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## Original Article

### Comparative study on the outcome of tube ileostomy and loop ileostomy as a temporary diversion procedure

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## ABSTRACT

**Background:** This study aimed to compare the outcomes of tube ileostomy and loop ileostomy in pediatric patients undergoing temporary fecal diversion, focusing on stoma-related complications and wound infection.

**Methods:** A randomized controlled trial was conducted at the Department of Pediatric Surgery, University of Child Health Sciences, Lahore, from August 2021 to July 2022. A total of 68 patients were enrolled and randomized into two groups: Group A (tube ileostomy) and Group B (loop ileostomy) through balloting. After an interim analysis at 40 cases, further recruitment to Group A was halted due to a high rate of re-explorations attributed to tube failure. The remaining patients were assigned to Group B. Variables compared included operative time, hospital stay, time to ileostomy function, stoma-related complications, wound infection, and reoperation rates. Statistical analysis was performed using chi-square and independent t-tests via SPSS 20.0.

**Results:** Of 68 patients, 20 underwent tube ileostomy and 48 had loop ileostomy. Both groups were similar in age, gender distribution, and disease profile. Group A had slightly longer operative time and hospital stay, with no significant difference ( $p=0.823$  and  $p=0.099$ , respectively). Time to ileostomy function was shorter in Group A ( $p=0.037$ ). Re-exploration was more frequent in Group A (30%) compared to Group B (12.5%), though statistically insignificant ( $p=0.085$ ). Stoma-related complications were significantly fewer in Group A ( $p=0.027$ ). Wound infection rates were comparable between groups ( $p=0.909$ ).

**Conclusion:** Although tube ileostomy demonstrated fewer stoma-related complications, the higher rate of re-explorations raises safety concerns. Based on current findings, tube ileostomy cannot be recommended as a routine diversion procedure in children. Larger multicenter trials using wider caliber tubes are recommended to evaluate its potential role in selected cases.

**Keywords:** Tube ileostomy, Loop ileostomy, Diversion procedure, Stoma complications, Wound infection.

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## INTRODUCTION

Despite considerable surgical expertise, numerous complications can still arise following the creation of an ileostomy, leading to social isolation and a negative impact on quality of life [1–4]. These complications may include stoma

retraction, stenosis, prolapse, or necrosis; para-ileostomy infections, abscesses, and fistulas; parastomal evisceration and hernia; intestinal obstruction; skin irritation or excoriation; mucosal ulceration; offensive odor; pre-stoma ileitis; diarrhea; and hemorrhage. Moreover, complications following stoma closure occur in

17%–27% of patients [3], and approximately 15%–20% may require reoperation on long-term follow-up [5].

Some studies have proposed proximal tube or catheter ileostomy as a viable alternative to defunctioning proximal loop ileostomy, reporting better functional outcomes [3,6]. The principle of tube or catheter ileostomy is based on the well-established concept of catheter feeding jejunostomy. Unlike loop ileostomy, tube ileostomy does not require surgical reversal, simplifies stoma output management, and avoids many complications associated with loop ileostomy.

Most existing research on tube ileostomy is in adult populations. Only limited studies have addressed its selective use in neonates with conditions such as meconium ileus, intestinal perforation, intestinal atresia, or perforated necrotizing enterocolitis (NEC) [7]. International and regional data on the use of tube ileostomy in children remains scarce.

Given the reported improved outcomes in adults, this study was designed to evaluate and compare the outcomes of tube ileostomy and loop ileostomy in pediatric patients, specifically in terms of post-operative stoma-related complications and wound infection.

## **METHODS**

It was a Randomized controlled clinical trial (unregistered) conducted at the Pediatric Surgery Department, University of Child Health Sciences Lahore, from August 2021 to July 2022. Informed written consent was obtained from each patient for inclusion in the study.

**Ethical Approval:** Approval was obtained from the Institutional Review Board (IRB dated 21-07-2020 Ref no 2020-121-CHICH).

A total of 68 cases were selected by non-probability purposive sampling and randomized by balloting method into Group A-Tube ileostomy, and Group B-Loop ileostomy, with a group allocation ratio of 1:1. However, after interim analysis at completion of 40 cases with 20 cases in each group, recruitment in intervention Group-A Tube ileostomy was stopped and study was completed by recruiting all remaining cases in Group-B loop ileostomy.

Patients of either gender with age of less than 14 years requiring temporary ileal diversion were

included in this study. None of the patients were excluded from the study. The intention to treat analysis principle was employed. In the included patients requiring temporary diversion, at laparotomy, the perforation site was identified and gut was looked for other perforations.

In Group 'A', A bi-channel Foley catheter (For neonates: 12Fr, for age up to 1 year: 14Fr, for age group 2-6 years: 16Fr, for age group 7-13 years: 18Fr) was taken into abdominal cavity after giving stab incision on lower half of abdomen. The catheter was inserted through perforation site or via another opening created 10-15 cm proximal to affected bowel with tip of tube directed proximally in the ileum in cases of friable, necrotic ileal or caecal wall where perforation site was repaired with 2-3 stitches, after refreshing the margins, loosely enough not to cut through the bowel wall or dealt with resection anastomosis. The balloon of catheter was inflated within the bowel lumen with distilled water in such a way that it was snugly fit to the bowel perforation site/lumen and it did not produce any ischemia of the bowel but closed the opening or perforation site. The catheter was fixed to gut by 3-0 Vicryl suture in a purse-string fashion. The adjacent bowel was anchored to parietal abdominal wall with interrupted 3-0 Vicryl. Tube was fixed to skin with 2-0 silk and attached with a drainage bag. Another drain tube was placed in pelvis in cases of peritonitis.

In Group 'B', the stoma was formed with standard technique.

In the postoperative period, the patient was kept nil per orally as per protocol of small/large bowel surgery, intravenous antibiotic continued, and fluid and electrolyte balance was maintained. Good post-operative analgesics were given. Tube was regularly checked for free flow of contents and flushed with 5-20 ml normal saline thrice daily to prevent tube blockade starting from 1st post-operative day. Sips of water by mouth were started on the third postoperative day or when patient had no evidence of peritonitis and bowel function have returned. Gradually semisolid to solid diet was introduced over the next week. Dressing was changed on the 3rd post-operative day (POD) and subsequently in postoperative days depending upon the severity of surgical site infection. If there was no suspicion of anastomosis leakage or peritoneal infection, the catheter balloon was started to deflate by

removing one third of distilled water in the balloon initially on every alternative day, starting from the fifth post-operative day, during this time any complications like peritonitis, abdominal pain, fever, peri-tubal leakage, peri-tubal abscess, drain tube collection were noted and the catheter was removed on 10-12th postoperative day leaving a controlled fistula at tube site [6]. Pelvic drain tube was removed if there was no clinical and radiological evidence of collection in the abdomen or drain output was nil for last 24 hours.

The complete record of the day when ileostomy (tube/loop) began to work, tube output, peritubal leakage, tube blockade, any sign of anastomosis leakage, or any other intricacy observed was kept up. The time of clamping & removal of tube catheter and the duration when catheter ileostomy fistula closed revealing no output was also noted. Similarly, a detailed record of loop ileostomy related complications was also maintained. Patients were discharged on oral antibiotics as per protocol of small bowel surgery.

Regular follow up of the patients were ensured on OPD basis for recording any complication for the next 3 months (1st week, 1st month & 3<sup>rd</sup> month). Each patient was assessed in terms of primary and secondary outcomes.

### Statistical Analysis

All collected data were analyzed with SPSS version 20 (Statistical Product and Service Solutions). Data were presented in tables and graphs for both quantitative and qualitative variables. Quantitative variables i.e. age, weight, operative time and hospital stay were summarized as mean and standard deviation or median. Qualitative/categorical variables i.e. gender, gestational age, etiology, stoma related complications and wound infection were presented as frequency and percentage. Mean of the variables were correlated using independent sample t-test. Chi square test was used for comparing proportions in both study groups. A p-value of  $\leq 0.05$  was considered as statistically significant.

### Interim Analysis

It was performed when more than fifty (50) percent of study data was completed. The interim analysis was reviewed by the data safety & monitoring board. As significant harm was identified clinically in intervention group (A), the

allocation ratio was changed by stopping recruitment of patients in intervention group and remaining patients were assigned to control group to complete the study [8]. The provision for these changes in allocation ratio was already approved in the synopsis for this trial from Advance Studies & Research Board of the University of Health Sciences, Lahore.

## RESULTS

Both groups were comparable with respect to mean age of patients and gender distribution (Table 1).

Mean operative time was slightly more in group-A as compared to group-B but was not statistically significant (Table 1).

Post-operative hospital stay was longer in tube ileostomy group but was statistically insignificant (Table 1).

Table 1: Results

Variable	Tube Ileostomy	Loop Ileostomy	P-Value
Age	39.7782±53.51	46.25±57.31	0.808
Gender Distribution	39.7782±53.51	46.25±57.31	0.808
Operative Time (Minutes)	128.75±46.478	116.94±27.657	0.535
Post-operative Hospital Stay (Days)	10.30±5.667	8.46±5.411	0.099
Time of Ileostomy Functioning (Days)	1.25±0.444	1.56±0.580	0.037
Need for re-exploration (n & %)	n=6/20 (30%)	n=6/48 (12.5%)	0.085
Wound Infection (n & %)	n=6/20 (30%)	N=16/48 (33.50%)	0.919

The mean time of ileostomy functioning was less in tube ileostomy group with statistically significant P-value (Table 1).

Table 2: Disease Spectrum

Disease Spectrum	Study Group		Total	P-Value
	Group A: Tube Ileostomy	Group B: Loop Ileostomy		
Enteric Perforation	6	12	18	0.06
Worm Infestation	1	0	1	
Meckel's diverticulum	0	1	1	
Mid gut Volvulus	0	1	1	
Perforated Appendicitis	0	2	2	
Intussusception	5	6	11	
Atresia	1	2	3	
NEC	0	10	10	
TB Abdomen	0	5	5	
Band Obstruction	2	7	9	
Adhesion Obstruction	2	0	2	
Obstructed Hernia	2	2	4	
Complicated Meconium Cyst + Ileal Atresia	1	0	1	
Total	20	48	68	

The data in Table-2 revealed that both groups had a higher incidence of enteric perforation cases, followed by intussusception and band obstruction while loop ileostomy group-B had significant number of Necrotizing enterocolitis cases. The disease spectrum was comparable with statistically insignificant p-value.

In both groups, six patients in each group were re-explored but P-value 0.085 was insignificant. In group-A, 30% of patients while in group-B, 12.5% of patients needed re-exploration (Table 1).

Both groups were comparable in terms of wound infection (Table 1).

On further analysis, six (06) patients developed superficial surgical site infection (SSSI) in group-A while in group-B, five (05) patients developed

SSSI, nine (09) patients had deep SSI, and two (02) patients had organ space infection.

In group-A, stoma related complications were significantly less compared to group-B (P-value 0.027). Peristomal excoriations was the most frequent complication noted in both groups but was considerably more in group-B (P-value 0.003). In group-B, stoma prolapse was the second most frequent complication (P-value 0.106). In group-A, peritubal leak was the most frequently observed complication while tube blockade was noted in one patient.

Mean time of tube clamping in tube ileostomy group was  $7.5 \pm 3.103$  post-operative days. Mean time of tube removal was  $12.10 \pm 3.932$  post-operative days. Mean time of closure of controlled fistula after removal of ileostomy tube was  $2.4 \pm 0.503$  days.

Table 3: Stoma related Complications

Sr. #	Stoma Related Complications		Study Group		Total	P-Value
			Group A Tube Ileostomy	Group B Loop Ileostomy		
1	Mucocutaneous Detachment	No	20	47	67	0.516
		Yes	00	01	01	
2	Peristomal Dermatitis	No	15	17	32	0.003
		Yes	05	31	36	
3	Stoma Retraction	No	20	47	67	0.516
		Yes	00	01	01	
4	Stoma Prolapse	No	19	38	57	0.106
		Yes	01	10	11	
5	Parastomal Evisceration	No	20	47	67	0.516
		Yes	00	01	01	
6	Tube Blockade	No	19	48	68	0.294
		Yes	01	00	00	
7	Peritubal Leak	No	14	48	68	0.000
		Yes	06	00	00	

In the experimental group, six (6) patients in the lately assigned cases had to undergo redo-laparotomy either due to peritonitis secondary to fecal contamination from leakage around the tube ileostomy, or complications directly related to the tube ileostomy.

At 1st week follow-up, skin excoriations was the most frequent complication noted in group-B followed by wound infection (SSSI & Deep SSI).

There was one case of burst abdomen and one expiry in group-B. In group-A, SSSI were observed in two patients and peritubal

excoriations in one patient. One patient in group-A developed intussusception around tube catheter that was re-explored and loop ileostomy was made after manual reduction of intussusception. The P-value 0.153 was statistically insignificant.

On the 2nd follow-up at 1st month, considerably high number of complications noted in loop ileostomy group as compared to tube ileostomy (P-value 0.026). Peristomal skin excoriations was the most frequent (22) complication noticed in group-B. Stomal diarrhea was observed in two patients while sub-acute intestinal obstruction,

stoma retraction, stoma prolapse, and burst abdomen were noted in one patient each in group-B. In group-A, excoriations, stomal diarrhea, and SSSI each were observed in one patient each.

On 3rd follow-up, Skin excoriations was the most frequent complication noted in nine (09) patients followed by stoma prolapse in six (06) and malnutrition in two (02) patients in group-B.

## DISCUSSION

The results of this study demonstrated that both groups—tube ileostomy (Group A) and loop ileostomy (Group B)—were comparable with respect to baseline demographics (age and gender), disease spectrum, operative time, postoperative hospital stay, wound infection, and need for redo-exploration. Statistically significant differences, however, were observed in the time to ileostomy functioning (earlier in tube ileostomy;  $p=0.037$ ) and stoma-related complications, which were more frequent in the loop ileostomy group ( $p=0.027$ ). Specifically, peristomal skin excoriations were significantly higher in the loop ileostomy group ( $p=0.003$ ), consistent with previous reports [3].

Despite these favorable early outcomes for tube ileostomy, including quicker return of gut motility and fewer stoma-related complications, six consecutive cases required clinically significant redo-exploration due to tube failure. These cases included obstructed inguinal hernia ( $n=2$ ), enteric perforation ( $n=2$ ), and intestinal obstruction caused by worm infestation and band obstruction ( $n=2$ ).

The first two failures involved patients with obstructed inguinal hernias. In one case, the tube caused intussusception, attributed to poor caregiver counseling and accidental over-inflation of the tube balloon. The second patient developed peritubal leakage and subsequent peritonitis following COVID-19 infection. Among the two enteric perforation cases, the tube ileostomy failed to function despite repeated flushing. Possible contributing factors included inadequate tube size, improper fixation to the abdominal wall, and the widespread inflammatory disease process involving Peyer's patches in enteric fever.

In the case of worm infestation, the tube was obstructed by a worm that had bypassed surgical

clearance, leading to anastomotic disruption. This scenario might have been prevented by using loop ileostomy, which is less prone to obstruction. The second intestinal obstruction case involved accidental tube dislodgement due to inadequate fixation, resulting in peritonitis.

Overall, redo-exploration was required in 6 of 20 (30%) cases in Group A and 6 of 48 (12.5%) cases in Group B. Although this difference was statistically insignificant ( $p=0.085$ ), it is clinically relevant and higher than reported in the literature (<5% vs <15%) [3]. Based on these interim findings and as per the pre-approved study protocol, further recruitment into the tube ileostomy group was halted.

In contrast to earlier studies, including the only randomized controlled trial by Vijayraj Patil et al., which reported a lower complication rate with tube ileostomy (33% vs 53%) [3], our findings challenge the perceived superiority of tube ileostomy. Their study, which used a 28Fr abdominal drain in patients aged 16–63 years (mean age 32.6 years), differs significantly from our pediatric population.

Various tube types have been used in previous studies—T-tubes, Foley catheters, abdominal drains, endotracheal tubes, and nasogastric tubes—but we selected Foley catheters based on availability, ease of use, reduced risk of intestinal injury, and routine use in pediatric feeding jejunostomy/gastrostomy. Catheter sizes were tailored to pediatric age groups: 12Fr for neonates, 14Fr for infants <1 year, 16Fr for ages 2–6, and 18Fr for ages 7–13.

Retrospective reviews support tube ileostomy's utility in neonates. Al-Zaiem et al. reported success using T-tube enterostomy for diverse neonatal GI pathologies [7]. Rygl et al. demonstrated its utility in extremely low birth weight neonates with focal intestinal perforation due to NEC [9]. These studies highlight tube ileostomy's advantages: simple technique, effective gut decompression, rapid return of motility, easy effluent management, and spontaneous fistula closure.

In our study, although the frequency of redo-exploration was statistically similar across groups ( $p=0.085$ ), the clinical impact was significant. In Group A, redo-explorations were due to peritubal leaks ( $n=3$ ), anastomotic leaks ( $n=2$ ), and tube-related intussusception ( $n=1$ ). In

Group B, the causes included burst abdomen (n=3), stoma retraction (n=1), peristomal evisceration (n=1), and peritonitis (n=1). Comparatively, Vijayraj's trial reported redo-exploration rates of 3.33% (tube) and 13.33% (loop), while Suryavanshi et al. reported 4.76% and 6.89%, respectively [3,10].

Stoma-related complications in our study were significantly higher in the loop ileostomy group (68.75%) compared to the tube group (40%) (p=0.027), aligning with trends in the literature [3,10,12]. In contrast, Cogbill and Millikan reported a 69% complication rate in neonates with ileostomy for NEC [12]. Our higher overall complication rates may reflect the unique challenges of pediatric care, where children rely on adult caregivers for ostomy maintenance, similar to the neonatal dependency in Cogbill's study.

Peristomal skin excoriation was the most common complication, seen in 5 tube and 31 loop ileostomy cases (p=0.003). In Group A, excoriations were transient and easily managed; in Group B, the severity varied, and moderate-to-severe cases were difficult to control, often due to poor caregiver compliance.

Peritubal leakage was the most frequent tube-specific complication (30%), while tube blockage occurred in only one case (worm obstruction). Comparatively, Vijayraj reported 10% peritubal leakage and 16.6% blockage [3], while Suryavanshi observed 14.2% and 19%, respectively [10]. Rehman et al. reported similar rates [6].

Other complications in our cohort included sub-acute obstruction (n=2, managed conservatively), malnutrition (n=2), and high-output stoma with dehydration (n=1). Dehydration, noted in 4 cases in Vijayraj's loop ileostomy group, is a well-documented complication with reported rates between 2.2% and 20% [3].

Tube ileostomy offers several advantages: it is technically simple, minimally invasive, and utilizes readily available Foley catheters. Pediatric patients experience less physical and psychological stress and return to normal activities sooner. The technique is cost-effective, avoids a second surgery for ostomy closure, and is particularly beneficial in resource-limited settings.

It also results in fewer stoma-related complications such as prolapse, necrosis, or

retraction. Skin excoriation is milder, stoma care is easier, and electrolyte imbalances are less severe. Postoperative imaging through the tube is feasible, and the cosmetic outcome is superior.

Despite its benefits, tube ileostomy has significant limitations. The tube can be easily obstructed by semisolid contents, requiring regular flushing. It may become kinked or dislodged, causing peritubal leaks or even peritonitis. It can also act as a lead point for intussusception, especially in short bowel syndrome. If defunctioning is incomplete, it can jeopardize the anastomosis. Failure of tube ileostomy often necessitates reoperation, adding to the burden on already vulnerable pediatric patients and their families.

This single-center randomized controlled trial included pediatric patients (<14 years) requiring temporary bowel diversion, excluding only cases of anorectal malformation and Hirschsprung's disease. Unlike most existing studies that are retrospective or include older populations, our study targeted a broader pediatric spectrum.

Although tube ileostomy demonstrated significantly earlier functioning and fewer stoma-related complications, the high rate of clinically significant redo-explorations due to tube failure is concerning. Contrary to existing literature, our findings do not fully support the routine use of tube ileostomy in the pediatric population.

The study was conducted during the COVID-19 pandemic, and limitations such as small sample size, external caregiving challenges, and surgical technique variability must be considered. Thus, results cannot be generalized to all pediatric populations. Further multi-center trials with larger sample sizes are needed to validate the findings and establish uniform standards for tube ileostomy in children.

## CONCLUSION

Although, the established importance of tube ileostomy as an effective and reliable alternative procedure compared to loop ileostomy cannot be over looked but considering the results of our study with high percentage of redo-exploration in tube ileostomy group in contrary to the literature, we cannot recommend it as a safe diversion procedure in pediatric age group. We recommend large randomized controlled trials to be conducted at multi centers with larger tube size to further elucidate this issue whether tube

ileostomy can be a safe alternate option to loop ileostomy as a proximal diversion technique.

**Consent to Publication:** Author(s) declared taking informed written consent for the publication of clinical photographs/material (if any used), from the legal guardian of the patient with an understanding that every

effort will be made to conceal the identity of the patient, however it cannot be guaranteed.

**Authors Contribution:** Author(s) declared to fulfill authorship criteria as devised by ICMJE and approved the final version. The authorship declaration form, submitted by the author(s), is available with the editorial office.

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