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**Original Research Article**

# A comparative study between early and conventional intestinal stoma closure in a tertiary care institute

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## ABSTRACT

**Background:** Little is known about ideal time for stoma closure. Therefore, the aim of this study is to compare early versus conventional stoma closure following bowel surgery in terms of quality of life (QoL), length of hospital stay (LoH), and postoperative complications.
**Methods:** This randomized controlled trial was conducted at a medical college affiliated teaching hospital from May 2023 to June 2024. The 116 patients undergoing bowel surgery with temporary stoma creation were randomized into early closure (3 weeks post-surgery) and conventional closure (8-12 weeks post-surgery) groups. Primary outcome was anastomotic leak rate. Secondary outcomes included other postoperative complications, LoH, and QoL assessed using the EORTC QLQ-C30 questionnaire.
**Results:** There was no significant difference in anastomotic leak rates between early (6.9%) and conventional (12.1%) closure groups. Overall complication rates were similar (56.9% early vs 50% conventional). LoH did not differ significantly between groups. QoL scores were significantly higher in the early closure group, with 100% of patients achieving considerable improvement (EORTC score 26-36) compared to 79.3% in the conventional group ($p<0.05$).
**Conclusions:** Early stoma closure is safe and feasible in appropriately selected patients, with no increased risk of anastomotic leak or other complications. It significantly improves QoL compared to conventional closure timing, without prolonging hospital stay. These findings suggest that early stoma closure may be a beneficial option for suitable patients following bowel surgery.

**Keywords:** Stoma closure, Bowel surgery, QoL, Postoperative complications, Randomized controlled trial

## INTRODUCTION

An intestinal stoma is one of the most common surgical procedures, in which exteriorization of either small bowel or large bowel through the anterior abdominal wall is performed. It may be performed for the management of wide ranges of benign and malignant gastrointestinal conditions on an emergency or regular basis. The word stoma or ostomy is derived from the Latin word ostium, which means opening or mouth. The exteriorization of either the small bowel (ileostomy) or large bowel (colostomy) through the anterior abdominal wall is performed.[1]

In spite of the fact that intestinal stoma creation is a procedure which saves live in the care of many gastrointestinal conditions, it's attendant morbidity and mortality have been the subject of many studies.[2,3] Complications following the creation of an intestinal stoma are experienced by 20-70% of the patients and are divided into early complications (up to 30 days after operation) such as ischemia, haemorrhage and infection, and late complications (more than 30 days after

operation) such as stenosis, fistula formation, prolapse, hernia formation, colonic and small bowel obstruction and denuded peristomal skin.[4-6]

The conventional idea of when to close a temporary ileostomy has been the subject of discussion for some time.[7] Thus, the purpose of this study was to compare the QoL, LoH, and frequency of problems after intestinal surgery between early and routine stoma closure to identify the best time for closing this temporary ileostomy.

## METHODS

We conducted this randomized controlled study for 116 patients who underwent stoma closure between May 2023 to June 2024 in the department of general surgery, SMS hospital, Jaipur, Rajasthan. An ethical clearance was obtained from the institutional ethics committee prior to commencing the study. A written informed consent was taken from each patient after informing them the objectives of the study, the risks and benefits, confidential handling of personal information, the voluntary nature of participation and the rights to withdraw from study.

The study comprised patients over the age of eighteen who were hospitalized to the department of surgery at SMS medical college after bowel surgery and had an intestinal stoma. Individuals with end stomas, diabetes/HIV, severe malnourishment, concomitant cancer, steroid treatment, linguistic challenges, and patients with anticipated low compliance were excluded.

After fulfilling inclusion criteria, A predesigned pro forma filled which included socio demographic factors like age, gender, etc. Upon admission to the hospital, a detailed medical history was taken, a clinical examination was conducted, and Each patient were assigned either group A (conventional stoma closure)/ group B (early stoma closure) on basis of systemic random sampling taking every alternate patient in group B.

In early stoma closure group stoma closure was done after 3 weeks of the index surgery. As majority of the patients underwent emergency surgical procedures for the index surgery, early closure of stoma was not carried out within the same admission. Because of this, most patients were readmitted following stabilization in order to have their stomas closed. While in conventional group the closure of temporary stoma was carried out as per unit protocol in our hospital ranging from 8 weeks to 12 weeks.

Both groups' QoL was evaluated using the EORTC QLQ-C30 (European organization for research and treatment of cancer QoL questionnaire, version 3.0). Due to logistical concerns, only symptomatic grading was done. Nine elements total, including thirteen questionnaires, were scored between one and four. For three of the nine items, several questionnaires were used for assessment; the average score was then used for additional computation. The symptoms were scored on a scale from 9 to 36 overall. By grouping the entire score into two categories, the quality improvement was evaluated. Six weeks after index surgery, both groups' patients completed the questionnaire as part of a standard evaluation process for stoma closure.[8,9]

## RESULTS

A total of 116 subjects were included in the study. Among 116, 58 belonged to conventional stoma closure group and other 58 belonged to early stoma closure group. Majority i.e., 28 (48.3%) in conventional group belonged to 20-30 years age group and in early group majority i.e., 31 (26.7%) belonged to 41-50 years age group. There was significant difference in age distribution between the groups ($p<0.05$). In conventional group, majority i.e., 40 (69%) were males and 18 (31%) were females. In early group, majority i.e., 34 (58.6%) were males and 24 (41.4%) were females. There was no significant difference in gender distribution between the groups ($p>0.05$). There was no significant difference in distribution of hypertension; smoking habits, alcohol consumption between the groups ($p>0.05$) (Table 1).

Preoperative biochemical parameters were compared between the groups but there was no significant difference in haemoglobin level; total protein levels as well as albumin level between the groups ($p>0.05$) (Table 1).

The 13 (22.41%) in conventional group and 8 (13.8%) in early group had stoma closure following colostomy.42 (72.42%) in conventional group and 46 (79.31%) in early group had stoma closure following ileostomy. Three (5.17%) in conventional group and 4 (6.89%) in early group had stoma closure following jejunostomy. There was no significant difference in type of stoma closure between the groups ($p>0.05$) (Table 1).

The 42 (72.4%) in conventional group and 40 (69%) in early group were operated under general anaesthesia. 16 (27.6%) in conventional group and 18 (31%) in early group were operated under spinal anaesthesia. There was no significant difference in type of anaesthesia between the groups ($p>0.05$). Intraoperative time was noted where it was <120 minutes in 34 (58.6%) in conventional group and 31 (53.4%) in early group; in 15 (25.9%) in conventional group and 16 (27.6%) in early group were operated for 120-240 minutes in 9 (15.5%) in conventional group and 11 (19%) in early group were operated for >240 minutes. There was no significant difference in operating time between the groups ($p>0.05$). Intraoperative bleeding was noted in 9 (15.5%) of the conventional group and 16 (27.6%) of the early group with no significant differences between the groups. Four patients (6.9%) in the early group and 6 patients (10.3%) in the conventional group underwent midline

laparotomies, with no significant difference in conversion rates (p>0.05) (Table 1).

**Table 1: Comparison of general characteristics of study population in the early and conventional stoma closure groups.**

| Parameters | Conventional stoma closure group, n=58 (%) | Early stoma closure group, n=58 (%) | P value |
|---|---|---|---|
| **Age distribution (in years)** | | | |
| 20-30 | 28 (48.3) | 4 (6.9) | <0.001 |
| 31-40 | 10 (17.2) | 8 (13.8) | |
| 41-50 | 10 (17.2) | 21 (36.2) | |
| 51-60 | 8 (13.8) | 19 (32.8) | |
| 61-70 | 2 (3.4) | 6 (10.3) | |
| **Gender distribution** | | | |
| Male | 40 (69) | 34 (58.6) | 0.334 |
| Female | 18 (31) | 24 (41.4) | |
| **Hypertensive** | | | |
| | 12 (20.7) | 19 (32.8) | 0.208 |
| **Personal habits** | | | |
| History of smoking | 17 (29.3) | 13 (22.4) | 0.525 |
| History of alcohol | 25 (43.1) | 19 (32.8) | 0.339 |
| **Biochemical parameters** | | | |
| Hemoglobin (>8 gm/dl) | 45 (77.6) | 45 (77.6) | 1.000 |
| Total protein (>8 gm/dl) | 40 (69) | 43 (74.1) | 0.681 |
| Albumin (>3.5 gm/dl) | 29 (50) | 29 (50) | 1.000 |
| **Operating time** | | | |
| <120 mins | 34 (58.6) | 31 (53.4) | 0.831 |
| 120-240 mins | 15 (25.9) | 16 (27.6) | |
| >240 mins | 9 (15.5) | 11 (19) | |
| **Type of stoma closure** | | | |
| Jejunostomy | 3 (5.2) | 4 (6.9) | 0.430 |
| Ileostomy | 42 (72.4) | 46 (79.3) | |
| colostomy | 13 (22.4) | 8 (13.9) | |
| **Type of anesthesia** | | | |
| General | 42 (72.4) | 40 (69) | 0.683 |
| Spinal | 16 (27.6) | 18 (31) | |
| **Peri operative complications** | | | |
| Bleeding | 9 (15.5) | 16 (27.6) | 0.743 |
| Conversion to midline laparotomy | 6 (10.3) | 4 (6.9) | |

Regarding post-surgical complications follow-up: Overall, 33(56.9%) patients in the conventional group and 29 (50%) patients in the early group experienced complications which did not significantly differ between the groups. 10 (17.2%) in the conventional group and 7 (12.1%) in the early group experienced intra-abdominal collection; 7 (12.1%) in the conventional group and 4 (6.9%) in the early group experienced anastomotic leak; 12 (20.7%) in the conventional group and 15 (25.9%) in the early group experienced wound infection. Complications from stomas were seen in 3 (5.2%) of the early group and 6 (10.3%) of the conventional group. The distribution of the complications between the groups did not significantly differ (p>0.05). Zero deaths were observed in both the groups (Table 2).

**Table 2: Comparison of post-operative complications in patients between early and conventional stoma closure groups.**

| Post-operative complications | Conventional stoma closure group, n=58 (%) | Early stoma closure group, n=58 (%) | P value |
|---|---|---|---|
| **Surgical complications** | | | |
| Wound infection | 12 (20.7) | 15 (25.9) | 0.661 |
| Intra-abdominal collection | 10 (17.2) | 7 (12.1) | 0.601 |
| Anastomotic leak | 7 (12.1) | 4 (6.9) | 0.528 |
| **Medical complications** | | | |
| Stoma related complications | 6 (10.3) | 3 (5.2) | 0.490 |
| Deep vein thrombosis | 3 (5.2) | 2 (3.4) | 1.000 |
| Pneumonia | 5 (8.6) | 2 (3.4) | 0.438 |
| Urinary tract infections | 4 (6.9) | 1 (1.7) | 0.364 |
| Overall complications | 33 (56.9) | 29 (50) | 0.577 |
| Overall deaths | 0 (0) | 0 (0) | |

The 36 (62.1%) of the early group and 38 (65.5%) of the conventional group spent less than 10 days in the hospital. Three (5.2%) on the early group and 3 (5.2%) of the conventional group spent more than 20 days in the hospital. For 10-20 days, 17 (29.3%) in the conventional group and 19 (32.8%) in the early group were hospitalized. Between the groups, there was no significant difference in the distribution of hospital stays' duration (p>0.05) (Table 3).

**Table 3: Comparison of length of hospitalization between early and conventional stoma closure groups.**

| LoH (days) | Conventional stoma closure group, n=58 (%) | Early stoma closure group, n=58 (%) | P value |
|---|---|---|---|
| **<10** | 38 (65.5) | 36 (62.1) | 0.948 |
| **10-20** | 17 (29.3) | 19 (32.8) | |
| **>20** | 3 (5.2) | 3 (5.2) | |

In the conventional group 12 (20.7%); and in the early group, none had an EORTC QOL score in the 16-25 range. The 58 (100%) of the early group and 46 (79.3%) of the conventional group had EORTC QOL scores between 26 and 36. The groups' EORTC QOL score distributions differed significantly from one another ($p<0.05$) (Table 4).

**Table 4: EORTC QoL scores among study subjects.**

| EORTC QoL scores | Conventional stoma closure group, n=58 (%) | Early stoma closure group, n=58 (%) | P value |
|---|---|---|---|
| **16-25** | 12 | 0 | <0.0001 |
| **26-36** | 46 | 58 | |

## DISCUSSION

In this RCT we compared post operative complications, length of hospitalization, and QoL between early and conventional stoma closure. Early stoma closure had significant improvement in the QoL as compared to conventional group.

In this study Majority in conventional group belonged to 20-30 years age group and in early group majority belonged to 41-50 years age group with statistical significance between the two groups. But there was no significant difference in gender distribution between the groups. Research by Nelson et al and Alves et al where gender distribution showed no significant difference, which was similar to this study, and also the median age in the conventional stoma closure group and early group were equivalent.[10,11]

When preoperative comorbidities and personal habits were evaluated in the two groups, it was discovered that the distribution in the groups did not differ significantly. The levels of albumin and haemoglobin in the two groups were likewise similar to research by Nelson et al and Alves et al.[10,11] The groups did not significantly differ in terms of anaesthesia type or operation duration. Furthermore, it was congruent with a study by Nelson et al and Alves et al that found no discernible variation in the types of anaesthesia across the groups as well as operation duration.[10,11]

In this study, 13 (22.41%) in conventional group and 8 (13.8%) in early group had stoma closure following colostomy. The 42 (72.42%) in conventional group and 46 (79.31%) in early group had stoma closure following ileostomy. The 3 (5.17%) in conventional group and 4 (6.89%) in early group had stoma closure following jejunostomy. There was no significant difference in type of stoma closure between the groups. Nelson et al found that 2% of the conventional group and none of the early group had stoma closure following jejunostomy, and that there was no discernible difference in the type of stoma closure between the groups.[10] Additionally, 50% of the conventional group and 36% of the early group had stoma closure following colostomy; 46% of the conventional group and 64% of the early group had stoma closure following ileostomy.

Additionally, there was no discernible difference in per operational complications between the two groups in this study. Similar to this study, Nelson et al found that there was no significant difference in the distribution of bleeding across the groups, with 16% of the standard group and 26% of the early group reporting bleeding.[10] The results of our investigation aligned with a study conducted by Alves et al which found that the intra-operative blood loss was comparable for both groups.[11]

In this study, 4 (6.9%) of the early group and 6 (10.3%) of the conventional group underwent midline laparotomy conversion. The distribution of conversions to midline laparotomies did not differ significantly between the groups. Similar to this study, a study by Nelson et al found that the distribution of conversion to midline laparotomy did not significantly differ across the groups (8% in the early group and 10% in the standard group).[10] The results of our investigation aligned with a study conducted by Alves et al which found that the two groups' conversion rates to midline laparotomies were similar.[11]

There were no differences in post-operative complications between the two groups, consistent with the findings of the Nelson et al study, which showed that 14% of the early group and 18% of the conventional group encountered intra-abdominal collection and wound infection.[10] Contrary to this study, Alves et al demonstrated that intra-abdominal collection occurred in 2% of the conventional closure group and not in any of the early closure groups, and surgical site infection more common in the early closure group (19%) than in the delayed closure group (5%).[11] The primary outcome in this study was to compare the anastomotic leak between the two groups which was found to be comparable between the early and conventional stoma closure. Velmahos et al showed that early closure was not found to pose a risk of anastomotic leak.[12]

In contrast to this study, Alves et al found that early closure was linked to decreased rates of medical problems (such as DVT, pneumonia, UTI, and stoma-related morbidity).[11] There were no deaths reported in either group during this trial. This was comparable to research conducted by Nelson et al.[10]

To compare the hospital duration between early and conventional stoma closure no significant difference was found where 38 (65.5%) in conventional group and 36 (62.1%) in early group stayed in hospital for <10 days; 3 (5.2%) in conventional group and 3 (5.2%) in early group stayed in hospital for >20 days; 17 (29.3%) in conventional group and 19 (32.8%) in early group stayed in hospital for 10-20 days. In a study by Nelson et al 60% in conventional group and 70% in early group stayed in hospital for <10 days; 2% in conventional group and 4% in early group stayed in hospital for >20 days; 38% in

conventional group and 26% in early group stayed in hospital for 10-20 days and there was no significant difference in distribution of LoH between the groups which was similar to this study.[10] Menegaux et al showed that median hospital stay was significantly longer in conventional closure group (36 days) than in early closure group (22 days) which was different form this study.[13] Similarly, Alves et al also reported that total hospital stay was significantly longer in the conventional group than in the early group [18 (9-262) days v/s 16 (6-59) days].[11]

In this study, 12 (20.7%) in conventional group and none in early group had EORTC QOL score between 16-25 (improved). The 46 (79.3%) in conventional group and 58 (100%) in early group had EORTC QOL score between 26-36 (considerably improved). There was significant difference in distribution of EORTC QOL score between the groups. ($p<0.05$) with significantly higher scores in early closure group. In a study by Nelson et al 12% patients in conventional closure group had symptom scores between 16 and 25 (improved) in contrast to none of them in early closure group which was consistent with this study.[10]

The 100% patients in early closure group and 44 (88%) patients in conventional closure group had scores between 26 and 36 (considerably improved) and the difference between the two groups was statistically significant, with a $p=0.027$. This was similar to the present study. Alves et al observed that QoL score was comparable between early and late closure groups [99 (32-142) v/s 102 (22-142)] using gastrointestinal QoL index which was different from this study.[11]

### *Limitations*

Study was carried out in a non-homogeneous population and that the ileostomy and colostomy groups were not considered separately. The sample size of the study was relatively small, which may affect the generalizability of the findings. The study didn't account for potential confounding factors such as surgeon's experience and variation in surgical technique. The study was conducted at single centre, which may limit the applicability of the results to other settings.

## CONCLUSION

In conclusion, with the right patient selection, early stoma closure is both safe and possible. There is no higher risk of bleeding, anastomotic leak, midline laparotomy requirement, or adverse medical events. In addition to improving QoL, early stoma closure significantly lowers the cost of stoma care.

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