



Diversion stoma versus no diversion after neoadjuvant chemoradiation in low anterior resection for carcinoma rectum: A retrospective comparison

Bonny Natesh P¹, Sindhu RS^{2*}, Ramesh Rajan³, Kushal B⁴

¹⁻⁴ Department of Surgical Gastroenterology, Govt. Medical College, Trivandrum, Kerala, India

Abstract

Background & objectives: Diversion stoma remains the standard protocol in low anterior resection (LAR) after neoadjuvant chemoradiation (NACRT) for carcinoma rectum, to prevent complications of anastomotic leak. However, literature shows controversies regarding potential benefits of diversion. Objective of this study was to compare post-operative complications in patients underwent LAR with or without diversion following NACRT.

Methods: Retrospective comparison was done with inclusion criteria; satisfying three intra-operative criteria (distal resection margin ≥ 2 cm, complete full thickness doughnuts and negative Jacuzzi's leak test). Exclusion criteria were age >70 years, major comorbidities, T4 lesion, ultra-low anterior resection, R1 resection and other postoperative infections. Two groups were compared statistically for significant differences in the postoperative outcome.

Results: 46 LAR patients; 25 in group-I and 21 in group-II, were comparable regarding demographic parameters, comorbidities, ASA grade, intraoperative blood transfusions, tumour site, CEA level, surgical technique, distal resection margin, level of anastomosis and stapling technique. Mean heart rate on post-operative day (POD)-5 was 84.08 ± 9.66 /minute in group-I; 81.66 ± 7.08 /minute in group-II ($p=0.346$). Median day of drain removal, antibiotics and oral fluids were same. Overall morbidity in group-I was 28% and in group-II was 20% ($p=0.533$). One patient in group-I had relaparotomy for peritonitis. Two patients in group-II had to undergo ileostomy on POD- 3. Clavein Dindo score of 3 was there in 8% Group-I and 9.52% Group-II ($p=0.858$) which was not statistically significant.

Interpretations and conclusion: There was no severe sepsis, organ failure or mortality in these selected patients for LAR after NACRT without diversion stoma.

Keywords: anastomotic leak, diversion stoma, Ileostomy, low anterior resection, NACRT

Introduction

Anastomotic leak is the most serious complication following surgery for carcinoma rectum; its reported incidence ranges from 3 to 11% for middle and upper third rectal anastomosis and 20% for lower third rectal anastomosis with mortality rates as high as 22% [1,2]. A diversion stoma is recommended in low anterior resection (LAR) for carcinoma rectum to protect the anastomosis; especially when it is preceded by neoadjuvant chemoradiotherapy (NACRT) and is combined with total mesorectal excision (TME) [3, 6, 7, 8]. However, the need for diversion stoma has been a point of dynamic discussions in the literature [9, 10, 11]. Many authors favour diversion suggesting that it reduces the clinically relevant anastomotic leak rates, especially in low rectal cancers [12]. Later studies have shown that the risk of leak rates after LAR is actually much low and diversion is not required routinely, but for the high-risk patients [13, 14].

The major arguments against the diversion stoma were; its postoperative morbidities which could considerably impair the quality of life of these cancer survivors [15, 16]. Moreover it was observed that a diversion stoma does not prevent or reduce the postoperative anastomotic leak rates. Rather, it reduces the sequelae of anastomotic leak if it occurs, such as fecal peritonitis and sepsis [17]. Diversion stoma itself can lead to complications which include fluid-electrolytes disorders, skin irritation, stoma-site hernia, and prolapse [18, 19, 20]. Furthermore, the stoma needs a reoperation for its closure, which itself could have 9.5–18.3% morbidity [21]. The overall morbidity and mortality rates for diversion stoma are reported

as 33.8 % and 6.4 %, respectively [22].

Many laparoscopic LAR series have preferred avoiding diverting ileostomy in LAR for selected group of patients [3]. Later there were studies comparing colostomy and ileostomy forgoing the extra segment of proximal colon, between the stoma and the anastomotic site in an ileostomy [4, 5]. These series also gave a conclusion that covering stoma does not offer benefit in 30-day mortality. Recently a RCT by Nelson T *et al* was favouring early closure of diversion stoma [6] in the LAR post-operative period itself, suggesting that early stoma closure does not increase the risk of postoperative complications, reduces cost towards stoma care and gives better quality of life.

All these evidences and an observed low rate of anastomotic leak in our LAR patients, LAR without covering stoma remained the protocol for the last few years; if the patient has not received NACRT and the anastomosis done was technically satisfactory for the operating surgeons. The postoperative profile of these patients was convincing to the extent that most of our LAR patients preferred to go without a covering stoma, with a consent to undergo a second surgical procedure for diversion stoma in case of any postoperative clinical suspicion of an anastomotic leak. Of late those patients with carcinoma rectum who received NACRT also preferred to avoid a covering stoma if their intraoperative assessment of the technical aspects of the anastomosis was satisfactory by the operating surgeon. The treatment protocol in these patients was to closely monitor them in the intensive care unit for clinical signs of anastomotic leak or sepsis. It

was decided to proceed to further laboratory investigations and cross-sectional imaging; and to do relaparotomy, lavage and covering ileostomy in case of clinical suspicion or imaging evidence of an anastomotic leak.

Hence a comparative study was proposed with an objective to compare the post-operative parameters and complications in those patients underwent LAR after NACRT for carcinoma rectum; done with or without a diversion stoma, based on the intra-operative assessment using three-point technical criteria.

Materials and Methods

This study was designed as a single centre retrospective comparative study on the postoperative complications of carcinoma rectum (ICD-9:154.1) patients who underwent LAR after NACRT; with or without a diversion stoma, in the Department of Surgical Gastroenterology, Govt. Medical College, Trivandrum, Kerala, India from 01/01/2016 to 30/06/2018.

Case selection strategy

Biopsy proven cases of adenocarcinoma involving the upper and middle rectum with imaging evidence of locally advanced tumours treated during the study period were subjected to NACRT (5FU/Capecitabine+long course radiotherapy; 50.4Gy in 28#) by protocol. These patients were taken up for LAR (open or laparoscopic) after 6-8 weeks. Routine preoperative mechanical bowel preparation was not given; instead these patients were given laxatives and fluid diet for 5 days prior to surgery (department protocol). An informed written consent was obtained from the patient and the close relatives explaining the existing guidelines on diversion stoma and the risk of a relaparotomy under general/regional anaesthesia, in case of anastomotic leak and sepsis. TME was done for all the cases and the anastomosis was done by the double stapling technique. Those cases having a technically satisfactory anastomosis on intraoperative assessment by the operating surgeon; objectively defined as satisfying a 'three point criteria' (gross distal resection margin ≥ 2 cm, complete macroscopically full thickness doughnuts and negative Jacuzzi's leak test) were considered for LAR without diversion stoma according to the surgeons preference and the consent given by the patient. The decision-making process was reviewed by a second surgeon before taking the final decision (by single blinded approach). To facilitate during a potential re-exploration for ileostomy, a loop of ileum 15-20 cm from the ileo-caecal junction was kept secured to the parietal peritoneum in the right lower quadrant of abdomen and a metallic clip in the jejunal mesentery close to the antimesenteric border before closing the abdomen. Those patients having age above 70 years, multiple comorbidities, T4 lesions, ultra-low anterior resection (level of anastomosis < 4 cm from the anal verge) were excluded from the study and were given a diversion stoma. The postoperative management protocol was to closely monitor those patients in the postoperative intensive care unit for early clinical / laboratory signs of anastomotic leak or sepsis. Those patients with uneventful postoperative clinical parameters; oral fluids were started from the second postoperative day and stepped up gradually and discharged once they were tolerating soft diet. The patients were closely followed up till 4 weeks after surgery and then merged with the standard surveillance protocol.

A routine postoperative rectal contrast imaging to check the integrity of the anastomosis was not done in them. Those patients showing any worrisome features in the postoperative period were taken up for proceeding with further necessary laboratory investigations and cross-sectional imaging. They will be managed by urgent covering ileostomy under general / regional anaesthesia. The definitions for grading of the leakages proposed by Rahbari *et al.* were used for streamlining the management protocol for anastomotic leak in this study [23].

The protocol was presented before the Institution Ethical Committee with the available literature review and acceptance was obtained after detailed discussions.

(The most surprising fact was that none of the patients refused to get enrolled in the study, with a desire to avoid a stoma life if feasible. They were willing to accept the potential risk for a relaparotomy under anaesthesia in a state of pelvic sepsis. Most of them had their final wording that, the decision on diversion can be taken by the operating surgeon according to the situation).

Data extraction and statistical analysis

The perioperative and postoperative data of these patients were subjected to a retrospective comparative study.

Inclusion criteria

Adenocarcinoma involving upper and middle rectum (locally advanced) subjected to NACRT; underwent LAR with or without a diversion stoma; satisfying the three-point criteria (gross distal resection margin ≥ 2 cm, complete macroscopically full thickness doughnuts and negative Jacuzzi's leak test).

Exclusion criteria

Patients with age above 70 years, multiple/major comorbidities, adjacent organ involvement, final histopathology report showing positive resection margin and other postoperative (culture positive) infections which could be confronting with the clinical picture of an anastomotic leak.

The enrolled cases were stratified as LAR following NACRT - with diversion stoma (Group-I) and LAR following NACRT - without diversion (Group-II). The objective assessment parameters available for the preoperative risk assessment and for the detection of anastomotic leak (including the Dutch Leakage Score) [24] were used for constructing the proforma for this study. The data on the variables regarding the peri-operative details and the post-operative complications were retrieved from the prospectively maintained department database and were subjected to statistical analysis.

The study proceedings were performed in accordance with the Declaration of Helsinki. Statistical analysis was done using SPSS-20. The continuous variables were studied using mean and standard deviation and the categorical variables by proportions. Bivariate analysis was done using student-t and Pearson Chi-square tests for a statistically significant difference ($P < 0.05$).

Results

The LAR patients (n=46) satisfying inclusion and exclusion criteria were enrolled into the study; 25 in group-I and 21 in group-II.

Demographic parameters

The mean age (years) in group-I was 59.52 ± 10.42 and in group-II was 60.04 ± 7.66 ($p=0.796$). Median age was 64 in group-I and 60 in group-II. 64% in group-I and 57.14% in group-II were males ($p=0.638$). 20% in group-I and 22.7% in group-II had diabetes ($p=0.073$).

Clinical parameters

The mean distance (cm) of lesion from anal verge was 7.65 ± 1.78 in group-I and 8.04 ± 0.97 in group-II ($p=0.374$). Mean serum CEA value ($\mu\text{g/L}$) was 5.42 ± 3.83 in group-I and

6.45 ± 7.93 in group-II ($p=0.601$). Macroscopic distal resection margin (cm) was 3.3 ± 0.66 in group-I and 3.36 ± 0.97 in group-II ($p=0.805$). 36% group-I and 54.5% group-II had laparoscopic resection ($P=0.213$).

There was no statistically significant difference between the two groups regarding the preoperative ASA grade, tumour stage, surgical technique, level of anastomosis, stapling technique (double stapling) or intra-operative blood transfusion. Thus, the two groups were found to be comparable as the p-values were statistically insignificant (table-1).

Table 1: Demographic and clinical parameters

Parameters	Group-I (n=25)	Group-II (n=21)	P value
Mean age	59.52 ± 10.42	60.04 ± 7.66	$p=0.851$
Male gender	64%	57.14%	$p=0.638$
Diabetes	20%	22.7%	$p=0.073$
Mean distance (cm) of lesion from anal verge	7.65 ± 1.78	8.04 ± 0.97	$p=0.374$
Mean serum CEA value ($\mu\text{g/L}$)	5.42 ± 3.83	6.45 ± 7.93	$p=0.601$
Macroscopic distal resection margin (cm)	3.3 ± 0.66	3.36 ± 0.97	$p=0.805$

Postoperative parameters

The mean heart rate on post-operative day (POD)-5 was 84.08 ± 9.66 /minute in group-I; 81.66 ± 7.08 /minute in group-II ($p=0.346$). The median day of starting oral fluids was POD-2 in both groups and none of these patients required total or partial parenteral nutrition. Abdominal drain was removed on POD-4 (median) in majority of patients in both the groups. Drain need to be retained for more than 7 days in 2 patients each in Group-I and Group-II. Antibiotics were given till POD-5 by protocol to both groups; extended till POD-7 in 4 patients in Group-I and 3 in Group-II.

Overall morbidity (Table-2) in group-I was 28% and in group-II was 20% ($p=0.533$). Wound collection in 3 patients in group-I (20%) and nil in group-II; one patient each in both the groups had respiratory symptoms (4% vs 4.7%; $p=0.094$) patients in the two groups. There were no serious complications like organ dysfunction, pancreatitis or thromboembolic events in either group. One patient in group-

I had relaparotomy for peritonitis. Two patients in group-II had to undergo ileostomy on postoperative day 3; as per the study protocol showing deviation from the expected recovery pattern. One patient had fever and another patient had ileus from day-3, Plain CT scan of abdomen and pelvis in these patients showed minimal fluid with air pockets in the pelvis, no free fluid or free air in the peritoneal cavity. They were subjected to ileostomy on the same day. Both these patients have improved and got discharged by POD-10. Both these patients had the level of anastomosis about 4.5 cm from the anal verge.

Clavien-Dindo score was 1; in one patient each among group-I and group-II. Score was 2 in 4 patients in Group-I and 2 patients in group-II. 2 patients each in group-I and group-II had a Clavien Dindo score of 3; 8% Group-I and 9.52% Group-II ($p=0.858$), and this was not statistically significant. None of the patients had a score of 4 or 5 No serious morbidities or mortality in either groups.

Table 2: Postoperative parameters on morbidity and mortality

Variable	Group-I (n=25)	Group-II (n=21)	P value
Mean heart rate on POD-5	84.08 ± 9.66 /min	81.66 ± 7.08 min	$p=0.346$
Overall morbidity	28%	20%	$P=0.533$
Clavien-Dindo score 3	8%	9.52%	$P=0.858$
Mortality	Nil	Nil	-

Discussion

Many studies have shown that anastomotic leak increases the rate of local recurrence; decreases overall survival and cancer-specific survival following curative anterior resection for rectal cancer [25]. Multivariate analysis on the risk factors for leakage in rectal anastomosis have shown that a very low anastomosis, preoperative radiation, intraoperative adverse events, stapled anastomosis, advanced malignancy and male sex were correlating with symptomatic anastomotic leakage [26, 28]. Later studies have suggested that unreliable anastomosis technique and patient's bad general conditions are the main risk factors for anastomotic leakage [29]. Studies on diverting stoma have concluded that it does not decrease mortality or sepsis in LAR after NACRT for mid-high rectal cancers and the decision on diversion stoma should not be taken solely on the receipt of NACRT [30]. Over the years, many authors have suggested that diversion stoma may be

restricted to patients with high risk for anastomotic leakage and for immunocompromised patients [31, 34].

In the present study, the LAR patients enrolled were comparable regarding their demographic parameters, comorbidities, ASA grade, intraoperative blood transfusions, tumour status, surgical technique, level of anastomosis and the stapling technique. Advanced age was shown as a risk factor for anastomotic leak in many studies. Here the exclusion criteria was formulated taking the age also into consideration; mean age (years) in Group-I was 59.52 ± 10.42 , that in Group-II was 60.04 ± 7.66 ; it was comparable between the groups. Male gender was reported as another risk factor for leak in open [35, 37] as well as laparoscopic LAR [38, 39] probably due to the technical issues in pelvic dissection. Here the proportion of male patients was also comparable statistically (64% in Group-I and 57.14% in Group-II). Blood transfusion requirement was reported by some authors as an

independent risk factor for postoperative complications and anastomotic leakage [40]. Here there was no statistically significant difference between the two groups regarding the transfusion requirement. The diabetic patient proportion was also comparable between the groups; 20% in Group-I and 22.7% in Group-II. Those patients having multiple comorbidities and angiopathies were excluded from the study by protocol.

The tumour characteristics were also found comparable between the two arms; the mean distance (cm) of lesion from anal verge (7.65±1.78 vs 8.04±0.97), the mean serum CEA value (7.65±1.78 vs 8.27±2.07) and the macroscopic distal resection margin (3.3±0.66 vs 3.36±0.97). T4 tumours were excluded from the study by protocol as advanced stage being a risk factor for anastomotic leak after LAR [41]. A number of studies reported that lower anastomosis level is an important risk factor for anastomotic leak after open LAR [42] as well as laparoscopic LAR [19, 27, 43, 45]. Here we have excluded the ultra-low anterior resection cases by protocol, taking this evidence into consideration. By minimising the known risk factors for anastomotic leak during the patient selection, the study could focus more on the potential benefit of a diversion stoma.

On analysing the postoperative parameters of the two groups; they were found to have no statistically significant differences regarding the mean heart rate on post-operative day-5, the day of starting oral fluids and the day of drain removal. The reported overall complication rate after LAR following NACRT in carcinoma rectum was 33% (with SSI being the most frequent complication (10.06%)); and grade 3 or 4 complications occurring in 14.2% [46, 47]. In this study; the overall morbidity was comparable between the two groups (28% vs 20) and it matches with the literature reports. The commonest morbidity encountered here also was SSI followed by respiratory symptoms. There were no serious complications like postoperative pancreatitis, thromboembolic events, severe sepsis or signs of organ dysfunction. The Clavien-Dindo score of the two groups were also found comparable, having no statistically significant difference.

Relaparotomy and lavage was done in one patient in group-I because of signs of peritonitis. Two patients in group-II had to undergo ileostomy on postoperative day 2; as per the study protocol showing deviation from the expected recovery pattern. One patient had fever and another patient had ileus from day-3, Plain CT scan of abdomen and pelvis in these patients showed minimal fluid with air pockets in the pelvis, no free fluid or free air in the peritoneal cavity. They were subjected to ileostomy on the same day. Both these patients have improved and got discharged by postoperative day 10. Both these patients had the level of anastomosis about 4.5 cm from the anal verge. None of the patients in group-II with the level of colo-rectal anastomosis above 5 cm from the anal verge had serious postoperative morbidities. Close monitoring in the postoperative period and planned re-exploration for ileostomy with earliest sign of deviation from the expected postoperative course was helpful in preventing severe sepsis and organ failure.

Those patients with great desire to avoid a diversion stoma, who is having a good performance status and when the growth is in the upper half of the rectum, it should be explored further that the diversion stoma can be made by patient preference, after explaining the risks of pelvic sepsis and subsequent re-exploration under general/regional

anaesthesia.

Further studies in the form of prospective trials may be done in order to explore whether it is safe to forgo a diversion stoma if the anastomosis is technically satisfactory; according to the comorbidity status and patient preferences, in LAR after NACRT for carcinoma rectum involving the upper half of the rectum.

Conclusion

This study did not show any statistically significant differences major post-operative morbidities or mortality in LAR after NACRT for carcinoma rectum done with or without a diversion stoma. This study may be continued to a larger comparative study to explore the feasibility and safety of avoiding a diversion stoma in a highly selected group of patients undergoing LAR following NACRT.

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Footnote

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Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical statement: The study was approved by the Institutional Ethics committee of Government Medical College, Trivandrum, Kerala and informed written consent was taken from all the patients.

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