



## Original research

## Role of diversion ileostomy in low rectal cancer: A randomized controlled trial



Mukhtar Thoker<sup>a</sup>, Imtiaz Wani<sup>a,\*</sup>, Fazl Q. Parray<sup>a</sup>, Nawab Khan<sup>a</sup>, Shabeer A. Mir<sup>a</sup>, Parvaiz Thoker<sup>b</sup>

<sup>a</sup> Department of General Surgery, Sheri-Kashmir Institute of Medical Sciences, Srinagar, Kashmir 190006, India

<sup>b</sup> Department of Surgical Oncology, Sheri-Kashmir Institute of Medical Sciences, Srinagar, Kashmir 190006, India

## HIGHLIGHTS

- LAR with ileostomy has certain advantages over LAR without ileostomy in terms of anastomotic leak, post operative ileus, resumption of diet, wound infection.
- Stoma related complications were main disadvantage in LAR with ileostomy group.
- A proactive approach needs to be adopted for decreasing problems of skin related local complications and electrolyte related systemic complications.

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## ABSTRACT

**Introduction:** Rectal cancer continues to be devastating malignancy worldwide. Sphincter preservation is the need of the hour. Distal anastomosis is more prone to leaks. Proximal diversion in form of ileostomy may be used to protect distal anastomosis. **Aim:** To compare two groups of low anterior resection with and without diversion ileostomy in rectal cancer patients. **Material and methods:** A prospective, hospital based study of 78 rectal carcinoma patients were taken for the study. Inclusion criteria was operable rectal cancer 4–12 cm from anal verge. Patients were randomized into two groups. Group – A (34 patient) patients with low anterior resection with ileostomy (LAR with ileostomy); Group – B (44 patients) patients with low anterior resection without ileostomy (LAR without ileostomy). Quality of life was assessed by scoring done by self designed method. A total score of 0–20 given for various parameters. **Results:** Skin excoriation was the commonest complication. Stomal retraction and stomal obstruction was seen in 1 patient each (3%). Hypokalemia was the commonest electrolyte imbalance present in ileostomy group. Anastomotic leak was present in 6% of Group A and 11% of Group B patients. Mean time of closure of ileostomy was  $16 \pm 4.3$  weeks. **Conclusion:** LAR with ileostomy has certain advantages over LAR without ileostomy in terms of anastomotic leak, postoperative ileus, resumption of diet, wound infection, small bowel obstruction and in terms mortality and recurrence. However stoma related complications were main disadvantage in LAR with ileostomy.

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## 1. Introduction

LAR is generally performed for lesions in the upper third of the rectum and middle and, occasionally, for lesions in the lower third. Restoration of intestinal continuity often results in poor functional outcome as a consequence of alteration of pelvic physiology. The

anastomotic leak ranges from 3 to 11% for middle-third and upper-third anastomosis and to 20% for lower-third anastomosis [1,2]. Proximal diversion in the form of loop ileostomy is adopted because of the high rates of anastomotic complications associated with low colorectal and coloanal anastomosis [3]. The formation of these protective type of stomas for fecal diversion after restorative procedures have been reported to have a great impact on surgical morbidity and mortality of restorative colorectal surgery [4].

**Aim:** To compare two groups of low anterior resection with and without diversion ileostomy.

\* Corresponding author.

E-mail address: [imtazwani@gmail.com](mailto:imtazwani@gmail.com) (I. Wani).

## 2. Material and methods

This study was a prospective Study from June 2008 to December 2010 for a period of 30 months. Inclusion criteria were all those patients who presented to Department of General Surgery with diagnosis of cancer rectum between 4 and 12 cm from anal verge. Exclusion criteria were all those patients who were otherwise planned for any such procedure (Sphincter saving) but ended up with abdomino-perineal resection, It included a total number of 78 patients. Patients were allocated randomly to two groups; group 'A' and group 'B' by systematic random sampling. Group A Patients comprised of those patients who underwent Low Anterior Resection with Ileostomy (LAR With Ileostomy) and Group B included patients LAR without ileostomy. A detailed history of each patient including age, sex, residence, blood group, presenting complaints with a special stress on history of bleeding per rectum, bowel habits, stool character, abdominal pain or distension and any such history in the family. A thorough physical examination with main emphasis on lymphadenopathy, anemia, edema, ascites or organomegaly. Local examination was emphasized on digital rectal examination (DRE), proctoscopy (PE), sigmoidoscopy or colonoscopy in case needed or in referred patients. A diagnostic preoperative biopsy was taken from the lesion and sent for histopathological examination (HPE). Routine investigations like CBC (Pre-op./Post-op./follow-up), CXR P/A view. Specific investigations like LFT (pre-op./Post-op./follow-up), KFT, and hepatitis B surface antigen. Specialized investigation like CEA levels (pre-op./Post-op./follow-up). Preoperative staging by "Duke's," Multi-slice CT scan, trans-rectal ultrasound or MRI. All patients were discussed with a Medical/Radiation Oncologist for a neoadjuvant/adjuvant therapy Preoperative optimization after admission in patients where it was required like building up Hb%, nutritional status etc. Preoperative bowel preparation with pегlec/coloclean 1 day prior to surgery. In obstructive lesions, no bowel preparation was given. Part preparation done on the evening before surgery and preoperative counseling by a stoma therapist was sought. A preoperative antibiotic in the form of 2nd or 3rd generation Cephalosporin, Metronidazole or Tinidazole on the day of surgery were given at the time of induction and was continued for 5–7 days after surgery. Cross matched whole blood were also reserved for surgery in patients with low hemoglobin and blood transfusion given pre-operatively to raise hemoglobin up to 1° mg per dl. Preoperative counseling and explaining the procedure, possibility of temporary stoma, permanent stoma and anastomotic leak, pelvic sepsis in detail to the patient and his attendants and written consent was taken for all possibilities. All cases were done under general anesthesia Intra-operatively every attempt was made to stick to oncological principles, with stress on the complete resection of the tumor. The operative findings, including the indication and type of procedure, were recorded in all the patients. The restoration of gut continuity i.e. anastomosis was done either by a circular stapler or by hand sewn closure depending upon the level of lesion or availability of stapler. Details of intra-operative findings like TNM staging, status of liver, ascites, Blummer's shelf, any synchronous/metachronous lesion were confirmed. Decision about protective stoma was taken on the basis of criteria already explained. Ileostomy bag was applied preferably on table before extubation. Patient was monitored critically in postoperative ward for 24–48 h and shifted to ward later on. Postoperatively patients were on prophylactic anticoagulants (low molecular weight heparin). Urinary catheter was removed after 5–7 days. All postoperative complications (procedure related/stoma related) were recorded. Any procedure like exploration or stoma revision if needed was performed in the postoperative period. Demonstration of leak or sepsis was confirmed by septic profile, USG abdomen/

pelvis or CT with oral contrast. Patients were assessed in outpatient department after discharge for any wound infection, pelvic sepsis, generalized sepsis, status of anastomotic line by DRE or P/E, stoma condition (moving, edematous, prolapsed, retracted, taken off), stoma appliances (application, any leakages, any other problems, change of bag) and any electrolyte imbalances because of stoma and local skin condition around stoma site. Postoperative/follow-up visits were planned. CBC, LFT, CEA levels were sent on monthly basis on follow-up. USG and CT scan were planned on 3–6 monthly basis on follow up. Stoma closure was done after 12 weeks, after doing a cologram by water soluble contrast somewhere between 4 and 8 weeks. Post-stoma closure follow-ups were planned and all morbidity/mortality were recorded. Ethical clearance was sought from post graduate ethical clearance committee of hospital before undertaking the study. All participants gave written consent before inclusion. A scoring done by self designed method to assess Quality of Life after LAR with ileostomy and LAR without ileostomy was done (Table 1). A total score of 0–20 given for various parameters as explained in table.

Any score >15	Excellent results
10–15	Good results
8,10	Average results
<8	Poor results

Manuscript fully compliant with the CONSORT 2010 statement and reported in line with CONSORT [5]: <http://www.sciencedirect.com/science/article/pii/S1743919111005656#>.

Descriptive statistical method used were chi-square, odds ratio and Mann–Whitney *U* Test. *P*-value <0.05 was considered statistically significant.

## 3. Results

Total 34 (44%) patients were subjected to LAR with ileostomy while as 44 (56%) patients were subjected to LAR without ileostomy. Majority of the cases (36%) were in the age group of 51–60 years. Male: female ratio was 1.2:1. Bleeding per rectum was the chief complaint in 76 patients (97%) followed by weight loss in 31 patients. Constipation was commonest bowel habit present in 47 patients (60%). Family history of rectal malignancy was present in 10% of cases. On examination pallor was the most frequent finding seen in 81% of patients. Growth was felt on DRE in 72% and blood smearing of finger occurred in 67% patients. Most of the lesions (50%) were at 5–8 cm from anal verge. Synchronous lesion was present in 5% of cases on colonoscopy. CEA levels were in the range of 6–10 ng/ml in 44% of cases in preoperative period. Blood group "O" was the commonest group in the studied subjects. Neoadjuvant treatment was given to 23 (29%) patients. Well differentiated adenocarcinoma was the commonest histopathological variant encountered. Most of the patients presented in T2N0M0 stage. In our series, 13 (17%) patients were in Duke's A stage. 46 (60) patients were in Duke's B stage and 19 patients (23%) were belonging to Duke's C.

Wound infection developed in 11 (32%) patients in Group A (LAR with diversion ileostomy) and in the 8 (18%) patients in group B (LAR without diversion ileostomy). Anastomotic leak were present in 7 patients (9%) of which 2 patients (6%) belonged to Group A (LAR with ileostomy) and 5 patients (11%) had LAR without ileostomy (Group B). Sexual dysfunction was seen in 21% patients. 32% of patients in Group A & 11% of patients in Group B

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