

# Outcomes of Early Versus Late Reversal in Patients with Loop Ileostomy Formation Secondary to Typhoid Perforation

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## ABSTRACT

**Objective:** To assess if there is significant risk associated with early reversal of stomas (less than 6 weeks) when compared to a delayed closure in the setting of a Tertiary Care Hospital in Karachi.

**Study design:** Observational longitudinal study

**Study place and duration:** Dow University, Karachi 6 months 1st April 2022 till 1st September 2022

**Methods:** Pre- and post-operative data were collected for 50 patients assigned to each group respectively. The parameters assessed were the American Society of Anesthesiologists (ASA) grade, Surgery duration, Post-operative and Overall Hospital Stay, Surgical and Medical complications and day of occurrence, Clavein-Dindo Classification, and mortality.

**Results:** Significant variance in ASA Grade was noted between the two groups, P-Value=0.005 with a lower grade observed in patients who underwent early closure. The post-operative and total hospital stay showed significant variation, with P-values of 0.011 and 0.011, respectively for both outcomes. The incidence of post-operative complications was also significant with p-value=0.004. The median day at which post-operative complication occurred was 4.5 vs 3 days with a significant p-value of 0.038.

**Conclusions:** Late closure is associated with a significantly higher risk of complications and a resultant greater length of hospital stay.

**Keywords:** Ileostomy, stoma, intestinal perforation, and typhoid.

## INTRODUCTION

A stoma is a surgically created opening on the abdomen linked to the digestive or urinary tracts and serves as a diversion to expel urinary or fecal contents outside the body<sup>1</sup>. The most common indications leading to stoma formation are colorectal and bladder cancers, Inflammatory Bowel Diseases, and accidental injury<sup>2</sup>. An ileostomy is a surgical procedure in which the lumen of the ileum, a part of the small intestine, is used to form the stoma. In regions where intestinal perforation secondary to typhoid is a usual complication, loop ileostomy is opted for in complicated cases as a contemporary route of fecal diversion<sup>3</sup>. A loop ileostomy is performed to bypass intestinal content to the exterior in the setting of distal colorectal anastomosis<sup>4</sup>.

Typhoid is a systemic bacterial infection spread via the fecal-oral route through contaminated food or water, causative of the gram-negative bacterium *Salmonella Enterica* subspecies Typhi<sup>5</sup>. It mandates a diverse clinical course with fever being the epitome of the illness, usually accompanied by generalized abdominal pain and nausea. Constipation may be a primal sign, with the emergence of diarrhea also being reported later in the course. Commonly deduced physical examination findings illustrate a slightly distended and tender abdomen with focal pain in the right iliac fossa. A skin rash over the abdomen and chest, also denoted as a rose spot owing to its color, is an occasional finding. While the illness is occasionally self-relenting and subsides on optimal medication, complications may arise with complete neglect of treatment. As assessed by Marchello et al., the most prevailing typhoid-related complication of the gastrointestinal tract was reported to be intestinal perforation between 1965-2018 across Asia, America, Oceania, and the Americas. This was followed by gastrointestinal hemorrhage and hepatitis<sup>6-8</sup>.

A loop ileostomy is generally reversed later to restore the small bowel's physiological functioning. Complications pertaining to the stoma and the associated small intestine,

amalgamating as stomal necrosis, small bowel obstruction, prolapse, among others, and further inadequacies posed by leakage, skin irritability, and other cosmetic features play a substantial role in the timely reversal of stoma. This association with a range of qualitative impacts on lifestyle and the current 8-10 weeks window before the closure is considered linked to a greater degree of patient morbidity and stoma-related complications<sup>9,10</sup>. The purpose of this study was to assess if there is significant risk associated with early reversal of stomas (less than 6 weeks) when compared to a delayed closure in the setting of a Tertiary Care Hospital in Karachi.

## METHODS

This study is an observational longitudinal study. It was approved by the Institutional Review Board of Dow University, Karachi, Pakistan, and data was accessed after the de-identification of the records. The patients' medical records were designated serial numbers to mask their identity, and collected data were stored in password-protected software, only being made available to the principal investigator.

Patients who underwent ileostomy secondary to intestinal perforation due to Typhoid fever was assessed throughout the preoperative workup with a detailed history obtained and synchronized with previous records. The patient was moved to the Operation Theatre after an assessment of medical fitness and an anesthetist examination. The procedures must be performed by a consultant surgeon having at least five years of experience and under general anesthesia. As per the hospital's protocol, post-operative patients must be kept under observation for a minimum of 6-7 days until they are stable and able to feed orally. Patients were followed up weekly for two weeks for surgical or medical complications. The data was collected from the Department of General Surgery, Civil Hospital, from 6 months after acquiring permission from the IRB Department, Dow Medical College. The records of the

patients were scrutinized for relevant data; baseline parameters assessed incorporated the gender, age, smoking status, hemoglobin levels, surgery time, and any co-morbidities present in the patient. The parameters included in the assessment were the American Society of Anesthesiologists (ASA) grade (Grade of 1-6), Surgery duration, Post-operative Hospital stay, Overall Hospital Stay, Surgical and Medical complications before discharge and at follow-up, Post-operative day at which complications occurred, Clavein-Dindo Classification (Grade I-V), and mortality. The most notable surgical complications analyzed were wound infection, anastomotic leakage, intra-abdominal collection and paralytic ileus, while noteworthy medical complications encompassed Urinary Tract Infections (UTIs), Pneumonia, and Deep Vein Thrombosis (DVT). The data was only analyzed for patients who met the pre-requisites to the study already established at the time of gaining IRB approval and was not altered to cater to any patient non-compliant with the criteria. This was to minimize the reporting bias in our study. Thus, data of patients who consented to their information being incorporated into the study was utilized. The patients must be 18 years or older with no gender discrimination and must have gone loop ileostomy secondary to typhoid perforation. Patients who had abdominopelvic or other nonsurgical complications were excluded from the study. The time to reversal of stoma is divided into two coherent groups; late closure and early closure. The time frame determined for these two groups is specified as early closure being done before six weeks and late closure being performed three months after stoma formation. The study was carried out for six months after acceptance by the Hospital Ethics Committee. Data was entered into the statistical software SPSS version 23 to perform analysis. Categorical variables are summarized as frequency and percentages. Numerical variables are presented as mean ± standard deviation or median with interquartile ranges depending on the normality assumption. The normality assumption is tested by the Shapiro-Wilk test. Categorical outcomes were compared among the early and late groups using Chi-square or Fisher exact test as appropriate. An Independent t-test is applied to compare normally distributed numerals among the two study groups, whereas non-normal distributed variables were compared among two groups by applying the Mann-Whitney U test. Two-tailed p-value ≤0.05 are defined as statistically significant.

**RESULTS**

One hundred patients who underwent loop ileostomy secondary to Typhoid perforation were recruited into the study, with 50 patients in each group. The median age of the patients was 26(18-48) and 33.5(19-58) in the early and late closure groups, respectively. The patient demographics as illustrated by the p-value, were insignificant between the two groups, with hemoglobin levels being an exception (Table I). The most common co-morbidities noted among both groups were Diabetes Mellitus, Hypertension, Chronic Kidney Disease, Cardiovascular Disease, and Chronic Liver Disease. Early closure was performed at a median time of 6 (4-6) weeks, while 12 (12-14) weeks was the median for late closure.

Table 1: Baseline parameters based on early and late surgery groups

Parameters	Early closure n=50	Late closure n=50	P value
Age, median(range)	26(18-48)	33.5(19-58)	0.005
Gender			0.224

Male, n (%)	26(52)	32(64)	
Female, n (%)	24(48)	18(36)	
Smoking status			0.414
Smoker, n (%)	22(44)	18(36)	
Non-smoker, n (%)	28(56)	32(64)	
Hemoglobin, mean ± SD	12.09±1.61	11.37±1.18	0.013
Surgery time, median(range)	6(4-6)	12(12-14)	0.000
Comorbidity, n	12	28	0.067
DM <sup>1</sup> , n (%)	4(33.3)	6(21.4)	
HTN <sup>2</sup> , n (%)	4(33.3)	2(7.1)	
CKD <sup>3</sup> , n (%)	2(16.7)	8(28.6)	
CVD <sup>4</sup> , n (%)	-	6(21.4)	
CLD <sup>5</sup> , n (%)	2(16.7)	6(21.4)	

Table 1 <sup>1</sup>Diabetes Mellitus, <sup>2</sup>Hypertension, <sup>3</sup>Chronic Kidney Disease, <sup>4</sup>Cerebrovascular Disease, <sup>5</sup>Chronic Liver Disease

Table 2: Outcomes of closure of Loop Ileostomy based on time of reversal

Parameters	Early closure, n (%) n=50	Late closure, n (%) n=50	P value
ASA grade <sup>6</sup>			0.005
1	36(72)	22(44)	
2	14(28)	28(56)	
3	0	0	
4	0	0	
5	0	0	
6	0	0	
Surgery duration			0.423
<120 minutes	28(56)	24(48)	
>120 minutes	22(44)	26(52)	
Post-op Hospital stay, mean ± SD	5.20±1.06	5.8±1.24	0.011
Overall hospital stay, mean ± SD	6.56±1.18	7.28±1.52	0.011
Post-op complications			0.004
Yes	12(24)	26(52)	
No	38(76)	24(48)	
Surgical complication before discharge, n=38	12	26	0.446
Wound infection	4(33.3)	14(53.8)	
Anastomotic leakage	0	0	
Intra-abdominal collection	2(16.7)	2(7.7)	
Paralytic ileus	6(50)	10(38.5)	
Medical complication before discharge, n=2	0	2	N/A
Urinary tract infection	-	0	
Pneumonia	-	2(100)	
Deep venous thrombosis	-	0	
Surgical complication at follow-up, n=4	2	2	N/A
Wound infection	2(100)	2(100)	
Anastomotic leakage	0	0	
Intra-abdominal collection	0	0	
Paralytic ileus	0	0	
Medical complication at follow-up, n=2	2	0	N/A
Urinary tract infection	2(100)	-	
Pneumonia	0	-	
Deep venous thrombosis	0	-	
Day of complication occurrence, median(range)	4.5(3-6)	3(3-5)	0.038
Clavein Dindo classification, n=38	12	26	0.453
Grade I	2(16.7)	8(30.8)	
Grade II	10(83.3)	18(69.2)	
Grade III	0	0	
Grade IV	0	0	
Grade V	0	0	

Mortality			N/A
Yes	0	0	
No	50(100)	50(100)	

Table 2 <sup>6</sup> American Society of Anaesthesiologists' (ASA) classification of Physical Health

Significant variance in ASA Grade was noted between the two groups, with no group reporting a value greater than Grade 2 (P-Value=0.005). A lower grade was observed in the patients who had undergone early closure compared to those undergoing a late closure. The timing of closure was insignificant when assessed for surgery duration with a P-Value of 0.423. The post-operative and total hospital stay were found to show significant variation, with P-values computed as 0.011 and 0.011, respectively for both outcomes. The mean post-operative hospital stay was calculated as 5.20±1.06 and 5.8±1.24 while overall hospital stay was found to be 6.56±1.18 and 7.28±1.52 in the early and late groups, respectively. Only 38 patients of the total sample underwent reversal of ileostomy and showed post-operative complications, whilst 62 patients did not exhibit any complication. The incidence of post-operative complications in the late group surpassed the incidence of complications of the early group, with 26 out of 50 patients showing complications in the late reversal group, whereas only 12 out of 50 patients showed complications in the early reversal group with a significant p-value of 0.004. The median day at which post-operative complication occurred was calculated as 4.5(3-6) in the early group and 3(3-5) in the late group with a p-value of 0.038, which is statistically significant. Paralytic ileus accounted for the most common surgical complication in the early group before discharge. On the contrary, wound infection is identified as the commonest complication in the late group. Only 2 patients exhibited medical complications before discharge in the late group in contrast to the early group, which showed no complications before discharge. The rate of surgical complication at follow-up was found to be the same in both groups. Medical complications at follow-up only occurred in 2 patients in the early group, while there were no medical complications in the late group. The detailed summary of the proportions of other complications is illustrated in Table II. According to Clavein Dindo classification, most of the patients underwent grade II complications in both groups (10 vs. 18). There were no mortalities recorded till follow-up in both groups.

**DISCUSSION**

Stoma formation is closely knit to drastic repercussions on an individual's social, sexual, mental, and functional capacities. Numerous studies have reported dyspareunia, impotence, self-unacceptance, social stigmas, depression, and adjustment issues<sup>11-13</sup>. These, superimposed on structural complications of stoma, demand closure at the earliest possible time. Among structural complications of stoma, contact dermatitis and leakage surpass all other factors<sup>14</sup>.

Given the results of this study, significant differences are noticeable in the late and early closure groups when assessed for post-operative hospital stay and overall hospital stay. The Clavein-Dindo classification also exhibits significant discrepancy between the two groups, emphasizing a better prognosis with early closure than late closure. Another corollary can be drawn between the mean hemoglobin levels and the time for closure. There is a significant difference between the mean hemoglobin values in each group (P-Value = 0.013), with the late closure group housing individuals with a lower level of hemoglobin (11.37 vs. 12.09). A correlation

between these results could be drawn with the respective ASA score, which is notably higher in the late closure group, with a greater number of co-morbidities (28 vs. 12) recorded in these patients at baseline. A potentially encouraging factor toward late closure may be a significantly lower frequency of post-operative complications in the early closure group (12 vs. 26). Post-operative complications arose significantly later in the early group in comparison to the late group (4.5 vs. 3 days).

Contradictory results have been noted across various other clinical trials held in order to assess the same outcome. In his multifactorial analysis, Pearce et al. evaluated 80 patients who underwent re-anastomosis after a previous Hartmann's Resection to find that 50% of patients developed a clinical leak when the procedure was performed prior to 3 months, in contrast to 25% and 0% when performed at 3-6 months and later than 6 months, respectively<sup>15</sup>. Other clinical conditions like deaths and septicemia were also reported when the reversal was performed before 6 months. Results contradictory to this study were published by Roe et al. in their study of 69 patients. Complications were recorded as 24% compared to 35% with 4 months demarcating the groups between early and late closure, respectively<sup>16</sup>.

The discord between the values may be attributable to the relatively small number of patients employed in each study and variable time-frames being allocated as the delineation between early and late closure groups.

Our study is in line with many other clinical trials held in order to assess the optimal reversal of stoma formation secondary to various primary causes. However, this study is subject to quite a few limitations that must be addressed when interpreting the results and assessing its quality for future reference. The population size adopted in this study is small and not an accurate representation of the actual population, as correlation to the prevalence of typhoid in the region has not been implicated. Moreover, patients have been followed up for a short duration post-operatively, which may lead to many late complications remaining unaddressed. Drawing further emphasis on this point, most patients did not comply with the rules and were lost to follow-up resulting in a scarcity of data which was crucial to assess the post-operative complications which may have arisen. Another factor that may come into interplay is surgeon bias where late reversal may be habitually employed by surgeons who occasionally prefer a longer hospital stay for patients. Furthermore, given that stoma formation has dramatic social and personal implications, a Quality of Life Assessment evaluating the preoperative and post-operative lifestyle is also necessary for a complete analysis of the most optimal time of closure for stomas.

**CONCLUSION**

Late closure parallels the patients' baseline haemoglobin levels and ASA grades, with more efficient recovery noted in the early closure groups. Late closure is associated with a significantly higher risk of complications and a resultant greater length of hospital stay.

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