Evaluation of factors determining oncological clearance with sphincter preservation in low rectal cancer
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Abstract

Background: Approximately one third of all colorectal cancers are rectal cancers. It is a peculiar malignancy as resection of this cancer may lead to loss of anal sphincter and the patient is condemned to a permanent colostomy. Aim of the surgery is oncological clearance and sphincter preservation. The optimal surgical management of rectal cancer requires detailed preoperative planning and to determine a logical approach to the management of this complex disease by analyzing the factors that determine its surgical outcome. This study was done to obtain a clear understanding of the factors determining the oncological clearance and sphincter preservation in low rectal carcinoma and thereby guiding surgeons to take appropriate decision in the surgical management.

Methods: This prospective observational study, involving 60 consecutive patients with low rectal cancer, was done in Sir Salimullah Medical College and Mitford Hospital, from January 2013 to December 2015. Data were prospectively collected, using detailed proforma and analyzed with a Statistical Package for the Social Sciences (SPSS) version 18.0 and the results were presented in tables.

Results: Out of the 60 patients, 40 (67%) had oncological clearance and 26 (43%) had sphincter preservation. A statistically significant number of patients with T1-T2 tumor had oncological clearance [40 (83%) vs 8 (17%), p<0.05]. None of the patients with T3-T4 tumor had curative resection. Whereas, a statistically significant number of patients with tumor distance beyond 5 cm from anal verge, had sphincter preservation [32 (94%) vs 2 (6%), p<0.05]. Most of the patients with tumor within 5 cm [24 (94%) out of 26] had sphincter resection.

Conclusion: Tumor factors, favoring sphincter preservation, were ≥5 cm distance from anal verge, whereas, circumferential spread limited to muscularis propria (T1-T2), favored oncological clearance.

Key words: Colorectal carcinoma, oncological clearance, sphincter preservation.

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Introduction

Worldwide colorectal cancer is the third most common malignancy. Approximately, one third of all colorectal cancers are located within the rectum. Approximately, 42,000 patients each year are diagnosed with rectal cancer in the United States, of which 8500 die of the disease. Although most common in the elderly, the incidence in young adults is increasing.

Rectal cancer is defined as a tumor with its lower edge within 15 cm from the anal verge. Radical surgical resection of the tumor is the only chance of permanent cure of the disease. According to Kerl R, surgery has 2 main objectives: cure of the cancer (oncological clearance) and restoration of bowel continuity (sphincter preservation), because a permanent colostomy results in significant reduction in the quality of life.

The optimal surgical management of rectal cancer requires detailed preoperative planning that includes the assessment of level of the tumor, macroscopic appearance, extent of circumferential involvement,
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histopathology, fixity, age, gender etc. On the other hand, pathologic TNM stage remained the strongest predictor for overall survival and disease free survival. Traditionally, surgeons assess patients with digital rectal examination, colonoscopy and computed tomography. Sound knowledge of these factors can make the difference between a permanent colostomy and normal bowel continuity. Without this knowledge, surgeons may resect the sphincter when it could have been preserved. Conversely, to avoid a permanent colostomy and to reestablish intestinal continuity, others may compromise the resection margin. The consequences may be tragic: recurrent disease, anastomotic obstruction, unremitting pelvic pain and requirement of subsequent surgery. Other patients may be candidates for neoadjuvant or adjuvant chemoradiotherapy. It is a challenging treatment problem as the spectrum of presentation and management of this disease is not well understood. However, only a few studies have been undertaken to address this issue. This study was designed to determine a logical approach to the surgical management of this complex disease by analyzing the factors that determine its surgical outcome.

Methods

This prospective observational study was done in the Department of Surgery, Sir Salimullah Medical College and Mitford Hospital from January 2013 to December 2015. Sixty consecutive patients with histologically confirmed low rectal carcinoma were selected. Sampling method was purposive. Patients with history of pelvic malignancy (other than rectal cancer) or pelvic surgery, pregnancy, fecal incontinence or rectal prolapse and acute complications like perforation were excluded. Informed written consent, informing about all relevant aspects of the study, was taken from the subjects. Ethical clearance was taken from the Ethical Review Committee of the institution.

Data were collected in a clinical data collection sheet (observational method) as a pre-designed proforma, according to structured questionnaire. Tumor related variables which were analyzed: distance from anal verge, tumor size (maximum dimension), extent of circumferential involvement, fixity to surrounding structures, histological grade. Outcome measure was the type of surgery done in terms of oncological clearance and sphincter preservation.

Statistical analysis of the results was obtained by Statistical Package for Social Science (SPSS) version 18, Inc., Chicago, IL, USA. A p value <0.05 was considered statistically significant. It was performed using ‘chi squared test’ for categorical variables and ‘student’s t-test’ for continuous variables.

Operational definition
Oncological clearance may be defined as ‘en bloc’ resection of the tumor with histological negativity of the cut margin (5 cm proximal and 2 cm distal to the tumor edge), together with lymphovascular clearance, in absence of distant metastasis (Fig 1, 2).

Sphinctor preservation is defined when normal bowel continuity and fecal continence is maintained by preserving the anal sphincter presentation (Fig 2).

Low rectal cancer is defined as rectal cancer within 7 cm of anal verge (Fig 1, 2).

Results

Total patients were 60 including 37 (62%) male and 23 (38%) female. Forty three (71%) patients were above 40 years and 27 (29%) were below 40 years including 2 (3%) patients below 20 years. Forty (66%) patients had oncologically curative operation and 20 (33%) had non curative operation. In 34 (57%) patients, sphincter was preserved and sphincter was resected in 26 patients. Sphincter preserving procedures were low and ultra-low anterior resection and sphincter resecting procedure was abdominoperineal resection.

When the tumor distance is > 5 cm from anal verge, a statistically significant number of patients had curative resection with sphincter preservation (Table 1).

| Table I | Surgical outcome according to the distance of the tumor from the anal verge in low rectal cancer (N=60) |
|---------|---------------------------------------------------------------|
| Distance | Oncological Clearance | Sphincter Preservation | |
|         | Curative | Non-curative | P value | Preserved | Resected | P value |
| <5 cm   | 14       | 12           | <0.005  | 2         | 24       | <0.005  |
| >5 cm   | 26       | 8            |         | 32        | 2        |         |
Out of 48 patients with T1-T2 tumor, 40 (83%) had curative resection (p<0.005) including 30 (62%) who had sphincter preservation. None of the 12 patients with T3-T4 tumor had curative resection (Table II).

Curative surgery was possible more commonly among patients with mobile tumors (Table III).

The type of procedure done, according to the histological grade of the tumor in low rectal cancer is shown in Table IV. No significant relationship could be established.

The type of operation according the tumor size (maximum dimension) in patients with low rectal cancer is presented in Table V. No significant relationship could be seen between tumor size and oncological clearance or sphincter preservation.

Sex of the patient had no significant influence on the outcome of surgery (Table VI).

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**Table II** Surgical outcome according to the extent of circumferential involvement in low rectal cancer (N=60)

| Extent of invasion       | Oncological Clearance | Sphincter Preservation |
|--------------------------|-----------------------|------------------------|
|                          | Curative | Non-curative | P value | Preserved | Resected | P value |
| Upto muscularis propria (T1-T2) | 40       | 8           | <0.005  | 30        | 18       | >0.07   |
| Beyond muscularis propria (T3-T4) | 0        | 12          |         | 4         | 8        |         |

**Table III** Surgical outcome according to the clinical fixity of the tumor to surrounding structure in low rectal cancer (N=60)

| Fixity   | Oncological clearance | Sphincter Preservation |
|----------|-----------------------|------------------------|
|          | Curative | Non-curative | P value | Preserved | Resected | P value |
| Fixed    | 10       | 16          | <0.005  | 16        | 10       | >0.51   |
| Mobile   | 30       | 4           |         | 18        | 16       |         |

**Table IV** Surgical outcome according to the histological grade of the tumor in low rectal cancer. (N=60)

| Histological grade         | Oncological Clearance | Sphincter Preservation |
|----------------------------|-----------------------|------------------------|
|                            | Curative | Non-curative | p value | Preserved | Resected | P value |
| Well/Moderately differentiated | 38       | 14          | <0.01   | 30        | 22       | >0.7    |
| Poorly differentiated      | 2        | 6           |         | 4         | 4        |         |

**Table V** Surgical outcome according to the tumor size in low rectal cancer (N=60)

| Size     | Oncological Clearance | Sphincter Preservation |
|----------|-----------------------|------------------------|
|          | Curative | Non-curative | P value | Preserved | Resected | P value |
| ≤4cm     | 20       | 8           | >0.4    | 18        | 10       | <0.5    |
| >4 cm    | 20       | 12          |         | 16        | 16       |         |

**Table VI** Surgical outcome according to sex of the patients with low rectal cancer (N=60)

| Sex     | Oncological Clearance | Sphincter Preservation |
|---------|-----------------------|------------------------|
|         | Curative | Non-curative | P value | Preserved | Resected | P value |
| Male    | 26       | 10          | >0.3    | 18        | 18       | >0.2    |
| Female  | 14       | 10          |         | 16        | 8        |         |
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Discussion

Treatment outcomes for rectal cancer have been dramatically improved by applying the total mesorectum excision (TME) principle\(^\text{10}\), the double-stapling technique\(^\text{11}\) and the concept of shorter distal margins over the past few decades.\(^\text{12}\)

Tumor distance from the anal verge is probably the single most important variable that aids the surgeon in the choice of the operation. The results of the study support this statement. With growing expertise, increased knowledge of the anorectal physiology and technological advancement, a move towards sphincter preserving operation has begun even for very low rectal cancers. We now know that the distal 1-2 cm of rectum and upper internal sphincter were not absolutely necessary for continence. Recent studies have shown that a distal clearance margin greater than 1.5 cm is sufficient to achieve curative resection of low rectal tumors.\(^\text{13}\) These have established the feasibility of ultra-low anterior resection for tumors at level as low as 3 cm from the dentate line.

Circumferential local spread is another important factors affecting surgical treatments and the outcome. Most accurate assessment of the involvement of the mesorectum can be done by pelvic Magnetic resonance imaging (MRI) and transrectal ultrasonography. Bouvet \textit{et al}\(^\text{13}\) found that T stage is the most important pathological factor for local rectal cancer recurrence after excision. It was reported that if tumor margin is positive, the recurrence rate of tumor will be high and its prognosis is poor.\(^\text{14}\) Local spread occurs circumferentially rather than longitudinal direction. Tumor size (maximum dimension) another variable in our study and an important prognostic factor. A smaller tumor usually means less invasion, more mobility and greater area for the surgeon to work with within the narrow pelvis. So, smaller tumors are easy to manipulate and disect out \textit{en bloc} from the narrow pelvis and have a definite advantage over larger ones for sphincter preservation.

Fixity of the tumor in the pelvis implies a poor prognosis. There is greater likelihood of residual tumor following...
resection and anastomotic recurrence is a frequent sequel. Fixity can be assessed preoperatively by digital rectal examination. Fixation does not necessarily indicate contiguous spread. In a study of 625 patients who had undergone rectal excision, Durdey and Williams\textsuperscript{15} noted that 27% of the patients had fixation by malignant invasion (20%) and by inflammatory tissue (7%). Inflammatory attachment does not increase the risk of recurrence or decrease survival. The presence of a fixed tumor should encourage the surgeon to consider neoadjuvant therapy.

As the number of patients was small in our study, many of the differences could not be proved to be statistically significant. In this study we were not able to include factors like preoperative chemo radiation, presence of obstruction, bowel preparation, general medical conditions of the patient, perineural and vascular invasion.

In this study, our observation revealed that tumor distance $\geq 5$ cm from anal verge, strongly favors sphincter preservation, whereas, circumferential spread limited to muscularis propria (T1-T2), favored oncological clearance.

**Recommendations**

A number of possible advances in the treatment of low rectal cancer are currently under evaluation, including novel techniques of robotics, reservoir construction, the use of neoadjuvant radiotherapy, advanced staplers and the role of local resection in early rectal cancer.\textsuperscript{16-18} These important factors have definite impact on surgical outcome in a patient with low rectal cancer. Future researchers should include these factors in their study.

**Conflict of interest:** Nothing to disclose.

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