

Randomized Clinical Trials of Mechanical Bowel Preparation Versus No Preparation in Elective Colorectal Surgery

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ABSTRACT

Objective: The study aim was to evaluate whether elective colon and rectal surgery can be safely performed without preoperative mechanical bowel preparation.

Study Design: Cross sectional study

Place and Duration of Study: This study was conducted at the Sindh Govt. Lyari General Hospital Karachi from March 2018 to March 2019.

Materials and Methods: A total population of 100 patients admitted for colon and rectal resections were prospectively randomized into two groups. Group A had mechanical bowel preparation before surgery and Group B underwent surgery without preoperative mechanical bowel preparation. Our investigation team followed up for 30 days for wound, anastomotic and intra-abdominal infections and subsequent problems.

Results: It was detected that out of 100 patients, after randomization 50 in Group A and 50 cases in Group B were studied in which the anastomotic leak, re-operation rate and mortality were 24%, 10% and 4% in Group A vs 16%, 6% and 6% in Group B respectively. And the hospital stay was 12 and 9 days in Group A vs Group B. However the resulting complication rates were similar in both the groups with Cardiovascular complications, deep Abscess, incisional hernia, peritonitis and wound infection at 48%, 36%, 45%, 44%, 54% in Group A and 52%, 64%, 55%, 56%, and 46% in Group B.

Conclusion: As per our study, we conclude that mechanical bowel preparation doesn't cause any harm and it's safe for patients undergoing elective colorectal surgery to undergo without mechanical bowel preparation.

Key Words: Colorectal Surgery, pre-operative mechanical bowel preparation, anastomotic leakage.

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INTRODUCTION

Surgeons believed that effective mechanical bowel preparation is a significant element and it can help in stopping infections and anastomotic dehiscence after colorectal surgery. Clinical incidents and experimental studies have verified that removal (mechanical) of gross feces (from the colon) has resulted in decreased rate of illness and death in patients undergoing operations of the colon. Although authors have different sides to it, some support the idea and some claim it to be risky as it increases the chances of inflammatory processes¹.

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The reason of suggesting this drill is to decrease problems after the operation and in easier handling of bowel during operation. Usually, bowel are cleaned using enemas and laxatives given to patients orally. Modern methods have now also introduced oral cathartic agents to tempt diarrhea and bowel cleaning. Mostly Polythene Glycol and Sodium phosphate are used to clean the bowel. In a study conducted by Platell and his group, it was found that Patient who received polyethylene glycol with phosphate enema for bowel preparation are better than the ones who doesn't undergo such procedures.² Further while performing the procedure it is indicated that patient's co-morbid disease and risk profiling is significant to assess respiratory and cardiac activity prior to admittance as it helps in identifying patients with greater risk of complications.

The exercise of bowel cleaning before colorectal surgery is now considered a principle in performing surgery and no bowel preparations are not suggested however it's still under study whether the rate of infectious problems is still to be verified.

MATERIALS AND METHODS

This cross-sectional study was carried out in Sindh Govt. Lyari General Hospital Karachi on March 2019. A total population of 100 patients aged above 45 who chose for elective laparoscopic colorectal surgery were eventually categorized into two groups : **Group A** in which bowel preparation (mechanical) done before surgery and **Group B** underwent surgery with no preoperative mechanical bowel preparation. Patients in Group A were given polyethylene glycol around 10 to 14 hours before their surgery was performed.

All Patients were open to normal diet until sometime before surgery and were also given antibiotic before and after the surgery procedure. We took written consent from all patients under study to ensure transparency.

Patients with or without mechanical bowel preparation were subdivided into gender and age. Our investigation team followed up for 30 day for wound, anastomotic and intra-abdominal infections and subsequent problems. Exclusion Criteria:

- (1) Patients suffering from Diabetes mellitus and serious malignancy

- (2) Patients with proximal colostomy and abdominal-perennial resection.
- (3) Patients suffering from middle or low rectal cancer,
- (4) Patients admitted in emergency procedures
- (5) Patients who require a diverting stoma proximal to the anastomosis
- (6) Patients having abdominal abscess at surgical point.
- (7) Patients undergoing elective colon and rectal surgery

We used SPSS version 20 for statistical analysis and the quantitative and qualitative variables like mean age, standard deviations gender were also assessed.

RESULTS

After statically presenting the cases, we observe that out of the total population of 100, patients that had undergone elective laparoscopic colorectal surgeries were falling between 45 to 75 year of age where 59% were males and 41% were females. Amongst these 23% of females and 27% of males underwent surgeries with mechanical bowel preparation.

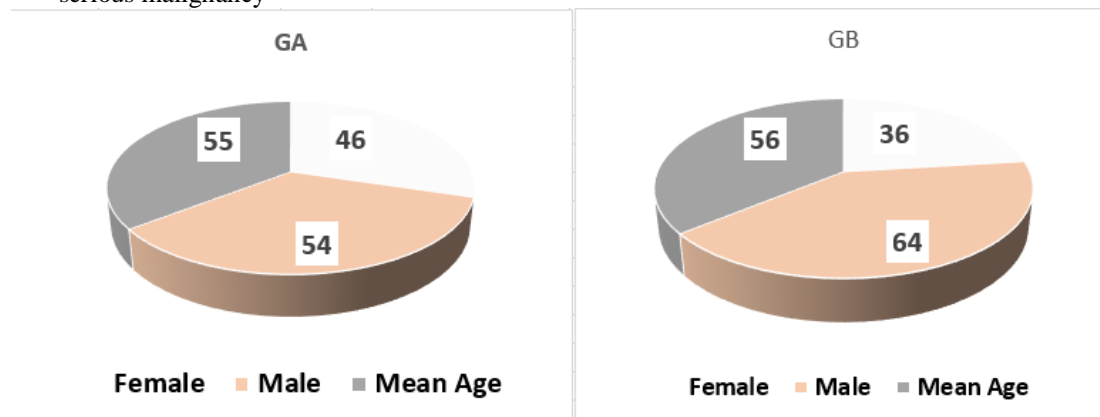


Figure No.1: Sex Distribution of Patients with or without interventions and their Mean

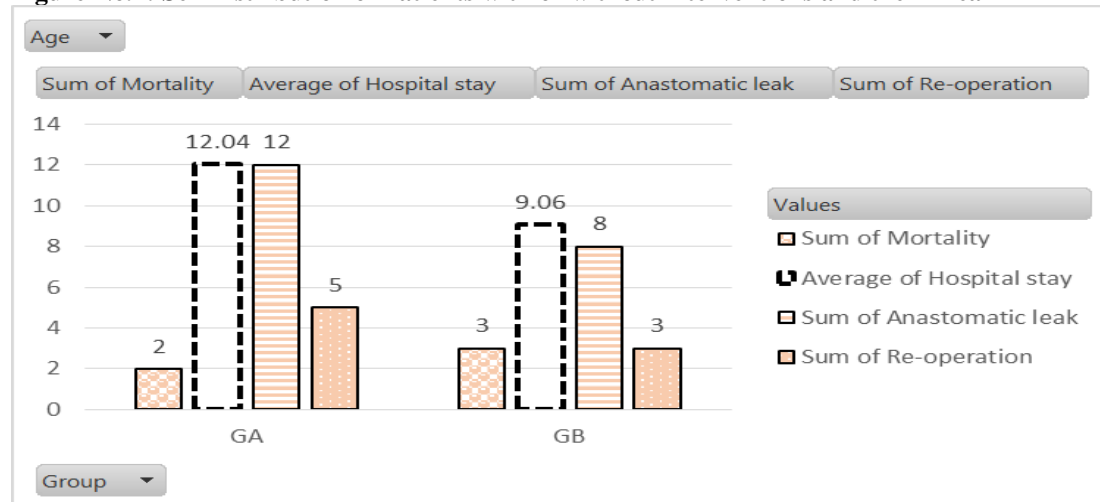


Figure No.2: Number of cases vs Mortality, Re-operation rate, Anastomotic leak and average Hospital stay

Table No.1: Summary of Groups Primary endpoints

Group	Anastomotic Leaks	Female	Male	Mean Age	Mortality	Hospital stay (Days)	Stay-SD	Re-operation Rate
GA	24%	23	27	55	4%	12	3.27593	10%
GB	16%	18	32	56	6%	9	1.69786	6%

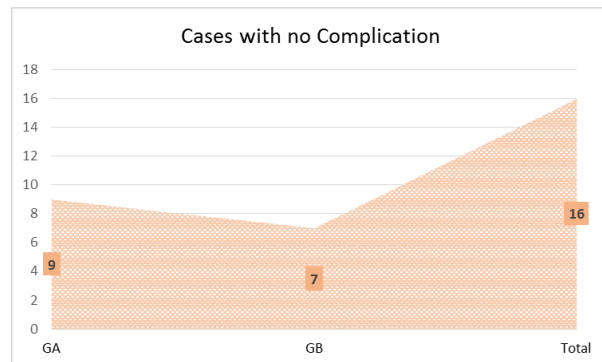


Figure No.3: Cases with no complications in GA vs GB

The mean age observed in both the groups wasn't significantly different where 55 being the mean age in Group-A and 56 in Group B. (Figure-1).

For the sake of understanding the outcomes of the study, we considered the primary endpoints to be the post-operative anastomotic leak, re-operation rate and mortality which were 24%, 10% and 4% in patients

who underwent bowel preparation group (GA) and the one who didn't prepare (GB) were observed to have anastomotic leak of 16%, mortality 6% and re-operation rate of 6% movement showing no significant difference between the both (Table-1). The mean duration of hospital stay in Group A was 12 (SD=3.27) and 9 (SD=1.69) days respectively in Group B (Table-1). Out of a population of 100, 2 people died in Group A and 3 in Group B (Figure-2). However the trend of no complications in Group A was almost similar to Group-B i.e. 9 cases vs 7 cases out of a total of 16 cases. (Figure-3).

Statically the secondary endpoints i.e. the cardiovascular complications, deep abscess, incisional hernia cases, peritonitis and wound infections were 48% ,45%,51%,44% and 54% in Group-A and 52%, 55%,49%,56% and 46% in Group-B respectively. (Figure-4) Overall similar level of complications faced by both group Patients.

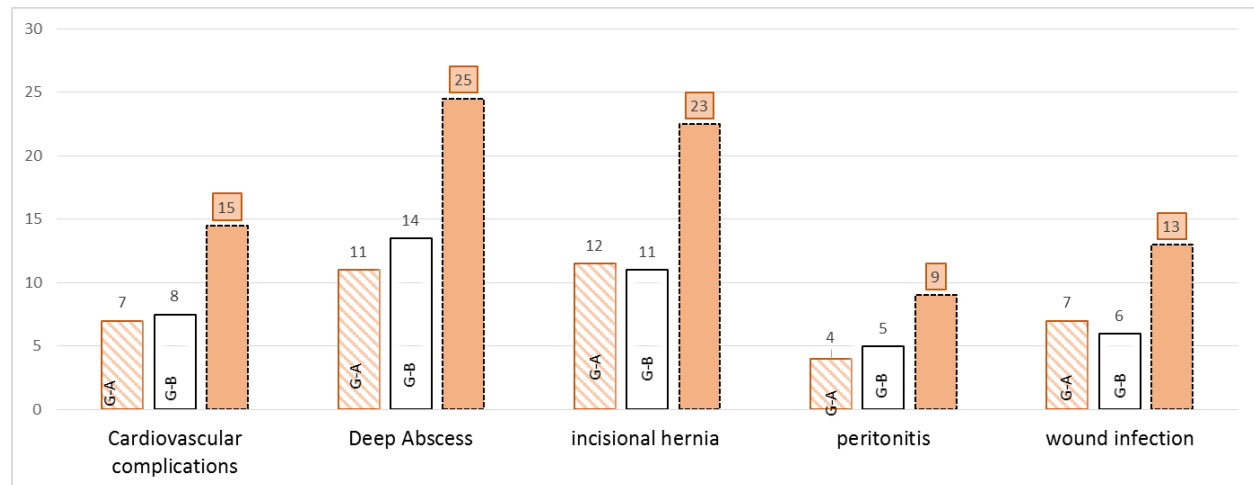


Figure No.4: Presenting Secondary endpoints i.e. complications occurring in Patients Group-wise

DISCUSSION

It has been found that preparation for colon rectal and elective surgery with mechanical cleaning of bowel and infusion of antibiotics has become quite commonly used by surgeons in order to mitigate the resulting complications after surgery.

We observe that the key elements are to get rid of causes that reduce the patient home returning (after surgery), particularly pain control, oral intake establishment and assuring sufficient mobility to allow daily life activities.

In our study, amongst the total responding population of 100 patients, rate of mortality was similar with supporting insignificant differences in re-operation rates although physiological effect on patients of GA i.e. the ones who underwent bowel preparation before elective colorectal surgery was better relatively. The hospital stay was significantly higher in Group A while no difference was observed overall in resulting complications in patients of Group A and Group B such that cardiovascular complications and wound infections were at 48%, 54% in Group-A and 52%, and 46% in Group-B respectively.(Figure-4)

We observed that Patients with elective colorectal surgery were mostly 50 years and above and mostly females. Although several published researches has been made on elective colorectal surgery and bowel preparations, some conclude it useless and propose to omit it and some find it otherwise and prefer it.^{1,2} Generally surgeons believe that bowel preparation reduces infections and it is observed that the use of antibiotics helps in lowering site infections in such patient.³ Although previous investigations shows that MBP doesn't improve postoperative outcomes in laparoscopic colorectal surgeries, yet there is a conflicting opinion and practices observed by different surgeons who often tend to use it in open and laparoscopic resections.⁴

In a cochrane assessment 2390 patients underwent bowel preparation vs 2387 who didn't and 13 RCT's derive that patients don't benefit from bowel preparation although we believe further research needs to be done as surgeries varies in mid and low rectal cancers after neoadjuvant therapy.⁵

In our sub grouping we observe of mortality in Group A and Group B was 2 and 3 showing clearly unrelated reasons of death as both the groups had similar set of incidence. A supporting study on multicenter randomized trial of 1354 patients found that colorectal surgery could be performed safely without MBP.⁶

The stated leakage rate differs slightly with 24% of GA patients busted into anastomotic leaks and 16% in Group B clearly no difference was observed in both. A local literature recorded anastomotic leak at 11.76% and 7.84 in Group 1 and Group 2 .In the total sample of 96 patients, the frequency of anastomotic leak in the individual groups A and B was 8 (16.7%) & 6 (12.5%) respectively⁸. There is an increased risk of anastomotic disruption in tough stools and mechanical bowel preparation diminishes bacterial clogging in bowel.

Scarborough et al in his study of colorectal surgeries found lesser occurrence of anastomotic leaks (MBP Prep: 2.8% vs No Preparation: 5.7%) in patients who had received MBP compared to those who did not underwent preparation⁷. However elsewhere in a recent investigation, anastomotic leakage was detected in 2 patients in each group (6.25% with MBP and 6.45% without MBP).⁸

Pena-Soria et al in 2007 studied the outcome of Group A (Prep) or Group B (no preparation) in 97 patients and found anastomotic failure in four patients in group A (8.3%) while two patients in group B (4.1%) developed anastomotic leakage.⁹

An organized study by Genera et al shows that effectiveness of bowel preparation is based on observational data and proficient opinions only. Two groups of 2390 and 2387 in prep and non-prep groups respectively showed higher rate of anastomotic dehiscence (4.2%) and infectious complications (9.6%) in the prep group.

Overall our study shows that the requirement for re-operation wasn't much affected by the group types as it was 10% and 6% in GA and GB supported by a local literature results with re-operation rate 9.8% and 5.88% in group-1 and group-2 (prep vs np prep group).¹⁰ While the incidence of incisional hernia in both group was similar 51% and 49%¹¹.

However complications occurring after colorectal surgery are unavoidable and can only be avoided by identifying high-risk patients and avoiding proximal diversions. Moreover our study is limited by the surveying study design and the relatively small size of the population.

CONCLUSION

Our investigation provides us enough evidence to assess that pre-operative bowel preparation in colorectal surgery does not cause any harm and as per the cumulative averages of mortality rates and anastomotic leaks and hospital stays, it can be concluded that performing colorectal surgery without mechanical bowel preparation is safe and doesn't cause any harm. However new protocols needs to be implemented for more accurate results. as our survey design is limited to certain conditions.

Author's Contribution:

Concept & Design of Study:	Munawar Mangi
Drafting:	Ameer Ali Kashkheli
Data Analysis:	Feroz Mahar
Revisiting Critically:	Munawar Mangi, Ameer Ali Kashkheli
Final Approval of version:	Munawar Mangi

Conflict of Interest: The study has no conflict of interest to declare by any author.

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