



THE FREQUENCY OF INFECTIOUS COMPLICATIONS BETWEEN MECHANICAL BOWEL PREPARATION AND NO PREPARATION IN ELECTIVE COLONIC SURGERY.

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ABSTRACT: Mechanical bowel preparation (MBP) is the cleansing technique used clean up the large gut using oral cathartic agents like polyethylene glycol, sodium phosphate, sodium Pico sulfate, and magnesium citrate. **Objectives:** To compare the frequency of infectious complications between mechanical bowel preparation and no preparation in elective colonic surgery. **Study Design:** Randomized control trial. **Setting:** OPD or Indoor Surgical unit 5, DHQ Hospital, Faisalabad. **Period:** 1st January 2017 to 31st Dec 2018. **Material & Methods:** Patients diagnosed of malignant tumors of colon, appendix or cecum were included in study. Group A: mechanical bowel preparation done according to standard protocols, group B no mechanical bowel preparation was done. All patients were followed regularly for 2 weeks for presence or absence of surgical site infections and anastomotic leakage. **Results:** In this study, surgical site infection in both groups was compared, it shows that 18.59% (n=37) in Experimental group and 9.55% (n=19) in Control group had SSI while 81.41% (n=162) in Experimental group and 90.45% (n=180) in Control group had no SSI, p - value was calculated as 0.009 showing a significant difference. Comparison of surgical anastomotic leakage in both groups was done, it shows that 2.51% (n=5) in Experimental group and 1.51% (n=3) in Control group had anastomotic leakage, p - value was calculated as 0.47 showing insignificant difference. **Conclusion:** We concluded that no mechanical bowel preparation is significantly better than mechanical bowel preparation in elective colonic surgery in terms of post-operative surgical site infection.

Key words: Elective Colonic Surgery, Mechanical Bowel Preparation, Post-operative Surgical Site Infection.

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INTRODUCTION

Surgical site infection (SSI) is a common presentation of patients undergone elective large gut surgery. It can be a mild lesion or it could be a deep abscess in the cavity or on the abdominal wall.¹ Patients sometime may even need a re-operation followed by prolonged hospitalization, with re-admission in the ICU with management. These infections further increases the treatment cost and morbidity due to operation.^{2,3}

Mechanical bowel preparation (MBP) is the cleansing technique used clean up the large gut using oral cathartic agents like polyethylene glycol, sodium phosphate, sodium Pico sulfate, and magnesium citrate.⁴ Although this practice before every large gut surgery has become a

major requirement and colorectal anastomosis is at risk of infection in gut with fecal matter.

Mechanical bowel preparation may decrease the intra luminal content of bacteria thus decreasing intra-operative leakage of gut contents with millions of bacteria to reach and cause peritonitis. Mechanical gut preparation have no risk of bacterial leakage out of the gut, but only if gut wall is disrupted.⁵ Although it is safe but it can lead to nausea, abdominal pain, and even diarrhea, thus leading to disturbance in electrolytes and dehydration further complicating the induction phase of anesthesia and preoperative care.⁸

A recent research done by Asis Kumar suggests that 'Not' preparing gut before surgery have no

disturbance in anastomosis strength with no increased chances of leakage. In this study wound infection was seen in 12% versus 11% cases with and without bowel preparation, respectively.⁶ Another study done by Stefano Scabini⁷, rate of infectious complications were found to be 20.0% after mechanical preparation of bowel versus 11.0% after no preparation in colonic surgery.

As there is controversy between results of recent research work regarding impact of omission of mechanical bowel preparation on frequency of complications like infections occurring after the operation, so the Rationale of my study is to conduct a randomized controlled trial to compare the frequency of infectious complications between mechanical bowel preparation and no preparation in elective colonic surgery. So that I can justify my results in a way that either omission of mechanical bowel preparation makes a difference in terms of reducing infectious complications or it will make no difference at all. If appropriate results are seen, it should be recommended as a regular common practice thus reducing hospital cost through reduction of post-operative infectious complications.

PATIENTS AND METHODOLOGY

Patients were included for our randomized control trial from the surgical floor of DHQ Hospital Faisalabad within 6 months once it was approved from hospital ethical review committee. Patients of both genders aging between 15 to 75 years presented in OPD having indications for elective colonic surgery for following colonic diseases: Malignant Tumors of right or left side of colon and Malignant Tumors of appendix or cecum.

Surgical Site Infections (SSIS) was defined according to center for disease control (CDC) classification. Superficial (SSIS) was defined as an infection involving only skin and subcutaneous tissues. Deep (SSIS) was defined as an infection that involves deep fascia or muscles and require debridement. Anastomotic leakage can be detected on clinical or radiological findings having clinical feature of fecal drainage through per anastomotic drain and radiological diagnosis was defined as leakage in cases of suspected

leak was made through contrast enhanced CT scan. On CT Anastomotic leakage was detected by air fluid collection at anastomotic site.

Patients with abdominal abscess seen at time of operation, on oral or inject able anti-coagulants or corticosteroid (assessed on history). Immuno compromised patients (assessed on medical record). Patients having any allergy or known contraindication to polyethylene glycol (assessed on history) and those who present with local skin site infections (assessed or clinical examination).

Sample size of 398 calculated using WHO sample size calculator with 5% margin of error, 80% power of study, taking percentage of surgical site infection after mechanical bowel preparation as 20.0% [8] and percentage of surgical site infection after no mechanical bowel preparation as 11.0%.⁸

All the patients were explained the details of the study and written informed consent was taken. Patients were admitted through OPD and diagnosed cases of malignant tumors of colon, appendix or cecum were included in study. All patients were randomized by using computer generated random number table. Group A included cases in which mechanical bowel preparation was done according to standard protocols. Clear liquid diet was started a day before surgery as a part of dietary modification and oral polyethylene glycol solution was given on evening (12-16) hours before surgery. In patient included in group B MBP was not done.

Demographic variables were obtained. Contact number of patients was taken for follow up. Patients were enquired about any drug allergy. General examination, systemic examination and assessment of airway were done. Baseline investigations including hemoglobin, serum blood sugar, and hepatitis B and C markers was done in pathological lab of DHQ Hospital Faisalabad and reported by the pathologist. 3ml blood for CBC and 3ml for the rest was taken. All samples were taken by staff nurse on duty. All patients were given premedication tablet Diazepam 10mg to alleviate anxiety and for sound sleep. All patients were given antibiotics

1 hour before surgery, ceftriaxone 2gm O.D and metronidazole 500mg TDS and was continued for 2 days postoperatively. Surgery was done by consultant surgeons of SU (IV).

All patients were followed regularly for 2 weeks for presence or absence of surgical site infections and anastomotic leakage (as per-operational definition). Findings or outcome were seen either clinically or through radiological means like contrast enhanced CT scan (as per operational definition). All variables were noted on pre-designed Proforma by principal investigator.

Data was analyzed using SPSS version 22.0. Mean and standard deviation for quantitative variables including age and BMI, while frequency and percentage was calculated for qualitative variable like gender, diabetes mellitus (present/no), type of operation (hemicolectomy, subtotal Colectomy/transverse Colectomy/sigmoidectomy / colostomy reversal) surgical site infections (present/no) and anastomotic leakage(present/no). Chi Square was applied to compare the frequency of surgical site infection and anastomotic leakage. P - value ≤ 0.05 was considered as significant.

Effect modifiers like age, gender, BMI (obese/non-obese), type of operation (hemicolectomy /subtotal Colectomy/transverse Colectomy/sigmoidectomy / colostomy reversal) and diabetes mellitus (present/no) were controlled through stratification and post-stratification chi square was applied to see their effect on outcome. P - value ≤ 0.05 was considered as significant.

RESULTS

Total 398 cases (199 in each group) fulfilling criteria were included in the study. Age distribution shows that 62.81%(n=125) in Experimental group and 59.80%(n=119) in Control group were between 15-50 years of age while 37.19%(n=74) in Experimental group and 40.20%(n=80) in Control group were between 51-75 years of age, mean \pm SD was calculated as 45.98 \pm 13.36 years in Experimental group and 47.52 \pm 13.21 years in Control group.

Gender distribution shows that 44.72%(n=89) in Experimental group and 48.24%(n=96) in Control group were male whereas 55.28%(n=110) in Experimental group and 51.76%(n=103) in Control group were females.

Mean BMI of the patients was calculated as 28.52 \pm 5.74 in Experimental group and 29.41 \pm 4.52 in Control group. Frequency of diabetes mellitus in both groups was recorded as 22.61%(n=45) in Experimental group and 39.20%(n=78) in Control group whereas 77.39%(n=154) in Experimental group and 60.80%(n=121) in Control group had no diabetes mellitus. (Table-I)

Diabetes Mellitus	Experimental Group (n=199)		Control Group (n=199)	
	No. of Patients	%	No. of Patients	%
Present	45	22.61	78	39.20
Not present	154	77.39	121	60.80
Total	199	100	199	100

Table-I. Frequency of diabetes mellitus in both groups (n=398)

Frequency of type of operations in both groups was recorded as 24.62%(n=49) in Experimental group and 20.60%(n=41) in Control group had hemicolectomy, 25.13%(n=50) in Experimental group and 23.62% (n=47) in Control group had subtotal colectomy, 18.09% (n=36) in Experimental group and 18.09% (n=36) in Control group had transverse colectomy, 13.06% (n=26) in Experimental group and 19.10% (n=38) in Control group had sigmoidectomy while 19.10% (n=38) in Experimental group and 18.59% (n=37) in Control group had colostomy reversal. (Table-II.)

Type of Operation	Experimental Group (n=199)		Control Group (n=199)	
	No. of Patients	%	No. of Patients	%
Hemicolectomy	49	24.62	41	20.60
Subtotal Colectomy	50	25.13	47	23.62
Transverse Colectomy	36	18.09	36	18.09
Sigmoidectomy	26	13.06	38	19.10
Colostomy reversal	38	19.10	37	18.59
Total	199	100	199	100

Table-II. Frequency of type of operations in both groups (n=398)

Comparison of surgical site infection in both groups was done, it shows that 18.59%(n=37) in Experimental group and 9.55%(n=19) in Control group had SSI while 81.41%(n=162) in Experimental group and 90.45%(n=180) in Control group had no SSI, p - value was calculated as 0.009 showing a significant difference. (Table-III).

SSI	Experimental Group (n=199)		Control Group (n=199)	
	No. of Patients	%	No. of Patients	%
Present	37	18.59	19	9.55
Not present	162	81.41	180	90.45
Total	199	100	199	100

Table-III. Comparison of surgical site infection in both groups (n=398) P - value =0.009

Comparison of surgical anastomotic leakage in both groups was done, it shows that 2.51%(n=5) in Experimental group and 1.51%(n=3) in Control group had anastomotic leakage while 97.49%(n=194) in Experimental group and 98.49%(n=196) in Control group had no anastomotic leakage, p - value was calculated as 0.47 showing insignificant difference. (Table-IV).

Anastomotic Leakage	Experimental Group (n=199)		Control Group (n=199)	
	No. of Patients	%	No. of Patients	%
Present	5	2.51	3	1.51
Not present	194	97.49	196	98.49
Total	199	100	199	100

Table-IV. Comparison of anastomotic leakage in both groups (n=398)

Effect modifiers like age, gender, BMI (obese/non-obese), type of operation (hemicolectomy/subtotal Colectomy/transverse Colectomy/sigmoidectomy / colostomy reversal) and diabetes (present/not present) were controlled through stratification and post-stratification chi square was applied. (Table-V to XIV)

Age: 15-50 years

Group	SSI		P-Value
	Present	Not Present	
A	27	98	0.002
B	9	110	

AGE: 51-75 years

Group	SSI		P-Value
	Present	Not Present	
A	10	64	0.85
B	10	70	

Table-V. Stratification for surgical site infection with regards to age (n=399)

Male

Group	SSI		P-Value
	Present	Not Present	
A	16	73	0.08
B	9	87	

Female

Group	SSI		P-Value
	Present	Not Present	
A	21	89	0.05
B	10	93	

Table-VI. Stratification for surgical site infection with regards to gender (n=399)

Present

Group	SSI		P-Value
	Present	Not Present	
A	9	36	0.04
B	6	72	

Not Present

Group	SSI		P-Value
	Present	Not Present	
A	28	126	0.08
B	13	108	

Table-VII. Stratification for surgical site infection with regards to diabetes mellitus (n=399)

Obesity

Group	SSI		P-Value
	Present	Not Present	
A	6	28	0.50
B	5	36	

Non-Obese

Group	SSI		P-Value
	Present	Not Present	
A	31	134	0.01
B	14	144	

Table-VIII. Stratification for surgical site infection with regards to BMI (n=399)

Type of Operation	Group	SSI		P - value
		Present	Not present	
Hemicolectomy	A	11	38	0.34
	B	6	35	
Subtotal Colectomy	A	9	41	0.88
	B	9	38	
Transverse Colectomy	A	5	31	0.72
	B	4	32	
Sigmoidectomy	A	4	22	0.01
	B	0	38	
Colostomy reversal	A	8	30	0.003
	B	0	37	

Table-IX. Stratification for surgical site infection with regards to type of operation (n=399)

Age: 15-50 years

Group	Anastomotic Leakage		P-Value
	Present	Not Present	
A	2	123	1.01
B	2	117	

Age: 51-75 years

Group	Anastomotic Leakage		P-Value
	Present	Not present	
A	3	71	0.27
B	1	79	

Table-X. Stratification for anastomotic leakage with regards to age (n=399)

Male

Group	Anastomotic Leakage		P-Value
	Present	Not Present	
A	2	87	0.71
B	3	93	

Female

Group	Anastomotic Leakage		P-Value
	Present	Not Present	
A	3	107	0.09
B	0	103	

Table-XI. Stratification for anastomotic leakage with regards to gender (n=399)

Present

Group	Anastomotic Leakage		P-Value
	Present	Not Present	
A	3	42	0.02
B	0	78	

Not Present

Group	Anastomotic Leakage		P-Value
	Present	Not present	
A	2	152	0.46
B	3	118	

Table-XII. Stratification for anastomotic leakage with regards to diabetes mellitus (n=399)

Obese

Group	Anastomotic Leakage		P-Value
	Present	Not present	
A	1	33	0.26
B	0	41	

Non-Obese

Group	Anastomotic Leakage		P-Value
	Present	Not present	
A	4	161	0.74
B	3	155	

Table-XIII. Stratification for anastomotic leakage with regards to BMI (n=399)

Type of Operation	Group	Anastomotic Leakage		P-Value
		Present	Not Present	
Hemicolectomy	A	0	49	--
	B	0	41	
Subtotal Colectomy	A	1	49	0.32
	B	0	47	
Transverse Colectomy	A	1	35	1.00
	B	1	35	
Sigmoidectomy	A	1	25	0.78
	B	1	37	
Colostomy reversal	A	2	36	0.57
	B	1	36	

Table-XIV. Stratification for anastomotic leakage with regards to type of operation (n=399)

DISCUSSION

Mechanical bowel preparation (MBP) before any elective large gut surgery is in common practice from decades. It is done in order to prevent post-op complications like infections; but there is nothing in support of this practice in the literature, still it is a common practice and done frequently in almost all the surgical facilities.

We planned this randomized controlled trial to compare the frequency of infectious complications between mechanical bowel preparation and no preparation in elective colonic surgery. So that we may justify the results in a way that either omission of mechanical bowel preparation makes a difference in terms of reducing infectious complications or it will make no difference at all.

In this study, mean age in Experimental group was 45.98 ± 13.36 years in Experimental group and 47.52 ± 13.21 years in Control group, 44.72%(n=89) in Experimental group and 48.24%(n=96) in Control group were male whereas 55.28%(n=110) in Experimental group and 51.76%(n=103) in Control group were females. Comparison of surgical site infection in both groups was done, it shows that 18.59%(n=37) in Experimental group and 9.55%(n=19) in Control group had SSI while 81.41%(n=162) in Experimental group and 90.45%(n=180) in Control group had no SSI, p - value was calculated as 0.009 showing a significant difference. Comparison of surgical anastomotic leakage in both groups was done, it shows that 2.51%(n=5) in Experimental group and 1.51%(n=3) in Control group had anastomotic leakage, p - value was calculated as 0.47 showing insignificant difference.

A recent research done by Kumar A, et al suggest that if MBP is not done, healing of anastomosis is not disturbed and there is no change in the risk of leakage.[6] This signifies that there is no statistically significant difference in the outcome of use of MBP compared to the outcome of cases done without preparation. In this study, wound infection was seen in 12% cases in experimental group and in 11% of controls without bowel preparation.⁶ The findings of our study are contrary

to this study. Another study done by Stefano Scabini⁷, rate of infectious complications were found to be 20.0% after mechanical preparation of bowel versus 11.0% after no preparation in colonic surgery. This study reported that MBP in elective colonic surgery may not be required. These findings are in agreement with our study.

Alison S McCoubrey⁹ searched the literature and in his review article reached a conclusion that many researchers have reported and recommended large gut surgeries without any pre-op bowel preparation to be safe and may not be required; although in some circumstances it can be valuable like in the presence of any tumor or in surgeries requiring colonoscopy during the gut surgery. Still to change a clinical practice evidences are not sufficient; a lot of research still need to be done.

Slim et al¹⁰ reported similar results but he studied in reverse order; he reported that cases with pre-op bowel preparation showed more leaks from the anastomotic site compared to the ones not receiving the preparation; along with more risk of infection and failure of surgery, thus increasing the hospital stay (all these results were not significant). The conclusion of his study was in favor of not preparing gut before surgery but this was not statistically significant.

Very few trials are done in this regard comparing the efficacy of not preparing gut before surgery with gut preparation before surgery; two studies have shown¹¹ Willie-Jorgensen et al¹¹ found no trend in either direction. But Guenaga et al¹² reported that 'no MBP' had a better outcome and this was not statistically significant. It is logically better as it is difficult to perform anastomosis with rectum full of stools. Guenaga et al¹² reported that many patients with small tumor also undergo radiotherapy for bowel preparation before gut surgery.

However, in our setup, we found outcome of no MBP was better compared to mechanical bowel preparation in elective colonic surgery in terms of post-operative infectious complications.

CONCLUSION



We concluded from all our data that after elective colonic surgery outcome without any complication or with minimal complication was seen with 'no' MBP before surgery and was significantly better as well compared to those in whom mechanical bowel preparation (MBP) was used. Further clinical trials should be done on larger scale to change this practice.

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