

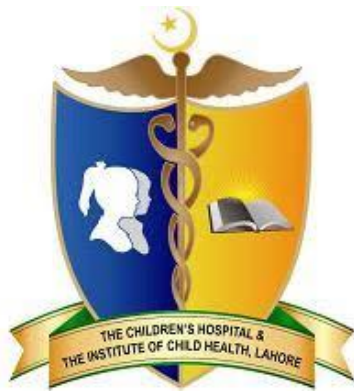
**Comparison Of Outcomes Of Three Days Vs No Mechanical
Bowel Preparation In Patients Undergoing Colostomy
Reversal**

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SYNOPSIS

“ COMPARISON OF OUTCOMES OF THREE DAYS VS NO MECHANICAL BOWEL PREPARATION IN PATIENTS UNDERGOING COLOSTOMY REVERSAL”



SUBMITTED BY:

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INTRODUCTION:

The term “stoma”/ostomy is derived from the Greek word meaning “mouth” or “opening” and characterized by the creation of an artificial opening of intestine on the surface of body. The first recorded surgical creation of a stoma was by a French surgeon Pillore in 1776. (. Stoma formation can be temporary or permanent in form of ileostomy or Colostomy (Harries and Torkington et al, 2018).

There are lot of indications of stoma formation in children such as anorectal malformation, Hirschsprungs Disease, enteric perforation, abdominal tuberculosis, abdominal trauma, bowel gangrene, intussusception, intestinal obstruction, large perineal wounds, etc.; all these need stoma reversal.(Jan et al, 2007)

Stoma reversal is the one of the most frequently performed surgeries. Stoma reversal has lots of complications such as surgical site infection, poor scar cosmesis, anastomotic leak, paralytic ileus, small bowel adhesive obstruction, bleeding, incisional hernia (Jan et al, 2017) , (Harries and Torkington et al, 2018) and hypertrophied scar/keloid, which leads to less patient satisfaction.(Sureshkumar et al, 2018).

Once the requirement of colostomy is over , reversal of colostomy should be done in which two ends of the colon or colon and rectum are reconnected. Purpose of mechanical bowel preparation is to clean the fecal matter from the large bowel. Cleaning prior to colorectal surgery is recommended in many studies. Mechanical bowel preparation before surgery have more benefits due to decrease fecal matter as well as count of bacteria, which one is the cause of anastomotic dehiscence in unprepared patients Mechanical bowel preparation can remove hard, impacted fecal matter which decreases the pressure in the lumen of colon (Khan et al.,2019).

Conventionally,Colostomy is closed after three days preparation of gut. Patient is shifted to non-stool forming diet three days prior to surgery. Broad

spectrum antibiotics are started two days prior the surgery. Mechanical gut wash is performed prior the surgery. The conventional preparation is difficult to perform in children as it requires prolonged preoperative NPO. It also prolongs the hospital stay of the patient and overburdens the parents socioeconomically (Zahra et al., 2018). Research on the adult population has failed to provide statistically significant evidence supporting its effectiveness in reducing perioperative complications . Moreover, recent evidence has linked MBP prior to colorectal surgery with a higher rate of wound infection . pain, distension, and fatigue, water and electrolyte imbalance. Now a days,by studying and reviewing local and international data,it is noticed that no bowel preparation is equally effective&safe technique for patients undergoing colostomy reversal.

Studies indicate that the quality of evidence for the use of MBP before pediatric colorectal surgery is low. On the basis of the existing evidence, MBP seems not to decrease the incidence of anastomotic leakage, intra-abdominal infection, or wound infection compared to no MBP and may therefore be safely omitted prior to colorectal surgery in children.

Hypothesis:

There is no difference in the outcomes after colostomy reversal done with three days bowel preparation versus no bowel preparation in terms of hospital stay, anastomotic leak and surgical site infection.

Objective:

To compare outcomes of colostomy reversal with three days bowel preparation vs no bowel preparation in terms of anastomotic leakage, surgical site infection and hospital stay.

Primary Outcomes:

- Surgical site infection
- Anastomotic leak

Secondary outcome:

- Hospital stay

OPERATIONAL DEFINITIONS:

Colostomy Reversal: It is the process of re-approximation of the exteriorized ends of colon for the re-establishment of flow of fecal matter through the gastrointestinal tract.

Surgical site infection: It is defined as infection of colostomy reversal wound site. Surgical Site Infection (SSI) is classified as a superficial, deep, and organ/space infection occurring in the surgical wound within 30 days after the operation. It will be calculated using Southampton scoring system (ANEXURE-I).

Anastomotic Leak: It is defined as disruption of the re-approximated ends of the colon. Anastomotic leak will be judged by checking patients clinically as well as other haematological and radiological factors (Rahbari et al., 2010).

Hospital Stay: Hospital stay will be defined as the number of days starting from the day of admission to the day patient is discharged.

MATERIAL & METHODS:

Study design: Prospective Randomized Controlled Trial

Setting: Department of pediatric surgery The Children's Hospital & University of Child Health Sciences, Lahore

Sampling Technique: purposive non-probability sampling

Sample Size: Calculated by WHO calculator version 12.2.6.

Group A: No Mechanical Bowel Preparation will be done according to standard protocols (Case Group), n= 30

Group B: Three days Mechanical Bowel Preparation will be done according to standard protocols (Control Group), n= 30

SAMPLE SELECTION:

Inclusion criteria:

- Children with colostomy including both gender between the age of 1 to 15 years.
- Children of whom parents/guardians will give informed consent.

Exclusion criteria:

- Consent withdrawn.
- Poor general condition.
- A previous history of anastomotic leakage.

- Lost to follow up
- Children with colostomy requiring pull through procedure.

Data collection procedure

Patients fulfilling selection criteria will be enrolled in the study. The study will be conducted at the pediatric surgery department, The Children's Hospital & University of Child Health Sciences, Lahore. All patients will be subjected to detailed perinatal history evaluation, general physical examination, necessary laboratory investigations, and imaging study (plain radiography, abdominal ultrasonography, and echocardiography where required). Informed consent will be obtained from the patient's attendant before surgical intervention. Demographic information like name, age, weight, and a contact number will be recorded. Patients will be randomly divided into two groups by the lottery method. Group A will include cases in which no mechanical bowel preparation will be done, while in group B, three days bowel preparation will be done. Equal pre and post-operative care will be given to all the patients. All patients will be operated on by qualified postgraduate surgeons with minimal 3 years of experience.

Methods:

The patients will be admitted into the hospital one day or three days before surgery depending upon the study group. All patients will have all important preoperative investigations and anaesthesia fitness before the surgery. Each patient will receive intravenous perioperative antibiotics of cephalosporin 50mg/kg and metronidazole 7.5mg/kg/8hourly. The antibiotics will be given after induction of anaesthesia. After surgery, IV antibiotics will be continued, and then on discharge oral antibiotics will be given for another 3 days.

Procedure for three days bowel preparation:

Mechanical cleansing of the bowel with three days of bowel preparation will be done by admitting the child 3 days before surgery and shifting the patient to a non-stool forming diet. The parent or caregiver will be counselled on the procedure. Digital rectal examination & stoma examination of every patient will be done. The patients will be restricted to a fibre-rich diet and milk from 72 hours before surgery. Then the patient will be shifted on clear liquid from 24 hours before surgery. And normal saline enema per stoma and through the rectum with Nelton tube will be given by the trained person. This will be done the day before

surgery in the afternoon(2PM),in the nigh(10PM) and in the morning (6AM) with the goal of clear discharge through rectum or stoma. The patient will be nil per oral, 6 hours before surgery (Serrurier et al., 2012).

STATISTICAL ANALYSIS:

All data will be entered, processed, and analyzed using SPSS version 24. Quantitative variables like age, gender, and hospital stay will be presented as frequency and percentage. Mean and S.D will be calculated for quantitative variables like age (months), and hospital stay. A Chi-square test will be used to compare, qualitative variables like SSI and anastomotic leak in both groups. A P-value of ≤ 0.05 will be considered significant.

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