

An Open-Label Prospective Randomized Controlled Trial of Mechanical Bowel Preparation vs Nonmechanical Bowel Preparation in Elective Colorectal Surgery: Personal Experience

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Abstract Over the last two decades, preoperative mechanical bowel preparation for elective colorectal surgery has been criticized. Yet, many surgeons are still in favor of its use simply because of the belief that it achieves better clearance of the colonic fecal load. The objective of this study is to compare the outcome with regard to patient compliance and postoperative complications following elective colorectal surgery between two groups of patients, one with bowel prepared mechanically and the other by nonmechanical means. This open-label prospective randomized controlled trial was conducted in a high-volume tertiary government referral hospital of Kolkata over a period of 3 years. It included 71 patients, divided into two groups, admitted for elective colorectal resection procedures in one surgical unit. Both methods of bowel preparation were equally well tolerated, and there was no statistically significant difference in the incidence of postoperative complications or mortality between the two groups.

Keywords Colorectal surgery · Mechanical bowel preparation · Nonmechanical bowel preparation

Introduction

Traditional belief, based mostly on observational data, was that colon cleared of its fecal load, prior to elective colorectal sur-

gery, by mechanical bowel preparation (MBP) not only makes the surgeon's work technically easier by reducing spillage but also reduces the postoperative complications, morbidity, and mortality by reducing the colonic bacterial load [1]. Bowel and rectum cleansing, first described by Maunsell in the early 1890s, remained a dogmatic practice and the standard of care amongst colorectal surgeons for decades, because of the concern for anastomotic leakage and surgical site infection [2].

This practice of vigorous preoperative mechanical cleansing of the bowel was first questioned in 1972 by Edward Hughes on the grounds of the physical discomfort which is inherent to the procedure [3]. Later in 1992, Brownson et al. published the first prospective randomized controlled trial (RCT) where MBP was surprisingly found to be associated with higher incidences of dreaded complications like anastomotic leak and intra-abdominal sepsis [4]. When the results of subsequent well-designed clinical trials were published, some colorectal surgeons started to doubt this traditional dogma of MBP in elective settings and started gradually shifting towards nonmechanical means of bowel preparation (NMBP).

This open-label prospective RCT sought to compare the outcome with regard to patient compliance and postoperative complications following elective colorectal surgery between two groups of patients, one with bowel prepared mechanically and the other by nonmechanical means.

Materials and Methods

This prospective RCT study was conducted over a period of 3 years from May 2010 to April 2013 in a high-volume tertiary government teaching hospital of Kolkata. Necessary clearance from the institutional ethical committee was obtained before the trial. Informed consent was obtained from all patients participating in the trial.

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This database included 71 patients admitted for elective colorectal resective surgical procedures in one surgical unit. The inclusion criteria were patients over 15 years of age admitted for elective colorectal resection, giving willful informed consent to participate in this trial.

Patients who were unwilling to take part in the trial or those with gross comorbidities (which may otherwise adversely affect the outcome of surgery) were excluded from the trial. Patients undergoing emergency colorectal surgeries were not included either.

To reduce experimental bias and to increase precision of inference while working with a small sample size as in our study, an effective method of randomization is vital. With this objective, our patients were allocated into two study groups (group I and group II) by adaptive biased coin design. Group I constituted of patients who received MBP prior to surgery, while group II included those who were prepared nonmechanically (NMBP).

All patients underwent open laparotomy and were primarily operated by consultants of the unit.

Available combined commercial preparation of polyethylene glycol (118 g), sodium chloride (2.93 g), potassium chloride (1.484 g), sodium bicarbonate (3.37 g), and anhydrous sodium sulfate (11.36 g) with choice of flavors (PEGWASH®) was used for MBP. Patients were asked to dissolve one pack with the flavoring agent in 2 l of water and start drinking from the afternoon prior to surgery, at the rate of 200 ml every 10–15 min so that 1 l is consumed in 1 h. They were told to drink the remaining solution till stool becomes watery.

Tolerability to MBP was assessed as per Likert scale (1=poor, 2=fair, 3=good, 4=excellent).

The patients included in group II undergoing NMBP were simply told to take clear fluids and avoid solid foods for 2 days prior to surgery and nothing per oral since the morning of surgery.

All patients were thoroughly optimized from a surgical point of view, before posting them for surgery; at the same time, we tried to make the preoperative hospital stay as short as possible to decrease the possibility of hospital-acquired, and often antibiotic-resistant, infection. All patients were started on intravenous fluid on the morning of surgery, and both groups of patients received single-dose prophylactic antibiotic injections (1.5 g cefuroxime and 500 mg metronidazole) 1 h before surgery.

Following the elective colorectal procedures, the two patient cohorts were compared for overall complications, if any. The primary outcome measure was anastomotic leak, manifesting as feculent discharge through drain or wound site. The secondary outcome parameters were wound infection, intraabdominal abscess, necessity for reexploration, and mortality. For assessment of these outcome measures, patients were followed up for a maximum period of 1 month from the day of surgery.

Observed data were entered in a MS Excel spreadsheet and analyzed by standard statistical tools. For drawing differences between the two groups of categorical variables like the post-operative complications, chi-square test or Fischer's exact test was used and a *P* value <0.05 was considered significant.

Results

The 71 subjects included in this study were clustered in two groups, group I (*n*=38) had MBP and group II (*n*=33) had NMBP prior to colonic resection. The mean age of patients in group I (21 males, 17 females) was 47.45 ± 10.34 , while that of group II (20 males, 13 females) was 46.64 ± 10.06 . Both the groups were matched with regard to age and sex distribution (*P* values 0.74 and 0.81, respectively).

Both methods of bowel preparation were well tolerated by patients, the mean Likert scale being 3.79 ± 0.33 and 3.85 ± 0.26 for group I (MBP) and group II (NMBP), respectively. The difference was not statistically significant.

Table 1 shows the various operative procedures on the patients included in the two groups. Eighty percent (*n*=57) of the patients of our series had malignant disease. Fourteen patients had benign conditions like polyposis coli, ulcerative colitis, and ileocaecal tuberculosis, including two patients with half turn volvulus who were initially treated conservatively. There was no statistical difference in the incidences of benign and malignant diseases between the two groups. Majority of the patients had hand sewn anastomosis, and only low anterior resections (without proximal diverting ileostomy) were done with circular staplers. Fifty-three percent (*n*=38) of our patients had ileo-colic anastomosis, and side to side or end to side anastomoses were preferred wherever feasible. No statistical difference was found in the frequency of ileo-colic and colo-colic anastomosis between the two groups.

Table 2 shows the primary and secondary outcome variables of the two groups and their comparative analysis. The incidence of the primary outcome measure, i.e., anastomotic leak was 10.5 and 6.06 % in group I and group II, respectively. The difference was not found to be statistically significant (*P*=0.679). The principle of managing anastomotic leak that we followed was early detection, appropriate systemic management, and a low threshold for reexploration and proximal diversion.

Similarly, the difference in the incidences secondary outcome parameters, i.e., wound infection (*P*=0.404), intraabdominal abscess (*P*=0.618), necessity for reexploration (*P*=1.000), and mortality (*P*=1.000) were not found to be statistically significant. Abdominal abscesses were managed by image-guided aspiration or reexploration. Both reexplorations of this series were done in cases of fecal fistulas associated with abdominal abscesses.

Table 1 Operative procedures

Procedures	MBP (N=38)	NMBP (N=33)	Total (N=71), N (%)
Right hemicolectomy*1	10	9	19 (26.7 %)
Abdominoperineal resection	9	5	14 (19.6)
Total proctocolectomy*	5	6	11 (15.5)
Extended right hemicolectomy	5	3	8 (11.3)
Sigmoid colectomy*2	4	3	7 (9.9)
Left hemicolectomy	2	4	6 (8.5)
Low anterior resection	3	3	6 (8.5)

*14 patients with benign conditions (1 patient of ileocaecal tuberculosis underwent right hemicolectomy, all 11 patients who underwent total proctocolectomy for polyposis coli / ulcerative colitis and 2 patients underwent sigmoid colectomy for volvulus)

There was one death in either group, the incidences being 2.63 and 3.03 % for group I and group II, respectively; the difference was once again found to be statistically insignificant. The death in group I was due to respiratory failure in an elderly diabetic woman who underwent right hemicolectomy for adenocarcinoma of caecum, while the other death was due to pulmonary embolism in a cachectic patient of ileocaecal tuberculosis.

Discussion

Surgeons would always prefer working on a bowel cleared thoroughly of its fecal load. The ritual of MBP prior to elective colorectal surgery was practiced over decades primarily with this objective and also because of the belief that it would reduce the colonic bacterial load, thereby addressing the concern of high incidence of infectious complications associated with colorectal procedures [1]. MBP is still commonly practiced in colorectal surgery, without evidence from randomized trials that it decreases postoperative complication rates [4, 5].

Though questions were raised regarding its routine use about two decades ago [3, 4], based on reviews of some recent studies from 2004 to 2007 [5–12], which expressed strong reservations against the practice of preoperative MBP, we hypothesized that routine mechanical bowel preparation has no benefit and may actually increase the likelihood of surgical complications associated with elective colorectal resection.

Some authors have even reported increased mean hospital stay and delayed return of bowel movements in patients prepared mechanically [5, 11]. In general, this has been attributed to the hyperosmolar nature of the PEG causing inflammation and ischemia of the colonic mucosa which may lead to bacterial translocation [13].

Inadequate bowel cleansing (semi prepared bowel), leading to liquid bowel contents, is thought to increase the rate of postoperative infectious complications because of intra-operative spillage of stool [13].

Moreover, MBP has been associated with increased patient discomfort and side effects such as fluid, electrolyte, and acid-base imbalances. The liberal fluid infusion, for correction of dehydration, may intensify these disturbances and also causes tissue edema which may compromise the integrity of the colonic anastomosis [14, 15].

In view of this paucity of evidences to support the practice of MBP in recent studies [13, 16], we planned this prospective randomized control study, over a period of 3 years, to compare the outcome of elective colorectal resective procedures following bowel preparations done mechanically in some and nonmechanically in others.

In our patient cohorts, the incidence of anastomotic leak (primary outcome measure) was 4/38 (10.53 %) for mechanically prepared group as against 2/33 (6.06 %) for the other. The difference was not found to be statistically significant. Similar was the inference drawn by some of the studies done of late [12, 17–20].

Table 2 Comparison of the outcome parameters

Outcome parameters	MBP (total N=38), N (%)	NMBP (total N=33), N (%)	P value
Anastomotic leak	4 (10.53)	2 (6.06)	0.679
Wound infection	11 (28.95)	6 (18.18)	0.404
Intra-abdominal abscess	3 (7.89)	1 (3.03)	0.618
Reexploration	1 (2.63)	1 (3.03)	1.000
Death	1 (2.63)	1 (3.03)	1.000

On the other hand, there are many authors who in their trials have found a significantly increased incidence of leak in patients prepared mechanically [5, 7, 9].

Regarding infective complications, the incidence of wound infection was 11/38 (28.95 %) and 6/33 (18.18 %) and intraabdominal abscess was 3/38 (7.89 %) and 1/33 (3.03 %) in group I and group II, respectively, the differences being statistically insignificant. The colon in patients of MBP was found to be clean in all cases, but in three patients with stenotic left colonic growth prepared nonmechanically, there was spillage of liquid stool preoperatively; all of them had postoperative wound infection and one of them was further complicated by intra-abdominal abscess. Our results are in conformity with the findings in some recent trials [19, 21, 22], but the RCT done in 2007 found a significantly higher incidence of abdominal abscesses with anastomotic leak in patients prepared nonmechanically (though the overall incidence of wound infection did not show any significant difference) [12].

Reexploration and mortality also showed no significant difference between the two groups of our study. This is similar to findings of some trials referred to before [7, 18, 19].

Conclusion

In the present-day scenario, the practice of MBP in patients of elective colorectal surgery is controversial as, on one hand there are no evidences to prove that it reduces postoperative complications, while on the other hand it has some definite disadvantages like fluid electrolyte imbalance and patient inconvenience.

But our study failed to show any statistically significant advantage of nonmechanical means of bowel preparation either.

In view of the above findings where neither method could be proven to be superior over the other, we in our unit presently prefer MBP simply because of the technical advantage of getting a clean colon during surgery.

Conflict of Interest Nil.

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