Early versus conventional stoma closure following bowel surgery: A randomized controlled trial

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Abstract

Background/Aim: To compare early stoma closure with conventional stoma closure following defunctioning diversion stoma surgery with respect to the frequency of complications, health-related quality of life (QoL), and length of hospitalization (LoH).

Patients and Methods: This study was designed as a prospective parallel-arm randomized controlled trial. Patients who underwent temporary stoma following bowel surgery between February 2014 and November 2015 were included. The rate of complications (medical and surgical) following early and conventional stoma closure was assessed. Health-related QoL and LoH were also measured.

Results: One hundred patients were included, with 50 cases in each group. Postoperative complications including laparostoma (6% vs. 2%; $P = 0.307$), wound infection (32% vs. 18%; $P = 0.106$), intra-abdominal collection (14% vs. 18%; $P = 0.585$), anastomotic leak (4% vs. 8%; $P = 0.400$), and medical complications were comparable (22% vs. 32%; $P = 0.257$). The length of hospital stay, overall mortality and morbidity (64% vs. 44%; $P = 0.05$) were similar across the two groups. There was a significant reduction in the cost towards stoma care (96% vs. 2%; $P = 0.001$) in the early stoma closure group. Patients in the early stoma closure group also had a significantly better QoL.

Conclusion: Early stoma closure does not carry an increased risk of postoperative complications, reduces cost towards stoma care, and leads to better a QoL.

Keywords: Early stoma closure, length of hospitalization, quality of life

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INTRODUCTION

A defunctioning stoma is used primarily to protect the anastomosis and prevent pelvic sepsis after bowel surgery.[1-4] A Cochrane review reported that temporary ileostomy is associated with fewer anastomotic leakages.[5] Matthiesen *et al.* reported that a defunctioning stoma reduces the need for urgent reoperation.[6] Stoma closure is usually performed after 8–12 weeks. However, quality of life (QoL) is affected due to stoma-related complications during this time period.[7-14]

Early closure of temporary stoma might reduce both stoma-related morbidity and patient discomfort. Alves *et al.* reported that reversal of temporary stoma 8–10 days after surgery is feasible; however, with higher wound complications.[15] Other studies have also found that

outcome did not differ significantly between early and late stoma closure regarding morbidity and mortality.[16-18]

Restoration of intestinal continuity is generally associated with a low mortality.[19] However, stoma reversal may cause major complications ranging from 0% to 9% and minor complications varying from 4% to 30%, requiring reoperation.[16]

The reports on early versus conventional stoma closure are conflicting.[20-22] Hence, this study was conducted to compare early and conventional stoma closure following bowel surgery in terms of frequency of complications, length of hospitalization (LoH), and QoL.

PATIENTS AND METHODS

The study was carried out in the Department of Surgery in a tertiary care hospital in South India, between February 2014 and November 2015. Ethics committee approval was obtained for the study. The nature, methodology, and risks involved in the study were explained to patients and informed consent was obtained. All information collected was kept confidential and patients were given full freedom to withdraw at any point during the study. All provisions of the Declaration of Helsinki were followed in this study.

The primary objective was to compare the rate of complications following early and conventional stoma closure. LoH, health related QoL, and cost towards stoma care were also studied in both groups. All consecutive patients between the ages of 18 years and 70 years who underwent temporary stoma following bowel surgery both in elective and emergency setting, irrespective of the indication for primary surgery were included in the study.

Patients in whom emergency stoma revision was done for necrosis or gangrene, those with evidence of sepsis or organ failure in the postoperative course, any radiological signs of primary anastomotic leak evident on water soluble contrast examination before stoma closure, and patients with poor nutritional status (Hb <8 g%, Albumin <2.5 g%) were excluded from the study. Patients with one or more comorbidities like diabetes, hypertension, and others were stabilized well before the stoma closure surgery.

Early stoma closure: This group comprised of those in whom stoma closure was done between 14 days and 28 days following 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. Hence, majority of patients were readmitted after stabilization for stoma closure.

Conventional stoma closure: This group comprised of those in whom the closure of temporary stoma was carried out as per unit protocol in our hospital ranging from 8 weeks to 12 weeks. The sample size for noninferiority design was calculated to be 50 considering the alpha error of 5%, power of 80%, and dropout rate of 10%.

The study was designed as a prospective parallel arm randomized controlled trial, with an allocation ratio of 1:1. All patients were assessed for eligibility at the end of 2 weeks following index surgery by biochemical, radiological, and clinical assessment. Randomization was then carried out using computer generated random numbers. Block randomization was done using computer program with randomly selected block sizes of 4 and 6. Allocation concealment was ensured by serially numbered opaque sealed envelope (SNOSE) technique.

The EORTC QLQ-C30(European Organization for Research and Treatment of Cancer Quality of Life Questionnaire) version 3.0 was used for assessment of QoL in both groups. Only symptomatic scoring was carried out due to logistical issues, assessing nine items including thirteen questionnaires, where the scoring ranged from 1 to 4. Three of the nine items were assessed using more than one questionnaire where the average score was taken for further calculation. The total score for symptoms ranged from 9 to 36. The improvement in quality was assessed by categorizing the total scoring into three groups. The questionnaire was applied at 6 weeks following index surgery in both groups during which time the patients were routinely assessed for stoma closure.[23,24]

Being a public-sector institution, the treatment in our hospital is provided free of cost. The income ceiling for free treatment in our hospital is $23 (average monthly income of the patient profile coming to the hospital), which was taken as a cut-off for calculating the cost burden to the patient towards stoma care.

Self-reported smoking status was noted using a questionnaire. Frequency and quantity of tobacco product used was collected.[25] Alcohol consumption among participants was measured using WHO STEPS (World Health Organization STEPwise approach to surveillance of noncommunicable diseases) questionnaire.[26]

Closure of temporary stoma was performed under general/spinal anesthesia with a peristomal skin incision, mobilization, and a sutured anastomosis by hand-sewn interrupted technique in two layers using polyglactin 2-0 for inner layer, and Silk 2-0 for outer seromuscular layer as routine practice. Stapled anastomosis was done in very few cases considering the cost factor.

Intraoperative complications were recorded in both groups including significant blood loss and conversion to midline laparotomy. Blood loss during stoma closure was categorized as "not significant" when it was less than or equal to 150 mL, and "significant" when it was more than 150 mL. Patients were assessed for blood loss and the number of patients who had significant blood loss was compared between both groups.[27] Duration of surgery was calculated from the start of skin incision till skin closure. Stratification of complications was done by Clavien-Dindo system of classification.[28]

Postoperative management was done as per unit protocol. Postoperatively, patients were given analgesic injection for 2–3 days followed by oral analgesics. Nasogastric tube was removed once the output was less than 300mL usually on third postoperative day (POD). Supplementary intravenous (IV) fluids were given till start of oral fluids. Oral fluids was started at fourth to fifth POD in majority of patients and resumption of normal diet ranges from 5 days to 7 days postoperatively. Intravenous antibiotics were given for 5 days postoperatively as routine protocol. Patients were monitored for vomiting, abdominal distension, length of ileus, tolerance of regular diet, and evidence of anastomotic leak.

The average duration of stay in patients undergoing stoma closure in our institute was 10 days based on previous records. Patients were admitted a day prior to the scheduled surgery in both groups. Assessment of LoH hence was categorized into three groups including those who stayed for less than 10 days, between 10 days and 20 days and who stayed more than 20 days to measure the impact of early vs. conventional closure on LoH.

Surgical complications such as wound infection, laparostoma, intra-abdominal collection, anastomotic leak, and medical complications such as deep vein thrombosis, urinary tract infection, pneumonia, and other stoma-related complications were analyzed in this study. From these parameters, the overall complication rate was calculated as the frequency of complications in each group. Patients were called for follow-up at 4 weeks and at third month following stoma closure surgery.

Statistical analysis

The difference in the proportion of surgical and medical complications between two groups was tested using Chi-square test. LoH was compared using Mann-Whitney test. Categorical variables like gender, comorbid conditions, Clavien-Dindo grade, etc., were assessed using Chi-square test. QoL was assessed using modified EORTC questionnaire which was analyzed by Fisher's exact test. A P value of less than 0.05 was considered as statistically significant.

Considering the dropout rate of 10%, per protocol analysis and intention-to-treat analysis was planned during research protocol.

RESULTS

A total of 100 patients were included in the study and prospectively randomized to early stoma closure group (50 cases) and conventional stoma closure group (50 cases). The schematic representation of patient allocation and analysis in the study was done according to CONSORT standards [Figure 1].

The distribution of age, gender, comorbidities, personal habits, biochemical parameters, and operating times were comparable across the two groups. In early closure group, 14 (28%) patients (5 diabetes mellitus [DM], 7 hypertension [HTN], 2 both) had comorbidities whereas in conventional closure group, it accounted for 10 (20%) patients (4 DM, 4 HTN, 2 both [Table 1].

During the period of study and follow-up, there were no unexpected complications or harms to the subjects. The median time to closure of ostomy in early closure group was 16 days whereas in conventional closure group, it was 86 days.

The majority of the patients underwent emergency index surgery in both groups, accounting to 41 cases (82%) in early stoma group and 33 (66%) in conventional stoma group with a statistically insignificant difference. The two groups are comparable with respect to ileostomy and colostomy cases ($P = 0.068$).

Acute intestinal obstruction (23 cases, 46%), and malignancy (7 cases, 14%) were the commonest indication for index surgery in early and conventional closure groups respectively. Other indications for index surgery were blunt trauma, ileal perforation, intestinal tuberculosis, rectovaginal fistulae, etc.

Out of 100 cases included in the study, 13 cases (26%) had significant bleeding (>150mL) intraoperatively
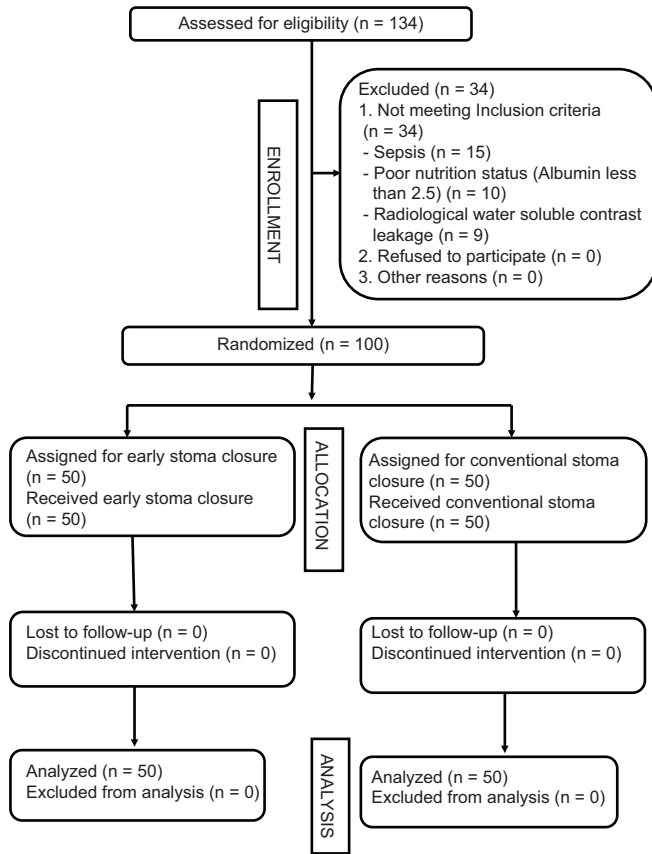
Figure 1: CONSORT flowchart representing patient allocation and analysis

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

Parameters	Early stoma closure group N=50(%)	Conventional Stomaclosure group N=50(%)	P
Age Distribution			
<30	10 (20.0)	7 (14.0)	0.603
31-40	18 (36.0)	20 (40.0)	
41-50	7 (14.0)	11 (22.0)	
>51	15 (30.0)	12 (24.0)	
Gender Distribution			
Male	32 (64.0)	29 (58.0)	0.539
Female	18 (36.0)	21 (42.0)	
Co-morbidities (HTN, DM)*	14 (28.0)	10 (20.0)	0.354
Personal Habits			
History of smoking	11 (22.0)	8 (16.0)	0.444
History of alcohol	9 (18.0)	10 (20.0)	0.799
Biochemical Parameters			
Hemoglobin (>8 gm/dl)	43 (86)	44 (88)	0.766
Total protein (>8 gm/dl)	19 (38)	19 (38)	1.000
Albumin (>3.5 gm/dl)	29 (58)	30 (60)	0.839
Operating Time			
<120 min	29 (58.0)	29 (58.0)	1.000
120-240 min	16 (32.0)	16 (32.0)	
>240 min	5 (10.0)	5 (10.0)	
Type of stoma closure			
Ileostomy closure	32 (64.0)	23 (46.0)	0.060
Colostomy closure	18 (36.0)	25 (50.0)	
Jejunostomy closure	0 (0.0)	2 (4.0)	
Type of Anesthesia			
General	37 (74.0)	34 (68.0)	0.509
Spinal	13 (26.0)	16 (32.0)	
Peri-operative Complications			
Bleeding	13 (26.0)	8 (16.0)	0.220
Conversion to midline laparotomy	4 (8.0)	5 (10.0)	0.727

*HTN – Hypertension, DM –Diabetes Mellitus

during early stoma closure and eight cases (16%) had the same intraoperatively during conventional stoma closure ($P = 0.220$). Even though wound infection was comparatively higher in early closure group (32% vs. 18%; $P = 0.106$), although the difference was not statistically significant. Overall morbidity rate was found to be 64% in early closure group and 44% in conventional closure group, with a statistically insignificant difference [Table 2]. LoH was found to be comparable between early closure and conventional closure groups [Table 3].

The distribution of complications across the two groups by Clavien-Dindo classification showed that most of them belonged to Grade 1 [Figure 2].

Expenditure incurred towards stoma care was analyzed between both groups. Forty eight (96%) patients who had an early closure and one patient (2%) who had conventional closure, had spent less than $23 for stoma care. Expenditure towards stoma care was high (exceeding $23) for 49 cases (98%) in conventional stoma closure group, whereas only two cases (4%) had exceeded this sum in early closure group ($P < 0.001$).

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

Post-operative Complications	Earlystoma closure group N=50 (%)	Conventional stomaclosure group N=50 (%)	P
Surgical Complications			
Laparostoma	3 (6.0)	1 (2.0)	0.307
Wound Infection	16 (32.0)	9 (18.0)	0.106
Intra-abdominal collection	7 (14.0)	9 (18.0)	0.585
Anastomotic Leak	2 (4.0)	4 (8.0)	0.400
Medical Complications			
Stoma related complications	2 (4.0)	3 (6.0)	0.257
Deep vein thrombosis	2 (4.0)	3 (6.0)	
Pneumonia	1 (2.0)	4 (8.0)	
Urinary tract infection	0 (0)	3 (6.0)	
Others	6 (12.0)	3 (6.0)	
Overall complications	32 (64.0)	22 (44.0)	0.05
Overall deaths	0 (0)	0 (0)	

QoL between both groups was compared using modified EORTC questionnaire. None of the patients in the study had symptom scores ranging between 9 and 15

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

Length of hospital Stay	Early stoma closure group *N*=50(%)	Conventional stoma closure group *N*=50(%)	*P*
<10 days	35 (70.0)	30 (60.0)	0.398
10-20 days	13 (26.0)	19 (38.0)	
>20 days	2 (4.0)	1 (2.0)	
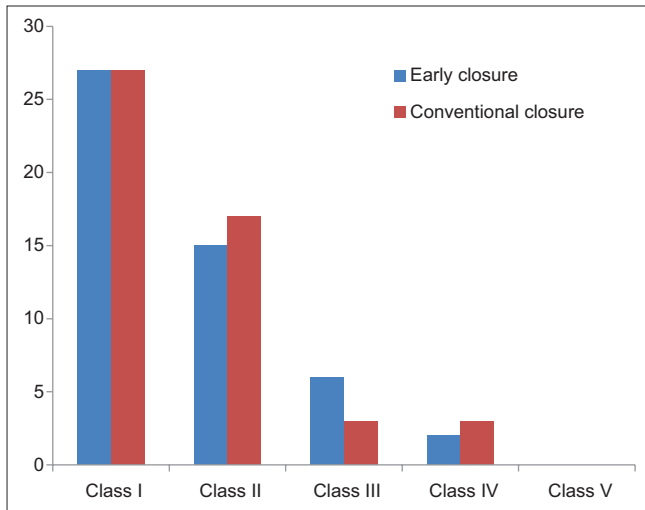
Figure 2: Distribution of complications by the Clavien-Dindo Classification across early and conventional stoma closure groups

(not improved). Six (12%) patients in conventional closure group had symptom scores between 16 and 25 (improved) in contrast to none of them in early closure group. All (100%) patients in early closure group and 44 (88%) patients in conventional closure group had scores between 26 and 36 (considerably improved). The difference between the two groups was statistically significant, with a *P* value of 0.027.

In all cases, intention-to-treat analysis was done, with the denominator being the original number of subjects recruited in the study as there were no loss to follow-up. No serious adverse events occurred during the follow-up period.

DISCUSSION

Stoma closure is conventionally performed between 8 weeks and 12 weeks following the index operation. Some studies have shown that early stoma closure is feasible and reduces morbidity and improves QoL.[16-18] Omundsen *et al.* found a 23% increase in overall complications in early closure group (63% vs. 40%).[29] Based on our previous records, the overall morbidity in conventional stoma closure was 40%.

In the present study, it was found that the rate of complications and LoH were comparable across early and conventional stoma closure groups. However, early closure group reported a significant improvement in QoL scores and a reduction in cost towards stoma care. In a study from Spain, majority of the patients were operated electively.[30] However, in our study, majority of patients in both groups underwent index surgery in emergency. In the present study, there is no significant difference in operating time between early closure group and conventional closure group. Comparable intraoperative blood loss and a similar number of conversion to laparotomy in both groups confirm the technical feasibility of early stoma closure and shows that early closure can be undertaken without additional operative morbidity. Similar findings were recorded by a previous study from France.[15]

In our study, the most common postoperative surgical complication is wound infection which is comparatively higher in early closure group (32% vs. 18%). However, the difference was not statistically significant. Similarly, Alves *et al.* showed that surgical site infection was significantly common in early closure group (19%) than in delayed closure group (5%).[15] The second most common complication in the present study is intra-abdominal collection, which is comparable between both groups. Velmahos *et al.* also showed that early closure was not found to pose a risk of anastomotic leak.[21] Postoperative medical complications and other surgical complications were also comparable between both groups in the present study. Moreover, most cases with surgical complications belonged to grade 1 of Clavien-Dindo classification system.[28] No previous study used this standard classification system in analyzing surgical complications between early and conventional stoma closure groups. There was no mortality observed in this study.

Menegaux *et al.* showed that median hospital stay was significantly longer in conventional closure group (36 days) than in early closure group (22 days).[31] In the present study, LoH remained comparable between both groups, indicating that early closure is feasible with no additional cost towards hospital care. The overall morbidity rate was also comparable between early (64%) and conventional stoma closure group (44%), similar to the results found in a previous study.[15] In the present study, QoL has been considerably improved in early closure group which is indicated by the symptom scores of the modified EORTC questionnaire.[23,24] However, Alves *et al.* observed that QoL score was comparable between early and late closure groups using gastrointestinal QoL index.[15]

Studies which compared early closure carried out the stoma closure within the same hospital admission following index

operation.[15,31] As majority of the patients in the present study underwent emergency surgical procedures for the index operation, early closure of stoma was not carried out within the same admission to allow the recovery of patients from their initial disease pathology. Patients were optimized before stoma closure and closure was carried out at the earliest possible elective operating time.

Our study has a few limitations. It was conducted in a non homogeneous population, i.e. ileostomy and colostomy groups were not considered separately. Also, there was no specific cut-off for early stoma closure; it was taken as a range between 14 days and 28 days. Only the cost of stoma care (stoma bags, etc.) was analyzed in the study. Total healthcare cost for the patient could not be analyzed as it was conducted in a public-sector hospital. Also, QoL was assessed subjectively and not objectively in this study.

CONCLUSION

In conclusion, early stoma closure is safe and feasible when patients are selected appropriately. It does not carry an increased risk of bleeding, need for midline laparotomy, anastomotic leak, or medical complications. However, further randomized controlled trials with a larger homogeneous population and further stratification of analysis into ileostomy and colostomy groups are required to confirm and appropriately interpret our findings.

Early stoma closure also improves the QoL with considerable reduction in cost towards stoma care.

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Conflicts of interest
There are no conflicts of interest.

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