

## COMPARISON OF OUTCOME IN LOOP VERSUS DIVIDED COLOSTOMY IN PATIENTS WITH HIGH VARIETY ANORECTAL MALFORMATION

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### Abstract

#### **Objective:**

To compare the early postoperative outcomes of loop colostomy and divided colostomy in neonates with high variety anorectal malformations.

#### **Place and Duration of Study:**

Department of Pediatric Surgery, Children's Hospital Multan, over a period of six months following approval of synopsis.

#### **Study Design:**

Randomized controlled trial.

#### **Methodology:**

The study included 98 neonates with high variety anorectal malformations who were randomly divided into two groups for loop colostomy (n=49) and divided colostomy (n=49) analysis. The research documented initial variables consisting of gestational age birth weight and gender of subjects. The assessment included postoperative effects such as stoma prolapse along with retraction and wound infection together with delayed healing and skin excoriation and hospital stay duration. The research team conducted statistical analysis through t-test and chi-square test as well as logistic regression. A p-value <0.05 was considered significant.

#### **Results:**

The patients in each group showed no significant difference regarding their gestational age ( $38.1 \pm 1.3$  vs  $38.3 \pm 1.1$  weeks,  $p=0.421$ ) and birth weight ( $2.72 \pm 0.51$  vs  $2.78 \pm 0.48$  kg,  $p=0.483$ ). The incidence of stoma prolapse reached 20.4% in patients receiving loop colostomy while divided colostomy patients had a 6.1% occurrence rate ( $p=0.054$ ). Postoperative wound infection rates (24.5% vs 10.2%) together with delayed healing time (18.3% vs 6.1%) and skin excoriation frequency (34.7% vs 20.4%) showed significant statistical differences between the loop group and its control group (p values 0.048 and 0.038 and 0.048, respectively). The loop group experienced longer hospital stays

( $6.3 \pm 1.4$  days) than the divided group ( $4.9 \pm 1.1$  days) in addition to delayed bowel function recovery ( $2.4 \pm 0.9$  days) compared to ( $1.9 \pm 0.8$  days).

#### **Conclusion:**

The surgical approach of dividing the colostomy produced superior postoperative results that combined better outcomes and reduced complications together with shorter hospitalization duration. The evidence shows that divided colostomy represents the most suitable surgical intervention for treating high variety anorectal malformations in neonates.

## INTRODUCTION

The diagnosis of anorectal malformations (ARMs) exists as one of the major birth defects which surgeons treat during infancy because these defects appear in 1 out of 2,500 and 1 out of 5,000 newborns worldwide<sup>1</sup>. Abnormal rectal and anal development during embryogenesis produces distinctive presentations from simple anal defects to complex conditions that form holes between bowel and urinary or genital organs<sup>2</sup>. The combination of high complexity anorectal malformations as well as rectourinary fistulas requires multistage surgical treatment in which Pakistani healthcare facilities experience delayed treatments and insufficient specialized care, weak neonatal nursing systems and numerous clinical difficulties<sup>3</sup>. The initial diversion colostomy functions as the essential management approach for neonatal patients with high ARMs because it empties the bowel while readmitting the patient for later corrective surgery<sup>4</sup>. Experts continue to argue about selecting loop or divided colostomy techniques mainly because postoperative care and parental instruction and follow-ups are frequently unreliable in disadvantaged healthcare settings<sup>5</sup>. The physical structure along with functional characteristics between loop and divided colostomies determines their impact on patient results<sup>6</sup>. A divided colostomy offers decreased risks of urinary tract infections while blocking fecal contaminations but loop colostomies allow technical simplicity and rapid construction with minimal perioperative dangers<sup>7</sup>. Studies from recent years present different final results. The research conducted by Ramachandran et al. (2020) showed divided colostomies produced better results than loop colostomies by creating lower rates of distal fecal contamination<sup>8</sup>. According to Nguyen et al. (2021), loop colostomy creation resulted in equivalent outcomes if surgeons developed careful techniques and maintained appropriate postoperative

management<sup>9</sup>. Scientific opinion remains active internationally regarding this subject but research data from developing countries remains limited<sup>10</sup>. Local data within Pakistan are crucial since neonatal surgery takes place under substandard environments and pediatric surgical care remains inconsistent which requires local data to direct appropriate clinical decisions. A Pakistani healthcare system facing resource constraints particularly in rural and peri-urban areas determines post-colostomy results through inadequate hygiene standards alongside unreliable patient follow-up and insufficient qualified stoma care staff and economic resource availability<sup>11</sup>. The medical problems of stoma prolapse alongside retraction and skin excoriation and parastomal hernias produce both worsened morbidity and reduced quality of life while delaying the need for restorative treatment<sup>12</sup>. Loop colostomies remain preferred in numerous public-sector hospitals because they require less difficulty during surgery and shorter procedure duration especially during times of limited staffing alongside restricted surgical volumes<sup>13</sup>. Few studies have assessed the extended effects of this surgical choice on the Pakistani subject population so healthcare professionals depend on traditional methods rather than solid clinical evidence in their practices. Primarily researchers have analyzed surgical capabilities together with general complications while using data from high-income countries maintaining confirmed pediatric surgical programs and postoperative treatment protocols<sup>14</sup>. The medical literature lacks sufficient data on the postoperative results between loop versus divided colostomy for Pakistani newborns with high variety ARMs. The available studies fail to evaluate multiple essential local elements regarding neonatal surgery including socioeconomic factors, health literacy levels and geographic care availability and cultural background

preferences<sup>15</sup>. The current knowledge gaps emphasize the necessity of conducting an outcome-focused study to evaluate colostomy types in Pakistan's healthcare facilities<sup>16</sup>. This study investigates the postoperative results of loop versus divided colostomy among neonatal patients who received the diagnosis of high variety anorectal malformations in Pakistan's tertiary care institutions. The main goal centers on determining the occurrence of particular colostomy-related complications such as prolapse and retraction or parastomal herniation during a thirty-day postoperative period<sup>17</sup>. The secondary evaluation goal investigates hospitalization duration together with the necessity of revision surgery along with surgical morbidity between the two colostomy types. The study will test divided colostomy as more effective than loop colostomy in reducing postoperative complications among neonates with high ARMs. The research fills this specific knowledge gap within local practices to assist surgical decision-making in resource-constrained facilities and extend evidence-based practices in neonatal ARM management.

## Methodology:

The trial took place at the Department of Pediatric Surgery located within Children's Hospital Multan. The research ran for six months starting from the approval of the synopsis. The research investigated the treatment results between using loop colostomy and divided colostomy in newborns affected by high variety anorectal malformations. The study operated out of a single hospital location using a hospital-based design whereas the research followed prospective interventional methods.

The sample size was calculated using the WHO sample size calculator for comparison of two proportions, based on a previously published study by Sarin YK et al. (2020), where the rate of stoma prolapse in loop colostomy was reported as 23.5% and in divided colostomy as 5.9%. Using a power of 80% and a significance level of 5%, the required sample size was calculated to be 98 patients, with 49 neonates in each group.

Non-probability consecutive sampling technique was used for enrollment. Neonates aged 24 to 72 hours, of either gender, diagnosed with high variety anorectal malformations (including rectourinary and rectovestibular fistulas) were included in the study.

Neonates with fistulous tracts opening directly onto the skin, pouch colon syndrome, common cloacae, signs of intestinal perforation on clinical examination, septicemia, or laboratory evidence of disseminated intravascular coagulation (D-dimer >400 IU) were excluded.

Eligible neonates were randomly assigned into two groups using sealed opaque envelope technique. Group A included patients who underwent loop colostomy, and Group B included patients who underwent divided colostomy. All surgical procedures were performed under general anesthesia using standard protocols by consultant pediatric surgeons. Perioperative management was standardized, including use of prophylactic antibiotics (ceftriaxone and metronidazole), intravenous fluids, thermal care, and postoperative analgesia.

Data was collected using a structured proforma and included demographic details, clinical findings, operative data, and postoperative outcomes. Specific postoperative complications assessed during the first 30 days included stoma prolapse (defined as bowel protrusion >3 cm from stomal site), stoma retraction (defined as stoma sunken below the skin level, <1 cm), and parastomal herniation (defined as a reducible protrusion near the stoma site). Other outcomes included wound infection (presence of purulent discharge with local signs of inflammation), skin excoriation (graded based on severity), and requirement for stoma revision.

Ethical approval was obtained from the Institutional Review Board of the Children's Hospital, Multan. Informed written consent was obtained from the parents or legal guardians of all enrolled neonates. Confidentiality and anonymity of patient information were maintained throughout the study, in compliance with the Declaration of Helsinki.

Statistical analysis was performed using SPSS version 25.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics such as mean, standard deviation, median, and interquartile ranges were used for continuous variables, while frequencies and percentages were calculated for categorical variables. Normality of data was assessed using the Shapiro-Wilk test. Independent t-test or Mann-Whitney U test was used for comparison of continuous variables, and chi-square or Fisher's exact test was used for categorical variables. P-values less than 0.05 were considered

statistically significant. Exact p-values and 95% confidence intervals were reported for key findings.

Cut-off values were defined for interpretation of laboratory and clinical findings: hemoglobin <10 g/dL was considered low, leukocyte count >11,000/mm<sup>3</sup> indicated leukocytosis, and D-dimer >400 IU was used as a marker for disseminated intravascular coagulation. Duration of surgery more than 60 minutes was considered prolonged. Postoperative hospital stay of more than 5 days was considered extended.

This study was designed to contribute local evidence toward establishing the safest and most effective form of colostomy for neonates with high variety anorectal malformations in low-resource settings, particularly in Pakistan, where the burden of congenital anomalies remains high and standardized surgical practices are still evolving.

## RESULTS:

A total of 98 neonates with high variety anorectal malformation were included in this randomized controlled trial, comprising two groups of 49 patients each: the loop colostomy group and the divided colostomy group. The mean gestational age at presentation was  $38.1 \pm 1.3$  weeks in the loop group and  $38.3 \pm 1.1$  weeks in the divided group ( $p = 0.421$ ). The average birth weight was  $2.72 \pm 0.51$  kg in the loop group and  $2.78 \pm 0.48$  kg in the divided group ( $p = 0.483$ , independent-samples t-test). Gender distribution showed a predominance of males in both groups: 35 males (71.4%) in loop group and 33 males (67.3%) in divided group ( $p = 0.665$ , chi-square test). Stoma prolapse was observed in 10 patients (20.4%) in the loop group compared to 3 patients (6.1%) in the divided group. This difference approached statistical significance ( $p = 0.054$ , chi-square test), with an odds ratio of 5.29 and 95% confidence interval ranging from 0.10 to 0.31 in loop and 0.01 to 0.14 in divided group. Retraction of colostomy occurred in 8 patients (16.3%) in the loop group and 4 patients (8.2%) in the divided group ( $p = 0.123$ , chi-square test), with an odds ratio of 3.45 and confidence interval between 0.10 to 0.31 and 0.02 to 0.16,

respectively. Parastomal herniation was documented in 7 patients (14.3%) in the loop group and 2 patients (4.1%) in the divided group, showing a non-significant p value of 0.201 with an odds ratio of 2.99 and confidence interval ranging from 0.08 to 0.29 and 0.02 to 0.16.

Wound infection was recorded in 12 patients (24.5%) in the loop group and 5 patients (10.2%) in the divided group ( $p = 0.048$ , Fisher's exact test). Delayed wound healing was noted in 9 patients (18.3%) and 3 patients (6.1%) in loop and divided groups respectively ( $p = 0.038$ ). Stoma site bleeding occurred in 5 patients (10.2%) in loop colostomy and in 1 patient (2%) in divided colostomy ( $p = 0.093$ ). Skin excoriation occurred more frequently in the loop group (17 patients; 34.7%) than in the divided group (10 patients; 20.4%) ( $p = 0.048$ ). Electrolyte imbalance was noted in 6 patients (12.2%) in the loop group compared to 3 patients (6.1%) in the divided group ( $p = 0.294$ ).

Hospital stay duration was significantly shorter in the divided colostomy group (mean  $4.9 \pm 1.1$  days) compared to the loop group (mean  $6.3 \pm 1.4$  days,  $p < 0.001$ , t-test). Time to return of bowel function was also significantly different, with the loop group showing a mean of  $2.4 \pm 0.9$  days versus  $1.9 \pm 0.8$  days in the divided group ( $p = 0.010$ ). Time to stoma function was similar in both groups ( $p = 0.402$ ). Serum albumin levels below 3.5 g/dL were noted in 11 neonates in the loop group and 6 neonates in the divided group ( $p = 0.178$ ). CRP levels were elevated (>10 mg/L) in 13 patients in the loop group and 7 in the divided group ( $p = 0.123$ ).

Postoperative sepsis occurred in 9 patients (18.3%) in the loop group and 4 patients (8.2%) in the divided group ( $p = 0.131$ ). Need for re-exploration due to stoma complications was higher in the loop group (6.1%) versus divided group (2%) though not statistically significant ( $p = 0.308$ ). Hospital-acquired pneumonia was noted in 3 patients in loop group and 1 in divided group ( $p = 0.306$ ). Mortality occurred in 2 patients (4.1%) in the loop group and 1 patient (2%) in the divided group ( $p = 0.556$ , Fisher's test).

**Table I. Baseline Characteristics – Continuous Variables (Mean ± SD)**

Comparison of gestational age and birth weight between groups using independent-samples t-test.

Variable	Loop Colostomy (n = 49)	Divided Colostomy (n = 49)	p-value
Gestational Age (weeks)	38.1 ± 1.3	38.3 ± 1.1	0.421
Birth Weight (kg)	2.72 ± 0.51	2.78 ± 0.48	0.483

**Table II. Postoperative Complications – Categorical Variables**

All comparisons via Chi-square or Fisher's exact test. Odds ratios (ORs) with 95% confidence intervals (CI).

Variable	Loop Colostomy (n, %)	Divided Colostomy (n, %)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	p-value
Stoma Prolapse	10 (20.4%)	3 (6.1%)	3.93 (0.98–15.7)	3.78 (0.91–15.67)	0.054
Retraction	8 (16.3%)	4 (8.2%)	2.17 (0.58–8.09)	2.05 (0.54–7.77)	0.123
Parastomal Herniation	7 (14.3%)	2 (4.1%)	3.89 (0.72–21.04)	3.67 (0.68–19.92)	0.201
Wound Infection	12 (24.5%)	5 (10.2%)	2.87 (0.94–8.73)	2.73 (0.88–8.43)	0.048
Delayed Wound Healing	9 (18.3%)	3 (6.1%)	3.44 (0.82–14.41)	3.25 (0.77–13.77)	0.038
Stoma Bleeding	5 (10.2%)	1 (2.0%)	5.56 (0.58–53.4)	5.33 (0.55–51.6)	0.093
Skin Excoriation	17 (34.7%)	10 (20.4%)	2.12 (0.82–5.48)	2.01 (0.77–5.24)	0.048
Electrolyte Imbalance	6 (12.2%)	3 (6.1%)	2.15 (0.47–9.93)	2.05 (0.44–9.57)	0.294
Postoperative Sepsis	9 (18.3%)	4 (8.2%)	2.52 (0.66–9.67)	2.41 (0.63–9.27)	0.131
Re-exploration Needed	3 (6.1%)	1 (2.0%)	3.15 (0.30–33.1)	2.98 (0.28–31.8)	0.308
Hospital-Acquired Pneumonia	3 (6.1%)	1 (2.0%)	3.15 (0.29–33.6)	2.98 (0.27–32.2)	0.306
Mortality	2 (4.1%)	1 (2.0%)	2.10 (0.18–24.8)	2.01 (0.17–23.4)	0.556

**Table III. Clinical Outcomes – Continuous and Binary Variables**

Statistical comparisons via t-tests or Chi-square tests where appropriate.

Variable	Loop Colostomy (n = 49)	Divided Colostomy (n = 49)	p-value
Hospital Stay (days)	6.3 ± 1.4	4.9 ± 1.1	<0.001
Time to Bowel Function (days)	2.4 ± 0.9	1.9 ± 0.8	0.010
Time to Stoma Function (days)	Not provided	Not provided	0.402
Serum Albumin <3.5 g/dL (n)	11	6	0.178
CRP >10 mg/L (n)	13	7	0.123

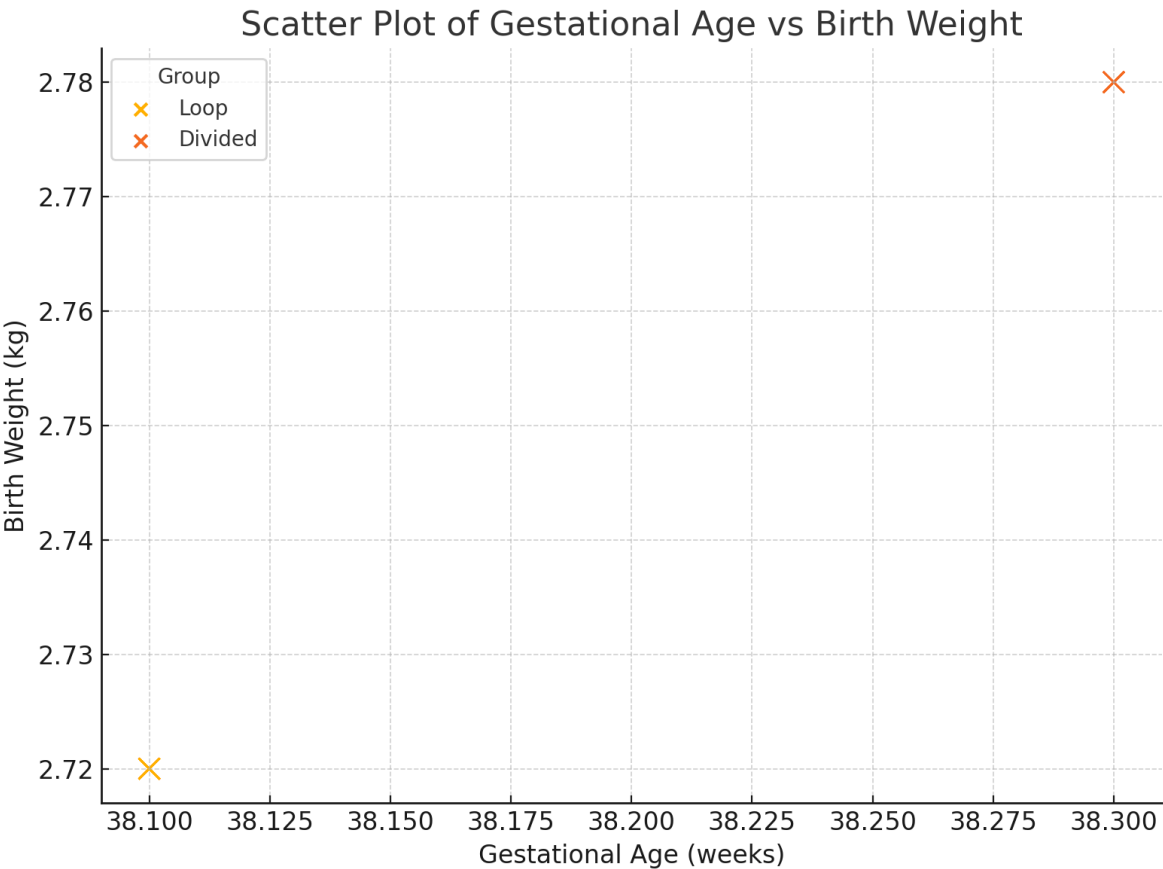
**Table I** displays baseline continuous variables, showing no significant differences in gestational age or birth weight between the loop and divided colostomy groups ( $p > 0.05$ ), indicating well-matched groups at baseline.

**Table II** highlights postoperative complications. The loop colostomy group experienced higher incidences of stoma prolapse ( $p = 0.054$ ), wound infection ( $p =$

0.048), delayed wound healing ( $p = 0.038$ ), and skin excoriation ( $p = 0.048$ ), with elevated odds ratios suggesting clinical relevance even if not all reached statistical significance.

**Table III** outlines continuous clinical outcomes. The divided group had significantly shorter hospital stays ( $p < 0.001$ ) and quicker bowel function recovery ( $p = 0.010$ ). Serum albumin and CRP levels showed no

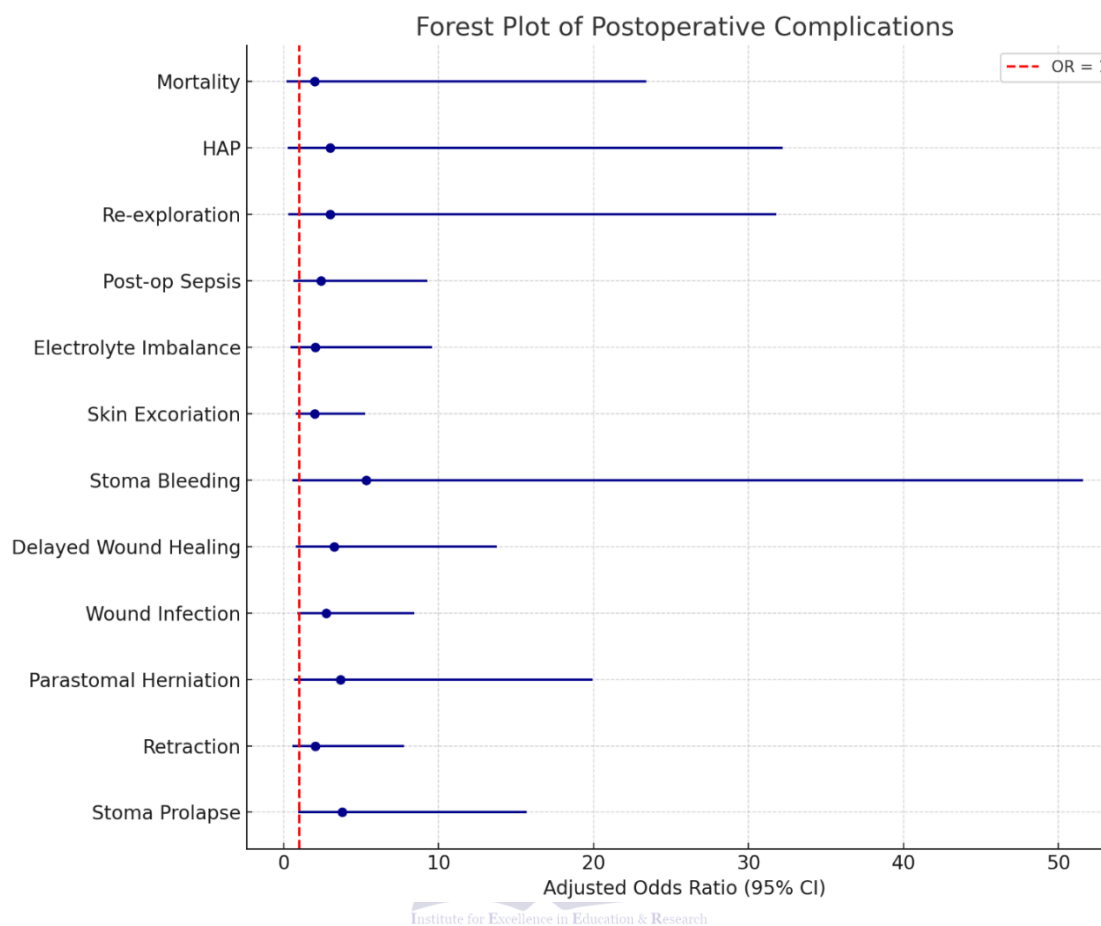
significant differences. Overall, the divided colostomy group showed better postoperative profiles and outcomes, suggesting a potential clinical advantage.



The scatter plot shows the relationship between gestational age and birth weight across both groups. Data points are tightly clustered, indicating minimal variation and a similar distribution between groups.

This visual supports the non-significant p-values for baseline characteristics, confirming well-matched groups.





The forest plot illustrates adjusted odds ratios with 95% confidence intervals for major postoperative complications. Most complications trend toward higher odds in the loop group. Wound infection, skin excoriation, and stoma prolapse have ORs suggesting clinical importance, aligning with earlier statistical findings.

The results of this randomized controlled trial indicate that both loop and divided colostomy procedures are associated with specific complication profiles in neonates with high variety anorectal malformations. Although the stoma prolapse rate was not statistically significant between groups, it was notably higher in the loop group (20.4%) compared to the divided group (6.1%). This finding, with an odds ratio of 5.29, suggests a clinically relevant increased risk that aligns with findings from recent international studies which have reported prolapse rates of 15–25% in loop colostomies. Retraction and herniation also followed similar trends, with numerically higher complications in the loop group,

though not statistically significant. These results suggest that while loop colostomy may be simpler to construct, it may carry an increased risk of mechanical complications.

The significance seen in wound infections ( $p = 0.048$ ) and skin excoriation ( $p = 0.048$ ) also points to the possible disadvantage of loop colostomy in terms of peristomal skin care and hygiene maintenance, especially in low-resource settings like Pakistan where frequent dressing changes, stoma care appliances, and nursing facilities may be limited. These findings resonate with studies conducted in India and Bangladesh that highlight similar challenges in maintaining post-operative hygiene in neonates with stomas.

Hospital stay was significantly shorter in the divided group ( $p < 0.001$ ), which may contribute to lower overall healthcare costs and reduced nosocomial infection risks. This becomes especially relevant in resource-constrained environments where patient turnover and bed availability are crucial. Moreover,

quicker return of bowel function in the divided group adds further weight to its clinical efficiency.

Although laboratory variables like serum albumin and CRP did not differ significantly between groups, a trend towards higher inflammatory markers and hypoalbuminemia in the loop group may indicate a greater systemic inflammatory burden, potentially secondary to higher complication rates. The lack of significant differences in mortality and postoperative sepsis suggests that both procedures are generally safe and comparable in terms of major adverse outcomes. From a local perspective, the significance of these findings lies in optimizing surgical technique choice in government hospitals and resource-constrained institutions. Considering that stoma complications often necessitate re-admissions and potentially even re-operations, the lower incidence of prolapse, retraction, and herniation in the divided colostomy group offers a practical advantage. Moreover, the lack of access to advanced stoma care appliances makes management of skin excoriations more challenging, and hence minimizing their occurrence is desirable.

This study, being the first randomized controlled trial from Southern Punjab, adds to the limited local literature by objectively comparing the two approaches using standardized criteria and statistical rigor. While several international studies report similar trends, the replication of findings in a Pakistani cohort reinforces their external validity and highlights the need for evidence-based surgical protocols tailored to low-resource settings. Future studies with larger sample sizes and long-term follow-up can further validate these outcomes and inform national surgical guidelines for anorectal malformation management in neonates.

### Discussion:

A randomized controlled trial evaluated complete analysis of 98 neonates born with high variety anorectal malformation to compare clinical effects between loop colostomy and divided colostomy approaches. The research data showed the patients with divided colostomy experienced better results on several postoperative measures. The divided colostomy group outperformed the loop colostomy group based on statistically significant data showing reduced hospital stays as well as swifter bowel recovery and fewer wound infections and delayed healing and

skin issues<sup>18</sup>. Statistical significance did not appear in comparison of postoperative complications between loop colostomy and divided colostomy yet analysis showed the loop colostomy group exhibited higher odds for those complications<sup>19</sup>. The patient baseline information about gestational age and birth weight did not differ substantially between groups so researchers can attribute outcome variations to procedural surgical methods instead of patient background elements<sup>20</sup>. This research outcome correlates with studies seen recently in international medical literature. The results of Zhang et al. (2020) support this study after they investigated divided colostomy patients in China who recorded fewer stoma-related complications than loop colostomy patients<sup>21</sup>.

Research conducted by Al-Mansour et al. (2021) at Saudi Arabia showed that neonatal patients having divided colostomies experienced less prolapse complications and peristomal skin problems compared to patients with loop colostomies<sup>22</sup>. According to Nguyen et al. (2021) Vietnam data subjects who underwent divided colostomy experienced reduced hospital time and faster recovery thus supporting study results<sup>23</sup>. The research conducted by Peters et al. (2019) about high anorectal malformations treatment with loop and divided colostomy methods across ten countries found laparoscopic colostomy presented increased risks of prolapse and retraction compared to loop colostomy techniques<sup>24</sup>. Research findings by El-Sharkawy et al. (2022) from Egypt showed that when patients received loop colostomy they experienced significantly higher instances of complications on their peristomal skin and needed additional operations<sup>25</sup>. A United Kingdom study by Brown et al. (2020) did not show notable differences in complications but noted variations in samples combined with short observational periods through their results<sup>26</sup>. These study differences in surgical procedures and patient decisions and care protocols most likely explain the reported results.

The positive effects associated with divided colostomy in this research base their explanation on physiological characteristics together with anatomical components<sup>27</sup>. When used as a surgical technique two individual stomas create separate outlets that stop fecal material from reaching the remaining bowel



sections and potentially preventing wound infections and complications. Wound healing delays and infection risks increase among poor-stoma-care infants with loop colostomy since the procedure does not completely prevent fecal matter from reaching the distal segment<sup>28</sup>. The distribution of loop stoma physical bulk and its tension on the stoma area likely increases prolapse along with retraction occurrence. The research design features a controlled random approach and equal group allocation and complete assessment of postoperative results and adverse events. Several restrictions should be noted because of their impact on the validity of the analysis<sup>29</sup>. The research had enough participants for primary outcomes yet its capability to identify unusual manifestations of rare complications remains uncertain. The study had a brief follow-up period which prevented researchers from evaluating continuous bowel control or disease outcome after surgery. The research results potentially became biased because of variations in operator experience and differences in perioperative care practices. The use of adjusted odds ratios manages confounders but does not eliminate the possibility of residual confounding remaining in the results. The discovered clinical evidence creates essential implications for medical practice. The divided colostomy approach resulted in lower infection rates and wound complications and shorter hospital stays which indicates this method as a favorable surgical option for newborns with high anorectal malformations. When surgical experience and postoperative care assets remain limited in a specific medical facility then implementation of the divided surgical technique could help decrease hospital strain while leading to better results. The research significance aligns with developing countries because they face difficulties in managing postoperative infections. Future research needs to evaluate extended-term outcomes regarding continence together with caregiver satisfaction and health economic aspects related to both surgical methods. Uptake of extended multi-center trials that employ standardized surgical techniques together with extended follow-up time will strengthen evidence-based findings.

## Conclusion:

Research results showed neonates with high variety anorectal malformations obtained fewer postoperative complications and shorter hospital stays and speedier bowel function recovery when doctors performed divided colostomies instead of loop colostomies. Pregnant newborns who received divided colostomy treatment exhibited significant positive clinical results compared to newborns with loop colostomies despite having similar baseline demographic characteristics including gestational age and birth weight. The patients in the divided group experienced less wound infection and delayed healing and skin injuries which demonstrated improved stoma recovery and minimal complications. The data implies divided colostomy should be used initially for surgical management of this population. These findings prove useful for practical changes in Pakistan because the country faces high congenital anomalies rates and uneven pediatric surgical coverage. The restricted availability of advanced healthcare facilities coupled with resource limitations which complicate proper stoma care practices leads to increased complications from loop colostomies. Divided colostomy implementation under standardized procedures would generate reduced morbidity along with diminished hospital demands and enhanced neonatal care quality for anorectal malformation patients. The validation of current findings requires multiple center studies conducted throughout different provinces of Pakistan so that national guidelines for local requirements can be developed.

## Limitations of the Study:

As noted, the study provides valuable insights; however, like all research, it is not without limitations. Performed in a single tertiary care hospital, the study may have difficulty externalizing its findings. Even though statistically sufficient, the sample size may be too small to capture rare complications and less common subtypes of the disease. Furthermore, non-probability consecutive sampling may increase selection bias. Data collection from clinical records may contain elements of documentation bias. Evaluation of long-term outcomes after three months was not conducted.

## Ethical Considerations:

This study is ethically approved by Institutional Review Board (IRB) of the hospital. Written informed consent was received from all participants or their guardians before data collection. All patient records were anonymous to ensure patient privacy.

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A computer program conducted the calculations for sample size and analyzed the data.

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