosis, which do not require bowel preparation[27,28]. The aim of the present study was to assess the value of MBP in elective left-sided colorectal surgery with primary anastomosis.

Patients and methods

This study was undertaken in two affiliated departments of surgery between 2001 and 2003, and included patients scheduled to undergo elective left-sided colorectal surgery with a primary colocolonic or colorectal anastomosis. The study was approved by the institutional review board (Helsinki committee), and all patients gave their informed consent before randomization. Included patients were aged 18 years or more, and had neither undergone MBP nor received antibiotics the week before inclusion. Exclusion criteria were immunosuppression, human immunodeficiency virus infection and liver cirrhosis. Furthermore, patients with tumours smaller than 2 cm were not included in the study as palpation of small tumours may be difficult in an unprepared bowel and intraoperative colonoscopy may be required to identify such lesions. The protocol specified that any patient who required a diverting stoma proximal to the anastomosis (proximal diverting ileostomy) and those with an abdominal abscess at the time of surgery would be excluded from data analysis.

Patients were allocated to one of two groups the day before surgery by individual computer-generated randomization. Patients in group 1 received MBP with 3 litres of polyethylene glycol (Bischel, Interlaken, Switzerland) 12–16 h before surgery and those in group 2 had no preoperative MBP. All patients were allowed a regular diet until midnight the evening before surgery. MBP usually took place after the last solid meal. All patients received perioperative broad-spectrum intravenous antibiotics (metronidazole and ceftriaxone), which were continued for at least 24 h after surgery. Prophylactic intravenous antibiotics could be continued for longer periods at the discretion of the surgeon; the duration of antibiotic treatment was recorded. Patients scheduled for an anterior resection of the rectum were given one 250-ml saline enema (Clyssie®, B. Braun Medical, Emmenbrucke, Switzerland) before surgery to avoid extrusion of stool when using a transanally inserted stapling device. No other preparation was carried out in group 2.

Data on demographic and clinical characteristics, operative procedures and findings, and 30-day postoperative follow-up were entered prospectively into a computerized database (FileMaker Pro 5.0™, FileMaker Inc., Santa Clara, California, USA) California, USA) and entry of main endpoints was rechecked for accuracy.

The primary endpoint for assessment of outcome was the incidence of postoperative abdominal infectious complications, including anastomotic leak, wound infection, abdominal abscess and/or peritonitis. Secondary endpoints were non-infectious abdominal complications, extra-abdominal complications, duration of postoperative ileus and length of hospital stay. Anastomotic dehiscence was defined by the demonstration of extraluminal leakage of contrast by imaging or was documented during reoperation. Wound abscess was defined as a wound requiring partial or complete opening for drainage of a purulent collection, or erythema requiring initiation of antibiotic treatment. Abdominal abscess was identified as a fluid collection by computed tomography (CT), in conjunction with a raised temperature and white blood cell count that required antibiotic treatment, or was documented at reoperation. Peritonitis was defined as infection of the peritoneal cavity at reoperation. The overall extra-abdominal complication rate was based on all significant events that necessitated treatment. The duration of postoperative ileus was the time required before removal of the nasogastric tube. The time from surgery to the first bowel movement and time to resumption of solid food intake were also recorded. Investigators assessing the endpoints were blinded to the use of MBP.

Statistical analysis

A power calculation was performed using Statistica 5·5 Software™ for Windows (Statsoft, Tulsa, Oklahoma, USA). A sample size of 74 patients per group was deemed adequate to achieve a power of 80 per cent with an α first-level error of 0·05 and β value of 0·05 using a one-sided statistical test.

Statistical analyses were performed using Fischer's exact test, χ^2 test or *t*-test as appropriate, in the statistical packages GraphPad (InStat, San Diego, California, USA) and GB-STAT version 10.0™ (Dynamic Microsystems Inc., Silver Spring, Maryland, USA). $P < 0{\cdot}050$ was considered significant. A relative risk of more than 1 was in favour of no MBP.

Results

One hundred and fifty-three patients were included in the trial and none was excluded from the analysis. Seventy-eight patients received MBP (group 1) and 75

did not (group 2). Demographic data and indications for surgery did not differ significantly between the two groups (*Table 1*). Around two-thirds of the patients in each group had an American Society of Anesthesiologists (ASA) score of II or more. MBP was associated with patient discomfort in 22 per cent, including difficulty in drinking the preparation, nausea, vomiting and abdominal pain.

All patients had left-sided colonic and/or rectal surgery with a primary anastomosis (*Table 2*). Around two-thirds of patients in each group had a laparotomy. Most of the anastomoses were performed mechanically. MBP did not influence the operating time (*Table 2*). In addition to left-sided colonic surgery, 38 per cent of patients in group 1 and 35 per cent in group 2 had another surgical procedure during the same intervention, including appendicectomy, cholecystectomy and hysterectomy with removal of adnexae. There were no operative deaths. The median duration of antibiotic prophylaxis was less than 2 days in the two groups.

Postoperative abdominal infectious complications were documented in 23 patients overall (15·0 per cent); anastomotic dehiscence occurred in six (3·9 per cent). The incidence of such complications (including anastomotic leak, intra-abdominal abscess, peritonitis and wound infection) was significantly higher in group 1 than group 2 ($P = 0·028$) (*Table 3*). There were five cases of anastomotic dehiscence in group 1 and one in group 2; all required either relaparotomy or CT-guided percutaneous drainage. The overall rate of reoperation was 5·9 per cent and the main indication was anastomotic leak necessitating faecal diversion (*Table 4*). Extra-abdominal complications

Table 1 Demographic and clinical characteristics

	MBP ($n = 78$)	No MBP ($n = 75$)	P*
Mean (range) age (years)	63 (43–89)	63 (21–92)	0·999
Male	47 (60)	34 (45)	0·092
Mean body mass index (kg/m^2)	24·9	24·8	0·858
ASA grade			0·633
I	26 (33)	27 (36)	
II	42 (54)	40 (53)	
III	10 (13)	8 (11)	
Diagnosis			0·412
Colorectal cancer	25 (32)	21 (28)	
Diverticular disease	45 (58)	45 (60)	
Hartmann's reversal	6 (8)	3 (4)	
Adenoma	2 (3)	4 (5)	
Endometriosis	0 (0)	2 (3)	

Values in parentheses are percentages unless indicated otherwise. MBP, mechanical bowel preparation; ASA, American Society of Anesthesiologists. *Student's t-test for continuous variables and χ^2 test for categorical variables.

Table 2 Treatment details

	MBP ($n = 78$)	No MBP ($n = 75$)	P*
Procedure			0·803
Sigmoidectomy	40 (51)	39 (52)	
Left colectomy	20 (26)	20 (27)	
Anterior resection	12 (15)	13 (17)	
Closure of Hartmann's	6 (8)	3 (4)	
Approach			0·824
Laparotomy	55 (71)	51 (68)	
Laparoscopy (completed)	20 (26)	22 (29)	
Scopy converted to laparotomy	3 (4)	2 (3)	
Type of anastomosis			0·99
Mechanical	47 (60)	46 (61)	
Manual	31 (40)	29 (39)	
Mean(s.d.) duration of procedure (min)	195(67)	189(38)	0·487
Associated operative procedure	30 (38)	26 (35)	0·737
Duration of antibiotic prophylaxis (days)			0·943
1	63 (81)	62 (83)	
2	12 (15)	12 (16)	
>2	3 (4)	1 (1)	

Values in parentheses are percentages unless indicated otherwise. MBP, mechanical bowel preparation. *Student's t-test for continuous variables and χ^2 test or Fischer's test for categorical variables.

Table 3 Infectious abdominal complications

	MBP ($n = 78$)*	No MBP ($n = 75$)*	P	Relative risk†
Anastomotic leak	5 (6)	1 (1)	0·210	1·68 (0·91, 2·49)
Intra-abdominal abscess‡	1 (1)	2 (3)	0·615	0·47 (0·04, 5·34)
Peritonitis‡	1 (1)	0 (0)	1	2·93 (0·12, 73)
Wound abscess	10 (13)	3 (4)	0·07	1·58 (0·97, 2·34)
Total	17 (22)	6 (8)	0·028	1·58 (1·16, 2·14)

Values in parentheses are *percentages or †95 per cent confidence intervals. ‡Abscess or peritonitis without demonstrable anastomotic leak. MBP, mechanical bowel preparation. Statistical analysis by Fischer's exact test.

Table 4 Reoperation for abdominal complications

	MBP ($n = 78$)*	No MBP ($n = 75$)*	P	Relative risk†
Anastomotic leak	4 (5)	1 (1)	0·367	1·6 (0·89, 2·55)
Haemoperitoneum	1 (1)	1 (1)	1	0·99 (0·24, 3·95)
Intra-abdominal abscess‡	1 (1)	0 (0)	1	2·93 (0·12, 73)
Peritonitis (small bowel perforation)	1 (1)	0 (0)	1	2·93 (0·12, 73)
All reoperations	7 (9)	2 (3)	0·167	1·58 (1·07, 2·32)

Values in parentheses are *percentages or †95 per cent confidence intervals. ‡Abscess without demonstrable anastomotic leak. MBP, mechanical bowel preparation. Statistical analysis by Fischer's exact test.

Table 5 Extra-abdominal complications

	MBP ($n = 78$)*	No MBP ($n = 75$)*	P	Relative risk†
Bronchopneumonia	6 (8)	2 (3)	0·277	1·51 (0·93, 2·33)
Cardiac	7 (9)	2 (3)	0·167	1·58 (0·97, 2·32)
Sepsis	1 (1)	1 (1)	1	0·99 (0·24, 3·95)
Urinary tract infection	4 (5)	3 (4)	1	1·13 (0·58, 2·18)
Cerebral embolism	1 (1)	0 (0)	1	2·93 (0·12, 73)
Total	19 (24)	8 (11)	0·034	1·5 (1·11, 2·04)

Values in parentheses are *percentages or †95 per cent confidence intervals. MBP, mechanical bowel preparation. Statistical analysis by Fischer's exact test.

Table 6 Postoperative data

	MBP	No MBP	P
Time to NGT removal (days)*	2·8(2·6)	1·9(1·1)	0·007
Time to first bowel movement (days)*	3·9(2·7)	2·5(1·1)	0·001
Time to realimentation (days)*	4·5(2·7)	3·5(1·1)	0·004
Hospital stay (days)			
All patients	14·9(13·1)	9·9(3·8)	0·024
Patients without abdominal complication	11·7(5·2)	9·1(2·7)	0·001

Values are mean(s.d.). *From day of operation. MBP, mechanical bowel preparation; NGT, nasogastric tube. Statistical analysis by student's t-test.

occurred in 27 patients (17·6 per cent), with a significantly higher incidence in group 1 ($P = 0·034$) (*Table 5*).

Recovery of bowel function was slightly delayed in patients who had MBP compared with those who did not (*Table 6*). The duration of hospital stay was significantly longer in the MBP group ($P = 0·024$). This might have been attributed to the higher rate of infectious complications in this group, but the difference in hospital stay between groups remained significant when patients with abdominal complications were excluded. No deaths were recorded during the study.

Discussion

Although MBP before elective left-sided colorectal surgery has become routine, there is a paucity of scientific evidence to support this practice[2,29,30]. Moreover, recent improvements in morbidity and mortality rates of bowel surgery resulting from advances in perioperative care and routine application of antibiotic prophylaxis[13], in conjunction with experience gained in emergency colonic surgery[20,22,23,31], have led surgeons to question whether bowel cleansing offers any benefit.

This randomized clinical trial showed that avoidance of bowel preparation before elective left-sided colorectal surgery was associated with a reduction in the rate of postoperative infectious and extra-abdominal complications, and a shorter hospital stay. These findings are in accordance with the results of other recent randomized trials that evaluated the role of MBP before elective right- and left-sided colonic surgery[16,24–26,32]. None of these studies demonstrated an advantage of bowel preparation and some reported an increased incidence of abdominal infectious complications in patients receiving MBP. A recent meta-analysis from the Cochrane collaborative group[29] revealed that MBP was associated with a significantly increased incidence of anastomotic dehiscence. Of note, most of these series involved not only left-sided procedures, but also right colectomies and other procedures for which the risk of anastomotic dehiscence is low[27,28]. This might have biased the evaluation of the role of MBP[33].

The overall rate of abdominal infectious complications and anastomotic dehiscence in this study compares favourably with previously published data[16,24,34]. Most patients were ASA grade II or III, which is a recognized risk factor for morbidity and death[13]. The extent to which results between studies can be compared is dependent on the differences in methods of determining adverse events[33].

Although there is little scientific evidence to support its use, many surgeons continue to advocate MBP for aesthetic or practical reasons. However, this procedure is not harmless, and almost invariably causes significant discomfort to the patients[35,36]. It has also been associated with bacterial translocation through the bowel wall[37,38] and electrolyte disturbance[39]. In the present series, extra-abdominal complications were more common in patients who had received MBP.

Some patients scheduled to undergo left-sided colorectal surgery will still benefit from MBP, such as those with tumours smaller than 2 cm in diameter who may require intraoperative colonoscopy; such patients were not included in the present trial. Similarly, patients with low rectal cancers who are candidates for a restorative proctectomy with diverting ileostomy require preoperative bowel preparation. In contrast, just one small enema is needed before low anterior resection to avoid gross faecal loading at the time of transanal insertion of the stapling device.

This study aimed to determine the value of MBP, while controlling for other factors that might affect the rate of infectious complications. The two groups were similar in terms of demographics, type of surgery and surgical technique. However, several surgeons were involved as this was a multicentre trial, which might partially bias the results. On the other hand, results from multicentre

trials may be more reproducible[13]. The present study showed with reasonable statistical power that MBP before elective left-sided colorectal surgery was associated with an increased incidence of infectious abdominal complications. However, if anastomotic leak rate were the primary outcome measure a much larger sample size would be required. Assuming an anastomotic dehiscence rate of 5 per cent in a study designed to detect a difference of 3 per cent with a one-tailed statistical test, with an α level of 0·05 and power of 80 per cent, at least 514 patients per group would be needed.

The present results confirm that left-sided colorectal surgery can be performed safely without MBP, but also suggest that bowel preparation may have a negative impact in terms of an increased complication rate and longer hospital stay. Such data should prompt colorectal surgeons to re-evaluate their current clinical practice.

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