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Novel self-reversing tube ileostomy as an alternative for conventional loop ileostomy for fecal diversion: A cohort tertiary care center study

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ABSTRACT

Objective: Anastomotic leakage following colorectal anastomosis poses substantial morbidity and mortality. Defunctioning loop ileostomy has been employed as a preventive measure, but has its own complications, including its reversal. In light of these challenges, tube ileostomy has emerged as an alternative, seeking to fulfil the same purpose as loop ileostomy while minimising complications associated with stoma creation and reversal.

Material and Methods: Conducted as a cohort study, a total of 88 patients were evenly distributed into two groups. Data collection spanned six months post-surgery or until the conclusion of the study period, with monthly follow-ups. Both types of ileostomy were performed in both elective and emergency settings.

Results: In this study comparing tube and loop ileostomy, tube ileostomy showed several advantages: Lower output (218±19 mL vs. 333.33±58 mL), shorter hospital stay (8.3 vs. 11.32 days), fewer stoma bag needs, and faster closure without surgical reversal. Complications like skin excoriation, electrolyte imbalance, and hypertrophic scarring were significantly lower in tube ileostomy. Although tube-related issues like blockade (40.9%) and leakage (15.9%) occurred, overall, comorbidity handling and patient independence were better. Statistical analysis confirmed significant differences in key parameters, favouring tube ileostomy as a safer, simpler faecal diversion alternative.

Conclusion: In the early phases of this investigation, tube ileostomy demonstrated favourable outcomes. The observed reduction in complications, ease of management for tube ileostomy-related issues, and decreased hospitalisation and reversion surgery requirements highlight its potential advantages. Further exploration and long-term follow-up are warranted to validate these initial findings and ascertain the sustained efficacy and safety of tube ileostomy.

Keywords: Tube ileostomy, loop ileostomy, colorectal cancer, anastomotic leak, stoma-related complications

INTRODUCTION

Anastomotic leak after distal bowel anastomosis and its resulting complications can be fatal. A defunctioning ileostomy does not entirely prevent an anastomotic leak, but diverting fecal matter may alleviate the severe complications of an anastomotic leak, such as fecal peritonitis and septicemia (1,2). However, complications associated with ileostomies, such as poor stoma siting, dehydration, electrolyte abnormalities, skin excoriation, ischemia, stenosis, parastomal hernia, prolapse, and psychological distress, can be detrimental. Reversal of conventional loop ileostomy (LI) itself is associated with complications (1).

Tube ileostomy offers an alternative approach to minimise complications associated with a defunctioning LI. The procedure was first performed in 1959 at Texas Children's Hospital for proximal fecal diversion; its use in adults with familial polyposis was later reported by Hojo, demonstrating comparable effectiveness to LI ileostomy (2,3). Incomplete fecal diversions have historically limited the widespread adoption of this technique (3). Early challenges, such as tube dislodgement and obstruction, restricted its use; however, recent improvements in fixation methods, devices, and perioperative care have renewed interest by reducing stoma-related morbidity and simplifying reversal. Proximal diversion is considered essential for anastomoses located within 5 cm of the anal verge, for patients who have received preoperative radiotherapy, for patients on steroids, for patients with intraoperative hemodynamic instability, and for those for whom the surgeon considers the integrity of the anastomosis to be questionable (4,5).

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Tube ileostomy is considered a strategic alternative to the conventional defunctioning LI, and we study the utility of tube ileostomy compared with LI as a diversion procedure.

MATERIAL and METHODS

Study Design: Cohort study.

Inclusion Criteria

A proximal diversion stoma is recommended when performing anastomosis in the distal bowel in the following situations where the integrity of the anastomosis is uncertain.

1) Perforated bowel,

2) Adherent loops of bowel and compromised anastomosis.

3) Post-radiotherapy patients.

4) Patients on steroid therapy and those in whom the integrity of the distal anastomosis was questionable were chosen for the study.

5) For patients with anastomosis less than 5 cm from the anal verge

Exclusion Criteria

- Patients who are not willing to participate in the study.

- Patients who do not require proximal diversion ileostomy are similar to healthy individuals. Deaths occurring within five days of surgery were unrelated to anastomotic complications.

- Patients who were lost to follow-up were excluded from the study.

Sample Size

A sample size of 88 is obtained using the hypothesis testing method and the following assumptions: A 95% confidence level; d as the minimum clinically relevant effect size; p1 as the percentage of the characteristic in the standard group; p2 = p1 + d or p1 – d (depending on whether p2 is assumed to increase or decrease); and p as the average percentage of the characteristic, p = (p1 + p2)/2. Assuming p=53%, a sample size of 44 subjects per group was required to detect a 30% difference in cure rate; participants were randomly assigned to one of the two groups.

Data Collection Tool and Method

A structured proforma was utilised for data collection. Each patient was monitored monthly for six months following surgery (6) and evaluated during each follow-up for the development of new complications or progression of existing ones. The study was initiated after obtaining approval from the Institutional Ethics Committee of the Government Medical College, Kozhikode, India (ref no: GMCKKD/RP2021/IEC/191, dated: 16/07/2021). Prior to participation, written informed consent was obtained from all patients. The consent form clearly explained the nature and purpose of the study; the procedures involved; the potential risks and benefits; the confidentiality of personal information; and the voluntary nature of participation, including the right to withdraw at any stage without affecting their clinical care.

Statistical Analysis

Data were collected using Microsoft Excel and analyzed with SPSS version 18. Baseline variables were summarized using means and standard deviations for continuous data, and frequencies and percentages for categorical data. Comparisons between the tube ileostomy group (n=44) and the LI group (n=44) were performed. Continuous variables (e.g., hospital stay, ileostomy output, time to stoma function, tube removal, and fistula closure) were compared using the independent-samples t-test to assess differences in means between groups. Categorical variables (e.g., skin excoriation, electrolyte imbalance, stoma care dependence, infection, scarring, and pain) were analyzed using the chi-square test to evaluate differences in their distributions between groups; relative risk (RR) was calculated to quantify the likelihood of complications in one group relative to another. A p-value <0.05 was considered statistically significant. Comparative outcomes and complication rates were illustrated using bar graphs. All analyses were two-tailed, with 95% confidence intervals applied where appropriate.

The Technique of Tube Ileostomy

A 28-French abdominal drain tube (soft thoracic catheter) (7) was inserted into the peritoneal cavity through a stab incision in the abdominal wall. The tube was inserted 10-15 cm proximal to the ileocecal junction for diseases involving the large bowel, and 10 cm proximal to the diseased bowel for ileal pathologies. The tube was positioned so that approximately 10 cm remained within the bowel, with the open end directed proximally. The tube was secured to the bowel wall with a 2-0 polyglyconate purse-string suture (Figure 1). The segments of bowel 1-2 cm proximal and distal to the tube insertion site were fixed to the parietal wall of the abdomen with interrupted 2-0 silk sutures (Figure 2). The tube was secured to the skin of the anterior abdominal wall with no. 1 silk suture; the distal end of the tube was trimmed and connected to the stoma bag (Figure 2).

We preferred an oral liquid diet during the initial week and, by the end of that week, an oral semisolid diet, with twice-daily saline irrigation and aspiration of the tube to prevent tube blockage. No radiological studies were performed to ensure the integrity of the distal anastomosis (8).

Tube blockage may be associated with diet and tube diameter; an easily digestible diet and a sufficiently large tube diameter would reduce this risk. It is managed with saline irrigation, dietary modifications, and laxatives, and is therefore treatable.

Formation of the stoma tract occurred approximately one week after ileostomy, providing a safe time frame for tube removal. Similar results were obtained, with the exact timing of

tube removal ranging from 7 d to >3 wk postoperatively (7). In the present study, the tube was removed on day 21 post-surgery, as in the study by Sheng et al. (7). Following tube removal, the ileostomy site behaves like a low-output fistula and typically heals spontaneously (Figure 2).

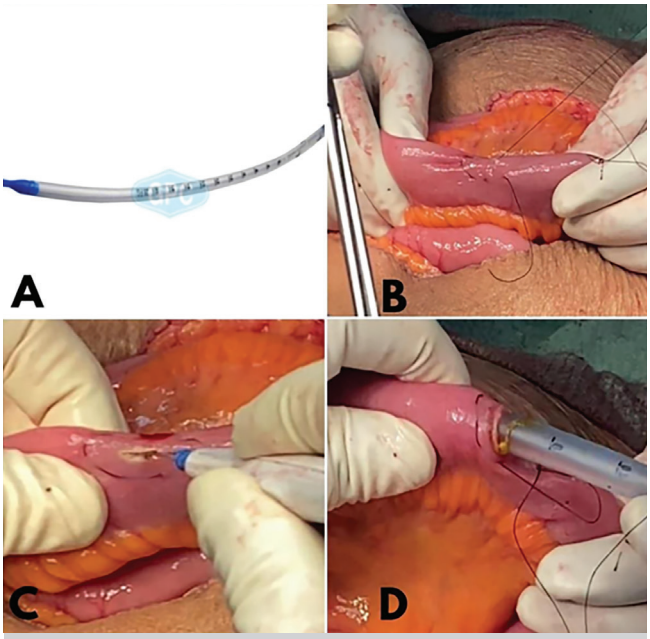

Figure 1. A) 28F soft thoracic catheter for insertion, B) Purse string suture on seleeted healthy segment of bowel, C) Cautery marking of site of tube insertion, D) Tube was secured to bowel wall by 2-0 polyglactin by purse string suture.

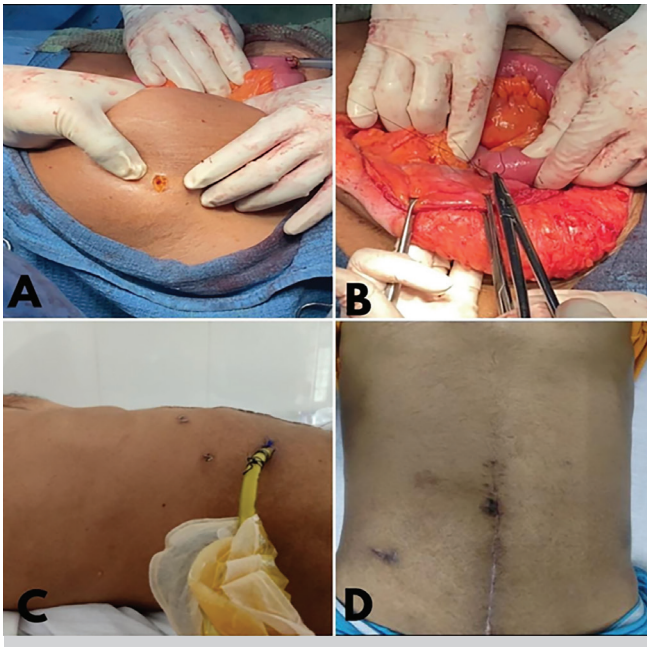

Figure 2. A) Site of tybe exit in anterior abdominal wall, B) Bowel proximal and distal to site of tube insertion was fixed to parietal wall of abdomen with interrupted 2-0 silk, C) Tube was fixed to skin with no. 1 sil and connected to stoma gag, D) Note the spontaneous closure of tube-ileostomy controlled fistula on pod-29.

RESULTS

66% of the patients who underwent LI (n=44) were male; of 44 patients who underwent tube ileostomy, 27 were male. The mean age of tube ileostomy was 61.43±1.09 years, and the mean age of LI was 58.50±1.39 years. In this study, most patients (72.8%) who underwent tube ileostomy for fecal diversion were aged 50-70 years. Tube ileostomy was performed primarily for patients with large-bowel malignancies as a fecal diversion procedure to protect the distal anastomosis. Thirty-six of 44 cases had significant bowel pathology (Table 1).

Table 1. Indications for tube v/s loop ileostomy

Indication for loop ileostomy	% n=44	Indication for tube ileostomy	% n=44
Acute intestinal obstruction	20.5	Acute intestinal obstruction	4.5
Ca ascending colon	4.5	Ca ascending colon	4.5
Ca transverse colon	6.8	Ca transverse colon	9.1
Ca descending colon	4.5	Ca descending colon	2.3
Ca sigmoid colon	6.8	Ca sigmoid colon	2.3
Ca rectosigmoid	22.7	Ca rectosigmoid	36.4
Ca rectum	11.4	Ca rectum	18.2
Familial adenomatous polyposis	2.3	Familial adenomatous polyposis	4.5
Recurrent incisional hernia + intestinal obstruction	2.3	Acute appendicitis with perforated caecum	2.3
S/P extended right hemicolectomy/ anastamotic leak	2.3	Ca ascending colon-hepatic flexure	2.3
Mesenteric ischemia	2.3	Ca caecum	4.5
Necrotising pancreatitis with pancreatico pleural fistula and colonic fistula	2.3	Ca caecum + Ca sigmoid	2.3
Anastamotic leak S/P exploratory laparotomy with ileotransverse anastamosis for intestinal TB	2.3	Ulcerative colitis S/P total colectomy+ end colostomy	2.3
Penetrating injury colon	2.3	Carcinoid tumor appendix	2.3
Ca transverse colon with coloduodenal fistula	2.3	UGI bleed, intestinal obstruction-stricture ileum, small bowel gangrene	2.3
Sigmoid volvulus	2.3		
Sigmoid diverticular perforation	2.3		

%: Percentage, Ca: Carcinoma.

In most elective cases, a tube ileostomy was performed as a diversion procedure. Four of 44 cases underwent tube ileostomy and 18 of 44 underwent LI, all performed in emergency settings. Comorbidities were considered a risk factor for healing of the anastomotic site; 70.5% of cases in which a tube ileostomy was performed had associated comorbid conditions, such as diabetes mellitus, chronic obstructive pulmonary disease, coronary artery disease, hypertension, and dyslipidemia. Of those in whom LI was performed, 52.3% had comorbid conditions unfavorable for anastomotic site healing.

In the present study, the mean ileostomy output was 218±19 mL in tube ileostomy and 333.33±58 mL in LI (p-value was <0.05) (Figure 3). The mean length of hospital stay was 8.30±3.06 days for tube ileostomy and 11.32±1.82 days for LI. In t-test analysis, p<0.05, indicating a statistically significant difference between the two groups (Figure 4).

The mean time to onset of function was 1.09±0.88 days for the tube ileostomy and 1.14±1.002 days for the LI (p=0.82).

For tube ileostomy, 3-4 stoma bags were required on average per month compared with 6-8 stoma bags for LI (t-test p-value =0.0), indicating a statistically significant difference between the groups (Figure 5).

The mean time to tube ileostomy removal was 18.91±4.26 days. Ileostomy-site discharge was observed in 6.8% of cases following tube removal. Because it was a controlled fistula and there was no distal obstruction, discharge from the ileostomy site following tube removal subsided gradually over 8-10 days. The mean time to spontaneous fistula closure following tube removal by granulation tissue formation was 26.86±5.07 days (Figure 6). No formal wound closure of the tube ileostomy site was required. The mean interval to LI reversal was 111.05±22.83 days. Comparison using an independent t-test showed a statistically significant difference (p<0.001).

Skin excoriation, a common complication following ileostomy, is reported in 20.50% of loop ileostomies and 4.60% of tube ileostomies (p=0.024; RR =0.2). Ileostomy-site infection following LI was reported in 11.40% of LI patients and in 6.80% of tube ileostomy patients (p-value =0.458), which is not statistically significant. Since the RR is 0.6, tube ileostomy is associated with a decreased risk of ileostomy-site infection compared with LI; tube ileostomy may protect against stoma-site infection by preventing spillage of stoma contents.

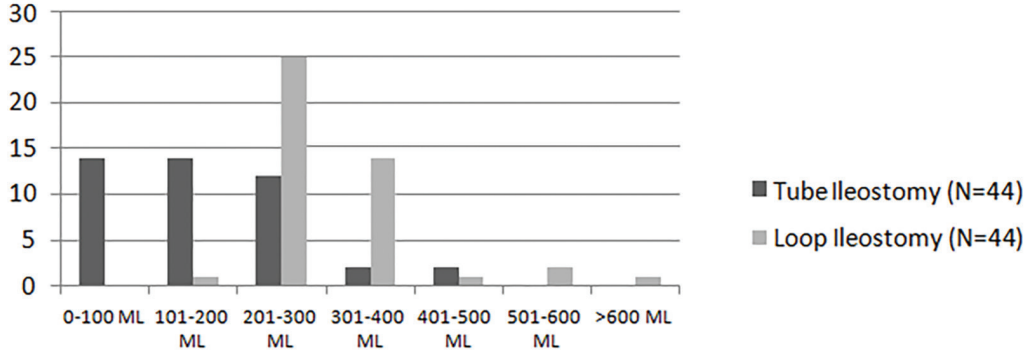

Figure 3. Average output pper day-tube v/s loop ileostomy.

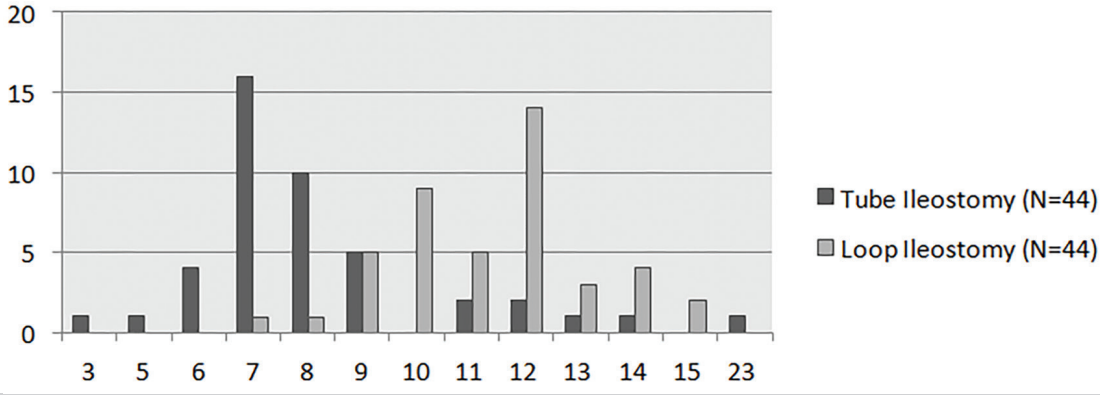

Figure 4. Number of days of hospital stay.

The Likert pain scale was used to assess pain. In both groups, the majority of patients experienced only mild pain on the scale. 13.60% of patients with LI experienced pain, compared to 6.80% of patients with tube ileostomy. The chi-square test was used for analysis. The p-value was 0.291; therefore, the result is not statistically significant despite an observed difference. Since the RR is 0.5, there is an inverse association between ileostomy site pain and ileostomy type. 2.3% of patients with tube-and-LI developed a suspected distal anastomotic leak with tachycardia and fever, which was managed conservatively. In the chi-square analysis, the p-value was 1.00; hence, it is not statistically significant. Since the RR is 1, no association was found between an anastomotic leak and the type of ileostomy. No patients in either group developed clinical features of intestinal obstruction after the procedure.

22.7% of patients with LI had an electrolyte imbalance, compared with 2.3% of patients with tube ileostomy. This may be attributed to the low output from the tube ileostomy, which is a partial diversion technique. Since the RR was 0.1, electrolyte imbalance was less likely to occur in those with a tube ileostomy used as a diversion procedure. A 90% risk of developing electrolyte imbalance is attributable to LI.

A stoma-site hematoma was present in 6.80% of patients with a LI. None of the tube ileostomy patients developed a hematoma. A chi-square test yielded p=0.07, which was not statistically significant. A hypertrophic scar at the stoma site was present in 11.4% of patients with a LI. Notably, none of the patients who underwent tube ileostomy developed hypertrophic scars. Statistical analysis using the chi-square test yielded a p-value of 0.02, which is statistically significant.

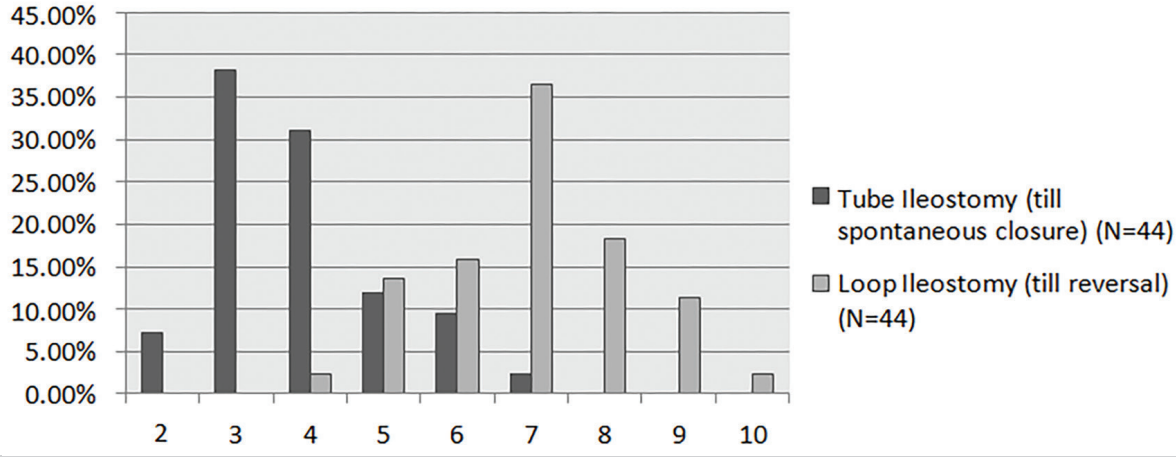

Figure 5. Number of stoma bags used in a month.

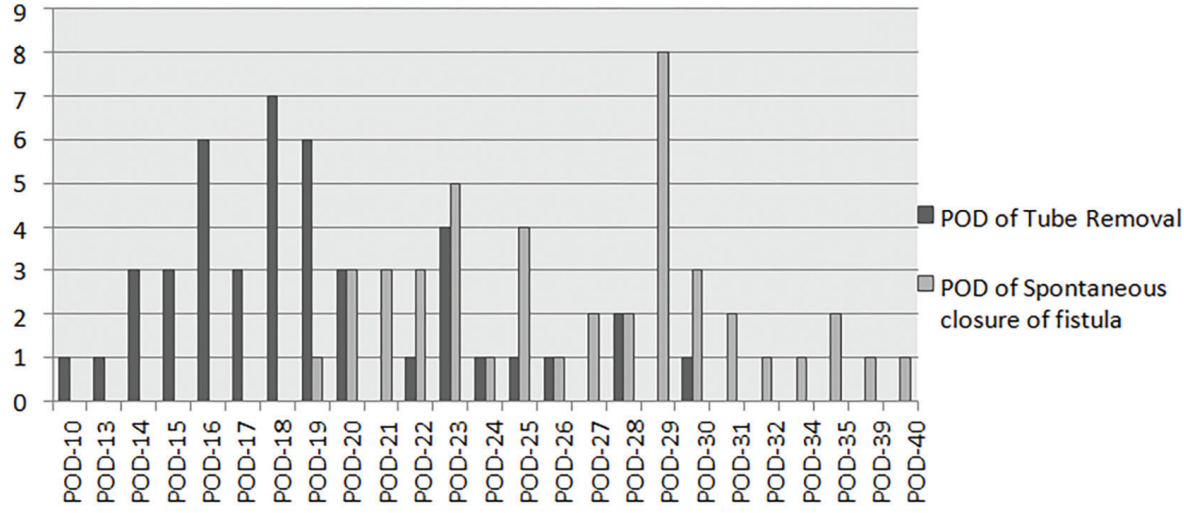

Figure 6. Post-operative day of tube removal vs. spontaneous closure of fistula.

40.9% of tube ileostomy cases developed obstructive features, 15.9% developed peritubal leakage, and 9.1% reported tube migration. 29.50% of patients with LI depended on others for proper stoma care, including changing and applying the stoma bag. 11.4% of patients with tube ileostomies required assistance with tube care. The chi-square test yielded a p-value of 0.34; although a difference was observed, it was not statistically significant.

DISCUSSION

Surgical fecal diversion was first reported in the 18th century and was initially used to relieve distal obstruction (6). During that era, diversion was utilised more frequently in the acute-care setting.

With surgical advances, defunctioning colostomies and ileostomies have become the mainstays of fecal diversion to protect primary colorectal anastomoses in the elective and emergency settings (3). The proximal diversion of a distal rectal anastomosis can be achieved using either a loop colostomy or a LI, although the latter is more common. Stoma-related complications affect up to 30% of patients (9); these include leakage around the appliance, skin rash and excoriation, high output, hernia, retraction, and prolapse (9).

The majority of patients in our study were male. The mean age in our study was 58.2±9.3 years in the LI group and 61.4±9.7 years in the tube ileostomy group, which were similar to those reported by Sheng et al. (7), Bugiantella et al. (8), Attaallah et al. (10) and Hua et al. (11). In a study by Sheng et al. (7), the length of postoperative hospital stay was 11.9±3.2 days (range 8-25), and in a study by Bugiantella et al. (8), the length of postoperative stay was 11.2±1.7 days (range 8-15). In the present study, the mean length of hospital stay after tube ileostomy was 8.30±3.06 days, and after LI was 11.32±1.82 days (p-value <0.05). The total hospital stay for the LI group is longer than for the tube ileostomy group, consistent with the findings reported in the studies mentioned. In a study by Liu et al. (12), the median follow-up was 17 months (range, 3-40 months) during which no bowel obstruction or anastomotic leakage was observed. In another study by Sheng et al. (7), patients were followed up for 17±3.4 months (range, 7-26 months). In the present study, all patients were followed up for six months postoperatively.

Liu et al. (12) reported that the time to first postoperative defecation after tube ileostomy was 13.7±2.1 days (range, 10-19). Bugiantella et al. (8) found that the average time for gas emission through the trans-temporary percutaneous ileostomy was 1.1±0.3 days (range 1-2), and the average time for faecal emission was 1.8±0.9 days (range 1-4). These data were similar to those in our study, in which the time to first anal defecation following tube ileostomy was 4.39±4.67 days (range 5-14 days). This indicates that our tube ileostomy provides a partial fecal diversion lasting 5-14 days and shows that the protective period for a tube ileostomy as a fecal diversion procedure has ended, after which the tube can be removed (9). The time required for ileostomy-site fistulous tract formation was approximately one week after the procedure. Similar results were observed in human studies, in which the timing of tube removal ranged from 7 days to more than 3 weeks postoperatively (7). In the present study, the tube was scheduled for removal on day 21 post-surgery but some were removed earlier because migration complications were suspected.

The data show that the day of tube removal in our study was 18.91±4.26 days, which was similar to Liu et al. (12) [27.8±6.9 (range, 20-44), Sheng et al. (7) [22.6±4.1 (21-28)], Hua et al. (11) (median time 20.5 days), and Attaallah et al. (10) reported balloon deflation and tube removal on postoperative day 21.

Liming Liu et al. (12) reported that the mean duration of continuous tract discharge before the fistula healed was 4.5±1.9 days (range, 2-10 days). Sheng et al. (7) reported that ileostomy wounds closed spontaneously at a mean of 13.1±1.9 days (range, 7-14 days). In our study, the mean time to complete fistula closure was 26.86±5.07 days. One patient experienced a low-output enterocutaneous fistula after tube removal, which was conservatively managed and resulted in closure during the second month of follow-up.

According to the Clavien-Dindo classification, Grades I and II complications were present in both loop- and tube-ileostomy candidates. Still, no grade 4 complications occurred, which was consistent with the findings of Bugiantella et al. (8).

Intestinal obstruction following tube ileostomy may result from blockage of the tube by solid food residue, which may, in turn, occlude the bowel lumen; in both groups, postoperative adhesions can lead to intestinal obstruction. Liu et al. (12) reported that two patients with intestinal obstruction completely recovered with conservative treatment. Bugiantella et al. (8) reported no intestinal obstruction in the early (30-day) postoperative period. None in the current study developed intestinal obstruction.

Nachiappan et al. (3) reported a re-emergence of interest in the use of tube ileostomy to defunction distal anastomoses. Pooled analyses of studies comparing tube ileostomy to LI did not show statistically significant differences in anastomotic leak rates; a similar pattern was observed in our study. In our study, Grade A anastomotic leakage was observed in one tube-and-loop group. It was managed conservatively. One case of abdominal collection requiring percutaneous drainage was recorded in a study by Bugiantella et al. (8). None of our patients developed abdominal collections during the study period. Four cases of peristomal cellulitis were observed and treated with antibiotics in the study by Attaallah et al. (10). In our study, peristomal cellulitis was managed with antibiotics, topical zinc oxide

powder, or application of aluminum paint around the stoma site. In the present study, one patient experienced a low-output enterocutaneous fistula after tube removal, which was managed conservatively and closed by the second month of follow-up. In the present study, one patient with LI developed stomal prolapse that required revision surgery with resection and anastomosis. This is similar to the study by Liu et al. (12), in which one case of stoma prolapse occurred, requiring intervention under general anesthesia. None of the 19 treated patients showed clinical or radiological evidence of anastomotic leakage. One of our patients in the LI group and one in the tube ileostomy group died during the post-discharge follow-up period; both deaths were related to their comorbid conditions.

The selection of a soft thoracic catheter was primarily aimed at reducing pressure-related necrosis associated with endotracheal tube use (6); this necrosis can be highly debilitating and carries a risk of bowel perforation. A limitation of this technique is that it provides only partial diversion. However, no association was observed between the type of ileostomy—loop (complete diversion) or tube (partial diversion)—and the incidence of anastomotic leak. Additionally, none of the patients in either group developed signs of intestinal obstruction post-procedure.

Study Limitations

The study's limitations also include a small sample size (n=88), a single-center design, and a short follow-up period of six months, thereby restricting assessment of long-term quality of life. Self-reported outcomes, such as pain and stoma bag usage, may be subject to bias. Variation in indications, such as emergency versus elective procedures and in underlying pathologies could affect outcomes.

CONCLUSION

Tube ileostomy is a well-established technique for temporary faecal diversion, though it is periodically reassessed. This study demonstrates that self-reversing tube ileostomy can provide superior outcomes compared with conventional LI, including fewer complications, reduced reliance on stoma bags, shorter hospital stays, and avoidance of additional reversal procedures and their associated costs. Renewed interest in this approach stems from the aim to minimise stoma-related morbidity, costs, and care burden, alongside selective evidence of favourable outcomes. These findings highlight the need for further research to clarify its optimal application.

Ethics

Ethics Committee Approval: The study was initiated after obtaining approval from the Institutional Ethics Committee of the Government Medical College, Kozhikode, India (ref no: GMCKKD/RP2021/IEC/191, dated: 16/07/2021).

Informed Consent: Written informed consent was obtained from all patients.

Footnotes

Author Contributions

Concept - S.K.R., J.N.P.; Design - S.K.R., J.N.P.; Data Collection or Processing - A.A.; Analysis or Interpretation - A.A.A., Y.S., I.H.; Literature Search - S.K.R., J.N.P.; Writing - Y.S., I.H.

Conflict of Interest: No conflict of interest was declared by the authors.

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