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Mechanical bowel preparation versus no preparation in elective colorectal surgery: A prospective randomized study

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ABSTRACT

Background: Mechanical bowel preparation (MBP) of gut is routinely done before colorectal surgeries in most surgical departments all over the globe. This gut preparation is aimed at reducing the risk of postoperative infections in patients undergoing colorectal surgery. Even though recent studies are more in favor of operating on gut without bowel preparation, controversies still exist. The aim of our study was to assess whether elective colorectal surgeries can be performed safely without preoperative MBP.
Methods: Patients undergoing elective colorectal surgeries were prospectively randomized into two groups with the help of random number table method; Group-1 had mechanical bowel preparation with polyethylene glycol (MBP group) before surgery, and Group-2 had no mechanical bowel preparation (NMBP group) before surgery. All patients in the study groups were followed up for at least 2 months after surgery for wound infection, anastomotic leak and intra-abdominal infections.
Results: Two hundred fourteen patients were included in this hospital-based systematic prospective randomized trial: 104 patients in Group-1 and 98 patients in Group-2. Twelve patients were excluded from the study. The type of surgical procedure and type of anastomosis did not significantly differ between two groups. There was no difference in surgical infections between two groups. The overall infection rate was 39.4% in Group-1 and 32.6% in Group-2 ($p = 0.31$). Wound infection ($p = 0.45$), anastomotic leak ($p = 0.45$) and intra-abdominal/pelvic collection ($p = 0.62$) occurred in 3.8%, 3.8% and 6.7% versus 6.1%, 2% and 5.1% in Group-1 (MBP group) and Group-2 (NMBP group) respectively. Our results showed that MBP does not offer any specific benefit in elective colorectal surgeries but in real sense may add to some problems, which, however, did not achieve a statistical significance.
Conclusions: Our study proved that no advantage is gained by pre-operative mechanical bowel preparation in elective colorectal surgery and can be easily avoided in order to save patients from unwanted exhaustion, distress and adverse effects related to it. It is actually the mindset that makes us to believe that MBP will reduce the incidence of infections rather than the evidence from literature. We conclude from our study that all types of elective colorectal surgeries can be performed safely without subjecting patients to mechanical bowel preparation before surgery.

1. Introduction

Morbidity and mortality have been a matter of main concern in colorectal surgery during the past several decades. Mortality was more than 20% in colorectal surgery in the first half of the 20th century [1], and was mainly attributed to sepsis and poor surgical techniques. In this modern era preoperative assessment, perioperative care, surgical techniques and concepts of multimodality treatment have led to a marked decrease in morbidity and mortality and improved survival with better QOL. However the septic complications are still the major cause of morbidity in colorectal surgery, leading to a prolonged hospital stay and occasionally even mortality [2]. Efficient mechanical bowel preparation (MBP) is generally supposed to help in preventing the infectious complications after elective colorectal surgery. Theoretically this practice diminishes fecal load in the bowel and prevents anastomotic disruption by reducing fecal impaction at anastomotic site. Therefore it was thought that the risk of fecal contamination or infection of peritoneal cavity and abdominal wound decreases [3–6]. Also it was seen that MBP liquefies the solid feces, which could increase the risk of intra-operative spillage of the bowel contaminant and hence contamination [5,7]. Still some investigators believe that MBP can reduce

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the bacterial load in the bowel, but the large number of microorganisms in the digestive tract makes this almost impossible [8,9]. It had been shown by various authors that although MBP does cause reduction in the fecal mass in colon, it does not cause any significant reduction in the concentration per milliliter of the bacterial count in the lumen of the colon in the absence of prophylactic antibiotics. Thus on its own MBP has no beneficial value [6,10,11]. Further it had been also seen that histological changes occur in the intestinal mucosa of patients who have received MBP. There was also significant loss of epithelial cells, edema of lamina propria, lymphocytic and polymorphonuclear cell infiltration in these patients. These changes could potentially result in bacterial translocation and anastomotic disruption [12,13]. Besides this, MBP has many negative side effects, like discomfort to patients and water and electrolyte imbalance, and is also not safe for elderly patients and those having underlying cardiac, renal or pulmonary disease [14–20]. Despite these drawbacks mechanical bowel preparation is still practiced by most of the colorectal surgeons worldwide in elective colorectal surgery without evidence from randomized trials [21–24].

2. Methods

Patients undergoing elective colorectal surgery in the Department of Colorectal Surgery, a division of General and Minimal Invasive Surgery, SKIMS (Kashmir), between August 2012 and September 2014 were included in this study. In this systematic prospective hospital-based randomized controlled study, patients were distributed into two groups: Group-1 (control), preparation group; and Group-2 (cases), a group without preparation. An informed consent was taken from all the patients included in the study. Randomization was done with the help of random number table by assigning serial number to all colorectal cancer patients, and with the help of the said table these colorectal cancer patients were distributed blindly into two groups; patients who got odd numbers were kept in a preparation group (control) and the patients who got even numbers were allotted to non-preparation group (cases) by a designated staff nurse. The patients in the preparation group received oral MBP by using two packs of polyethylene glycol in four liters of water over four hours, 12–16 hours before elective surgery. Vital parameters like blood pressure, pulse rate, hydration status and electrolytes both before and after preparation were monitored, and if any deficit was found it was corrected accordingly. They were allowed to take only liquid diet until midnight, the evening before surgery; on the other hand, low residue diet was allowed until midnight the evening before surgery in patients with no preparation. All patients in both groups in their peri-operative period received broad-spectrum intravenous antibiotics at the time of induction before the start of procedure (Ceftriaxone injection 1 gm and Metronidazole injection 500 mgs), and was continued postoperatively also for 48 hours. The operating surgeon was completely blinded about the preparation status of the patient in order to eliminate bias in interpretation.

In both groups patients were comparable in terms of demographic and clinical characteristics, associated co-morbidities, type of surgery performed, intra-operative findings, type of anastomosis and one month postoperative follow-up. All these parameters were prospectively entered in a Microsoft Excel database. Final analysis of finding the p-value for calculating the statistical significance and insignificance between the two groups, drawing of charts, and cross tabulation were done by SPSS and Excel software. The statistical analysis was performed by using chi square and "t" test; probability values of less than 0.05 were considered significant. The main outcome was the rate of postoperative surgical infectious complications and medical complications. Surgical complications include wound infection, anastomotic leak and abdominal/pelvic collection. Wound infection was defined as a wound requiring partial or complete opening for drainage of collection. Anastomotic leak was identified if fecal drainage was evident from abdominal drains or documented by imaging modalities. Abdominal/pelvic collection was defined as a collection demonstrated by ultrasonography or computed tomography scan in conjunction with elevated temperature or total leukocyte count. All the medical complications were treated with the help of broad spectrum antibiotics or by sensitivity selected antibiotics on the basis of blood, urine or sputum cultures.

3. Results

Two hundred fourteen patients were enrolled in this study between August 2012 and September 2014. Twelve patients were excluded from the study due to loss of follow-up. Finally 104 patients had their surgery with pre-operative mechanical bowel preparation and 98 had their surgery without mechanical bowel preparation. Demographic and clinical characteristics, associated comorbidities, biopsy and final diagnosis, type of surgical procedure, intra-operative findings, type of anastomosis, and bowel handling did not significantly differ between the two groups (Tables 1–7). When we assessed the main outcome of this study, there was no significant difference between the two groups in terms of postoperative infections, like wound infection, anastomotic leak and intra-abdominal/pelvic collection (Table 8). The overall complication rate in the non-preparation group was 32.6% while it was 39.4% in the preparation group (p-value = 0.31). There was no significant difference in the average days of regular feeding and to the first bowel movement between the preparation and non-preparation group (6.2 ± 1.7 versus 5.8 ± 1.3 days and 5.45 ± 2.5 versus 4.9 ± 1.8 days, respectively) (Table 9). There was no significant difference in terms of length of hospital stay, with a mean stay of 9.32 ± 2.21 days in the preparation group and 8.87 ± 1.67 days in the non-preparation group. We had no mortality within two months of follow-up in both groups; however, 7.6% (8/104) patients from the preparation group and 6.1% (6/98) from the non-preparation group were re-admitted for mild wound infection, pain abdomen and mild abdominal/pelvic collection (Table 10). Even readmission rates were compared in both groups within 30 days of previous admission and the comparison did not show any significant difference in the two groups (Table 11). All these patients were managed conservatively and no surgical intervention was required.

4. Discussion

The use of MBP before elective colorectal surgery has become a surgical dogma; there is a paucity of scientific evidence demonstrating the efficacy of this practice in reducing the rate of infectious complications. Still pre-operative MBP is a standard practice in elective colorectal surgery adopted by majority of surgeons worldwide. The ideal MBP should be safe, cost-effective and easy to administer, and have minimal acceptable side effects. The goal of MBP before

Table 1
Age distribution.

Age distribution of 202 patients in each group				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Age (years)	≤30	12 (12%)	14 (13%)	0.69 (NS)
	31 to 45	16 (16%)	15 (14%)	
	46 to 60	39 (40%)	43 (41%)	
	61 to 75	26 (27%)	29 (28%)	
	>75	5 (5%)	3 (3%)	
	Total	98 (100%)	104 (100%)	
	Mean ± SD	**51 ± 18.15 (16.87)**	**50 ± 17.76 (16.85)**	

Bold indicates that the patients in both groups belonged to same age group.