RESEARCH PAPER

Survival Outcomes in Locally Advanced Rectal Cancer (LARC) Treated with Neoadjuvant Chemoradiation Therapy (NACTRT) Followed by Chemotherapy and Surgery in a Tertiary Care Centre in India

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ABSTRACT

Background: Locally advanced rectal cancer (LARC) requires a multidisciplinary treatment approach to optimize tumour control and improve long-term survival. Neoadjuvant chemoradiotherapy (NACTRT) followed by systemic chemotherapy and curative surgery has become the standard treatment for stage II and III rectal cancer, resulting in improved pathological response, reduced local recurrence, and enhanced survival. However, real-world data evaluating survival outcomes from Indian tertiary care centres remain limited.

Aim and Objective: To assess survival outcomes in patients with locally advanced rectal cancer treated with neoadjuvant chemoradiotherapy followed by chemotherapy and surgery at a tertiary care center in India.

Materials and Methods: This prospective and retrospective observational study was conducted in the Department of Medical Oncology at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and KLES Belgaum Cancer Hospital, Belagavi, between January 2020 and December 2025. Fifty-one patients aged ≥18 years with histologically confirmed stage II or III rectal adenocarcinoma were included. All patients received neoadjuvant chemoradiotherapy followed by consolidation chemotherapy and curative surgery with total mesorectal excision. Demographic, clinicopathological, treatment, pathological response, recurrence, and follow-up data were analysed. The primary outcomes were pathological complete response (pCR), disease-free survival (DFS), and overall survival (OS). Survival analysis was performed using the Kaplan–Meier method, while prognostic factors were evaluated using Cox proportional hazards regression analysis.

Results: The mean age of the patients was 55.8 ± 11.2 years, and 66.7% were males. Stage III disease was present in 70.6% of patients, while clinical T3 tumours accounted for 78.4%. Radiotherapy was completed by 94.1% of patients, and 84.3% received adjuvant chemotherapy. Pathological complete response was achieved in 11 (21.6%) patients. Recurrence occurred in 11 (21.6%) patients, with distant recurrence being more common than local recurrence (63.6% vs. 36.4%). Patients achieving pCR demonstrated significantly superior survival outcomes, with 3-year overall survival of 100% versus 80.0% (p=0.040) and 3-year disease-free survival of 90.9% versus 65.0% (p=0.027) compared with patients without pCR. The overall cohort demonstrated a 3-year overall survival of 84.3%, an estimated 5-year overall survival of 76.5%, while the 2-year and 3-year DFS rates were 78.4% and 70.6%. Node-positive disease (HR 3.28; p=0.047), R1 resection margin (HR 4.52; p=0.036), and failure to achieve pCR (HR 3.74; p=0.049) were independent predictors of poorer disease-free survival.

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Conclusion: Neoadjuvant chemoradiotherapy followed by chemotherapy and curative surgery produced favourable survival outcomes in patients with locally advanced rectal cancer. Pathological complete response was associated with significantly improved overall and disease-free survival, while node-positive disease, R1 resection margin, and failure to achieve pathological complete response adversely affected prognosis. These findings support the effectiveness of multidisciplinary treatment and emphasize the importance of achieving optimal pathological response and complete surgical resection to improve long-term oncological outcomes.

Keywords: Locally advanced rectal cancer, neoadjuvant chemoradiotherapy, pathological complete response, disease-free survival, overall survival, total mesorectal excision, consolidation chemotherapy, rectal adenocarcinoma, prognosis, Kaplan–Meier survival analysis.

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INTRODUCTION

Locally advanced rectal cancer (LARC) represents a major therapeutic challenge despite substantial advances in multidisciplinary cancer care. Rectal cancer accounts for approximately one-third of all colorectal cancers and remains one of the leading causes of cancer-related morbidity and mortality worldwide [(1)]. Patients with LARC, defined as clinical stage II (T3–T4, N0) or stage III (any T, N1–N2) disease, have a significantly increased risk of local recurrence and distant metastasis when treated with surgery alone [(2)]. Consequently, multimodal treatment strategies incorporating neoadjuvant chemoradiotherapy (NACTRT), systemic chemotherapy, and total mesorectal excision (TME) have become the standard of care for improving oncological outcomes. These advances have substantially reduced local recurrence rates while improving long-term survival and quality of life [(3)].

The rationale for administering neoadjuvant chemoradiotherapy before surgery is based on its ability to reduce tumour size and stage, enhance the likelihood of achieving complete surgical resection with negative circumferential margins, facilitate sphincter preservation in low rectal cancers, and eradicate microscopic disease [(4)]. Concurrent fluoropyrimidine-based chemotherapy acts as a radiosensitizer, enhancing the effectiveness of radiotherapy while simultaneously targeting systemic micrometastases [(5)]. Following chemoradiotherapy, consolidation chemotherapy using oxaliplatin-based regimens such as FOLFOX or CAPOX has gained increasing acceptance because of its potential to improve tumour regression, increase pathological complete response rates, and reduce the risk of distant recurrence before definitive surgery [(6)].

Pathological complete response (pCR), defined as the absence of viable tumour cells in the resected specimen after neoadjuvant treatment, has emerged as an important surrogate marker of favourable prognosis [(7)]. Patients achieving pCR generally demonstrate significantly improved disease-free survival (DFS), overall survival (OS), and lower rates of local and distant recurrence compared with those with residual disease [(8)]. Nevertheless, treatment response varies considerably among patients owing to differences in tumour biology, stage at presentation, molecular characteristics, and treatment compliance. Therefore, evaluating survival outcomes together with pathological response remains essential for assessing the effectiveness of current treatment protocols [(9)]. Several landmark clinical trials have established the superiority of neoadjuvant chemoradiotherapy over postoperative chemoradiotherapy in reducing local recurrence and treatment-related toxicity [(10)]. More recently, the concept of total neoadjuvant therapy, in which systemic chemotherapy is delivered before surgery in addition to chemoradiotherapy, has demonstrated encouraging improvements in pathological response and disease control [(11)]. However, most available evidence originates from large randomized trials and high-volume cancer centres in Western countries. The applicability of these findings to Indian patients requires careful evaluation because of differences in disease presentation, nutritional status, socioeconomic factors, treatment accessibility, and healthcare infrastructure [(12)].

In India, rectal cancer is increasingly recognized as an important public health problem, with many patients presenting at locally advanced stages requiring multimodality treatment. Although tertiary oncology centres have adopted evidence-based treatment protocols, published Indian data evaluating long-term survival outcomes following neoadjuvant chemoradiotherapy, chemotherapy, and surgery remain relatively limited [(13)]. Institution-specific outcome analyses are therefore valuable for assessing real-world treatment effectiveness, identifying prognostic factors, and benchmarking clinical outcomes against international standards [(14)].

The present study was undertaken to assess survival outcomes in patients with locally advanced rectal cancer treated with neoadjuvant chemoradiotherapy followed by chemotherapy and curative surgery at a tertiary care centre in India. By evaluating pathological complete response, disease-free survival, overall survival, treatment characteristics, and prognostic factors, this study aims to provide comprehensive evidence regarding the effectiveness of the current multidisciplinary treatment approach and contribute to optimizing the management of LARC in routine clinical practice.

AIMS AND OBJECTIVES

- To assess survival outcomes in LARC patients treated with neoadjuvant chemoradiotherapy followed by chemotherapy and surgery at our institute.

MATERIALS AND METHODS

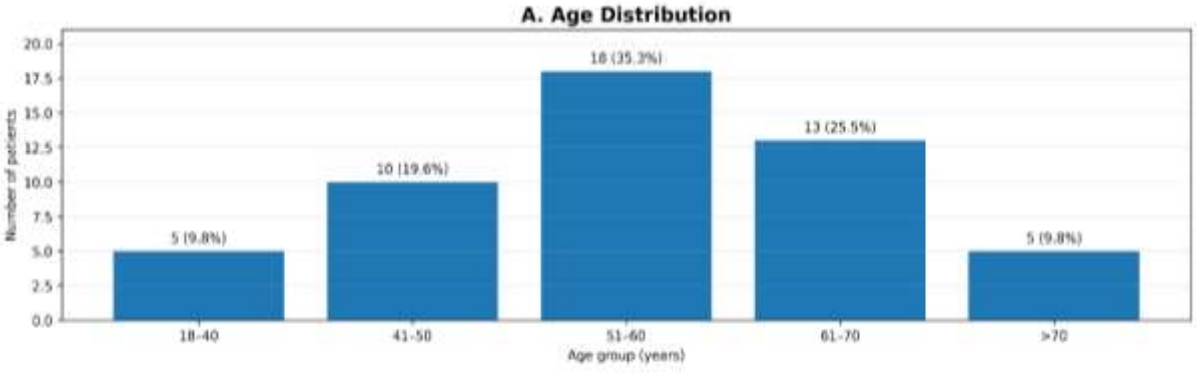
This prospective and retrospective observational study was conducted in the Department of Medical Oncology at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and KLES Belgaum Cancer Hospital, Belagavi, India, over a six-year period from January 2020 to December 2025. A total of 51 patients aged 18 years and above with histologically confirmed locally advanced rectal adenocarcinoma were included. Eligible patients had clinical stage II disease (T3/T4N0) or stage III disease (any T, N1/N2) according to the American Joint Committee on Cancer (AJCC) 8th edition staging system. Patients with stage I disease, metastatic or recurrent rectal cancer, non-adenocarcinoma histology, previous malignancy, or pregnancy were excluded. Institutional Ethics Committee approval was obtained before commencement of the study, and written informed consent was obtained from all prospectively enrolled participants.

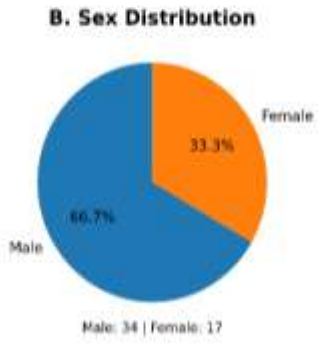
All patients underwent a standardized multimodality treatment protocol comprising neoadjuvant chemoradiotherapy followed by systemic chemotherapy and curative surgery. Neoadjuvant treatment consisted of external beam radiotherapy delivered to a total dose of 50.4 Gy in 28 fractions with concurrent capecitabine (825 mg/m² twice daily on radiotherapy days) or continuous infusion 5-fluorouracil. This was followed by consolidation chemotherapy using FOLFOX4, FOLFOX6, modified FOLFOX6, or CAPOX regimens according to institutional protocols and patient suitability. Definitive surgical management consisted of total mesorectal excision with curative intent, while adjuvant chemotherapy was administered when indicated based on pathological findings and clinical status. Demographic details, clinicopathological characteristics, imaging findings, treatment details, pathological response, treatment-related adverse events, and follow-up information were collected from hospital records and outpatient follow-up visits. Adverse events were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

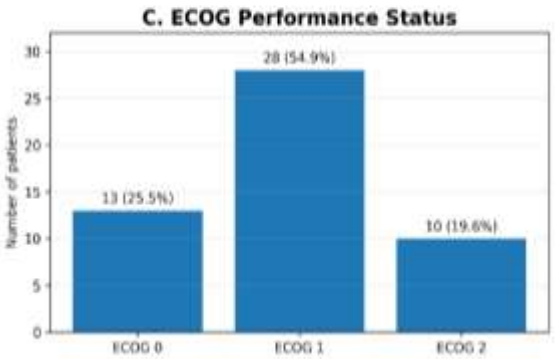
The primary study outcomes included disease-free survival (DFS), and overall survival (OS). Descriptive statistics were used to summarize baseline demographic, clinical, pathological, and treatment-related variables. Survival outcomes were estimated using the Kaplan–Meier method and compared using the log-rank test. Prognostic factors associated with DFS and OS were evaluated using univariate and multivariate Cox proportional hazards regression analyses. Statistical analyses were performed using IBM SPSS Statistics version 28.0.1.1, and a p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1. Baseline Demographic and Clinicopathological Characteristics of Patients (n = 51)

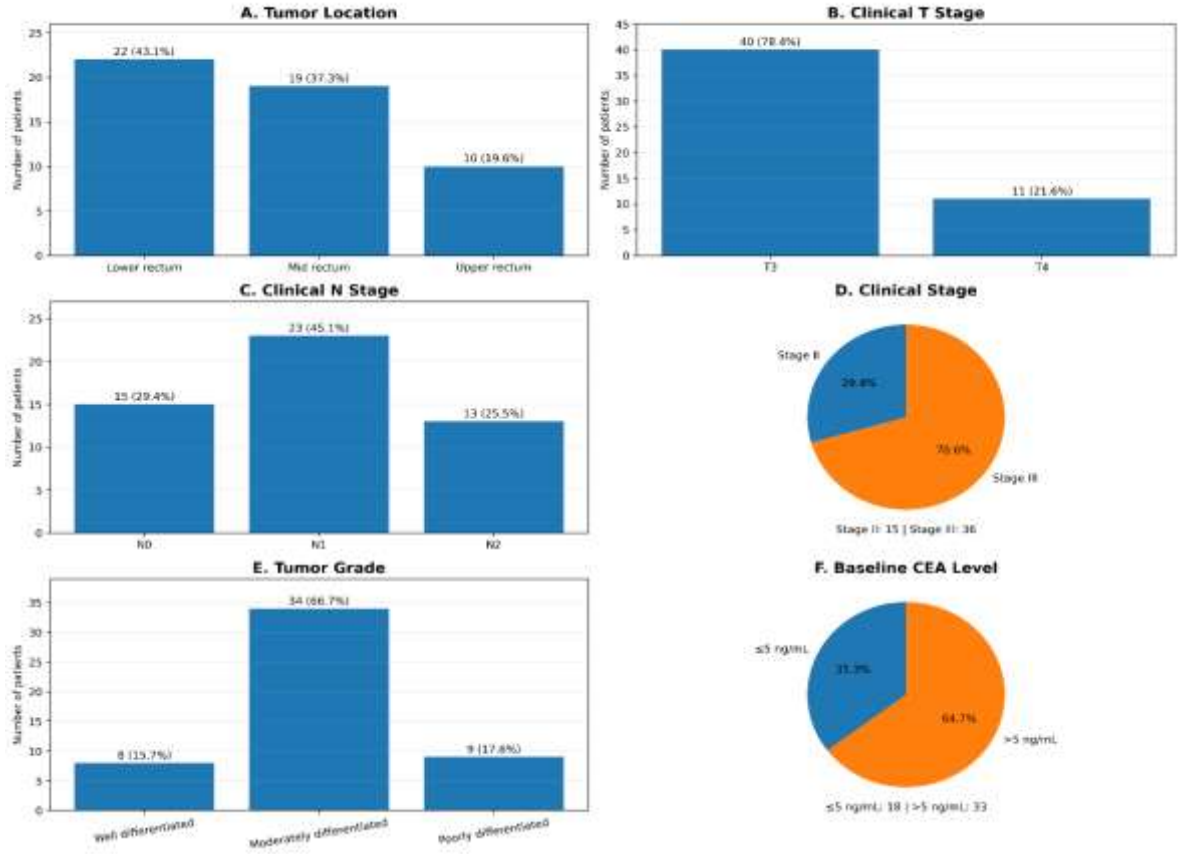






A total of 51 patients with locally advanced rectal cancer were included in the study. The mean age of the study population was 55.8 ± 11.2 years, with a median age of 56 years (IQR: 48–64 years). Most patients were aged 51–60 years (35.3%), followed by 61–70 years (25.5%). There were 34 males (66.7%) and 17 females (33.3%). An Eastern Cooperative Oncology Group performance status of 1 was observed in 28 patients (54.9%), while 13 (25.5%) and 10 (19.6%) patients had performance status scores of 0 and 2, respectively.

Table 2. Treatment Characteristics of Patients with LARC (n = 51)



In the present study, the lower rectum was the most common tumor location, identified in 22 patients (43.1%), followed by the mid rectum in 19 (37.3%) and upper rectum in 10 (19.6%). Clinical T3 disease was present in 40 patients (78.4%), while 11 patients (21.6%) had clinical T4 disease. Regarding nodal status, 15 patients (29.4%) had N0 disease, 23 (45.1%) had N1 disease, and 13 (25.5%) had N2 disease. Overall, 15 patients (29.4%) had clinical stage II disease and 36 (70.6%) had stage III disease. Moderately differentiated adenocarcinoma was the predominant histological grade, observed in 34 patients (66.7%). Baseline carcinoembryonic antigen levels were greater than 5 ng/mL in 33 patients (64.7%).

Table 3. Pathological Outcomes after Neoadjuvant Chemoradiotherapy Followed by Chemotherapy and Surgery (n = 51)

Variable	Category	n	%
Pathological T stage	**ypT0**	11	21.6
	ypT1–2	9	17.6
	ypT3	27	52.9
	ypT4	4	7.8
Pathological N stage	**ypN0**	32	62.7
	ypN1	14	27.5
	ypN2	5	9.8
Pathological complete response (pCR)	**Achieved**	11	21.6
	Not achieved	40	78.4

In the present study, pathological assessment demonstrated residual ypT3 disease in the majority of patients, whereas pathological nodal clearance (ypN0) was achieved in 62.7% of patients. Pathological complete response was achieved in 21.6% of patients, demonstrating a favourable tumour response following neoadjuvant chemoradiotherapy and chemotherapy.

Table 4. Recurrence and Follow-up Outcomes (n = 51)

Variable	Category	n	%
Recurrence	**Yes**	11	21.6
	No	40	78.4
Site of recurrence (n = 11)	**Local**	4	36.4
	Distant	7	63.6
Mean recurrence time		14.2 ± 5.6 months	
Median recurrence time (IQR)		13 (10–18) months	

In the present study, recurrence occurred in 21.6% of patients during follow-up, whereas the majority remained disease free. Distant recurrence was more common than local recurrence. The median recurrence time of 13 months indicates that most recurrences occurred within the first two years after treatment.

Figure 1. Kaplan-Meier Curve for Overall Survival of the Entire Cohort (n = 51)

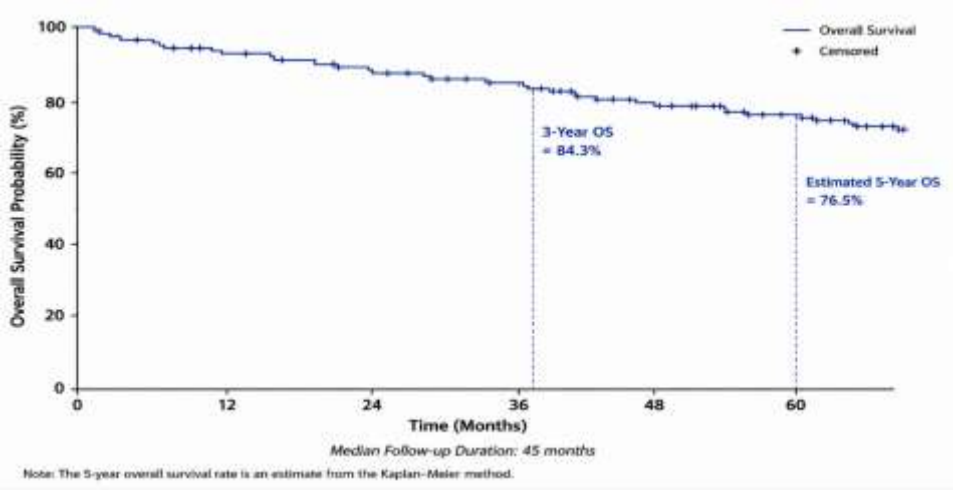
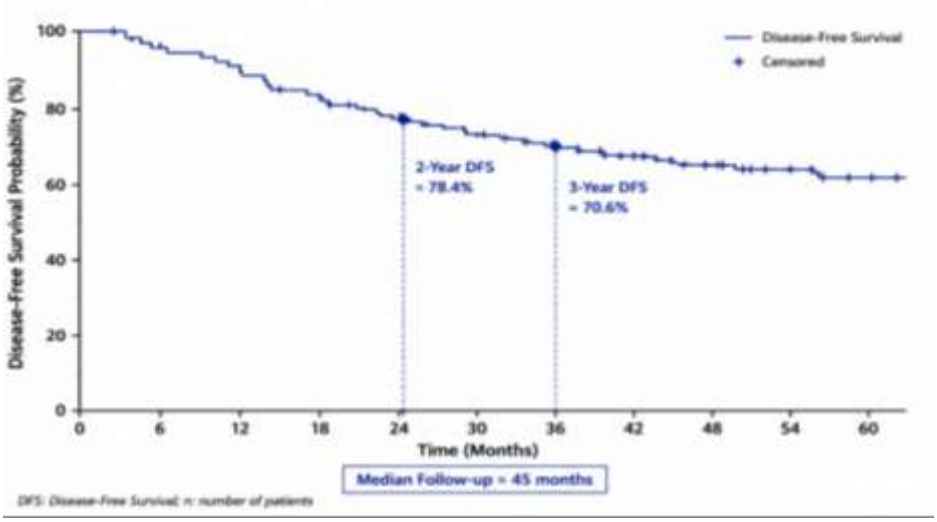


Figure 2. . Kaplan-Meier Curve for Disease-Free Survival of the Entire Cohort (n = 51)



In the present study, the 3-year overall survival was 84.3%, with an estimated 5-year overall survival of 76.5%. Disease-free survival was 78.4% at two years and 70.6% at three years. The median follow-up duration of 45 months provided adequate assessment of long-term survival outcomes.

Table 5. Multivariable Cox regression analysis for disease-free survival

Variable	Adjusted HR	95% CI	p value
Node-positive disease	3.28	1.01–10.68	0.047
R1 resection margin	4.52	1.10–18.54	0.036
No pathological complete response	3.74	1.00–13.92	0.049

On multivariable Cox proportional hazards regression analysis, node-positive pathological disease, R1 resection margin, and failure to achieve pathological complete response were independently associated with poorer disease-free survival. Patients with node-positive disease had a 3.28-fold higher hazard of recurrence or progression compared with node-negative patients (adjusted HR: 3.28; 95% CI: 1.01–10.68; p = 0.047). Patients with an R1 resection margin had a 4.52-fold higher hazard of recurrence or progression than those with negative resection margins (adjusted HR: 4.52; 95% CI: 1.10–18.54; p = 0.036). Failure to achieve pathological complete response was associated with a 3.74-fold higher hazard of recurrence or progression compared with achievement of pCR (adjusted HR: 3.74; 95% CI: 1.00–13.92; p = 0.049). These findings indicate that residual nodal disease, incomplete tumour resection, and lack of complete pathological response significantly increase the risk of disease recurrence after multimodality treatment

DISCUSSION

The present study evaluated survival outcomes in patients with locally advanced rectal cancer (LARC) treated with neoadjuvant chemoradiotherapy (NACTRT) followed by chemotherapy and surgery at a tertiary care centre in India. Multimodality treatment has become the standard of care for LARC because it improves local disease control, enhances pathological response, and contributes to improved long-term survival. In the present study, the majority of patients were between 51 and 60 years of age (35.3%), with a mean age of 55.8 ± 11.2 years, and males constituted 66.7% of the study population. Similar demographic characteristics have been reported by Biswas et al. (2024), who observed that rectal cancer predominantly affected middle-aged to elderly individuals with a clear male predominance in patients managed at a tertiary care centre in Eastern India (13). These findings suggest that the demographic profile of the present cohort is representative of Indian patients with locally advanced rectal cancer.

Most patients in the present study had Stage III disease (70.6%), clinical T3 tumours (78.4%), and moderately differentiated adenocarcinoma (66.7%), indicating that advanced locoregional disease constituted the major burden at presentation. These observations are consistent with the patient populations described by Bunjo and Sammour (2025), who highlighted that most contemporary studies evaluating neoadjuvant therapy include patients with stage II–III rectal cancer because these patients derive the greatest benefit from multimodality treatment [(2)]. Similarly, Airoldi et al. (2025) emphasized that accurate staging before treatment remains fundamental for selecting appropriate candidates for neoadjuvant therapy and optimizing oncological outcomes [(1)].

Treatment compliance in the present study was favourable, with 94.1% of patients completing the planned course of radiotherapy and 84.3% receiving adjuvant chemotherapy. Capecitabine was the most frequently administered concurrent chemotherapy regimen (76.5%). High treatment completion rates are important determinants of therapeutic success and are consistent with current recommendations supporting fluoropyrimidine-based chemoradiotherapy as standard neoadjuvant treatment. Marco et al. (2018) demonstrated that consolidation mFOLFOX6 administered after chemoradiotherapy improved long-term survival outcomes in patients with locally advanced rectal cancer, supporting the treatment sequence adopted in the present study [(6)]. Likewise, Barba et al. (2025) reported encouraging treatment completion rates and acceptable toxicity with total neoadjuvant treatment strategies, reinforcing the feasibility of multimodality management in routine clinical practice [(11)].

Tumour response following neoadjuvant treatment was encouraging. Clinical complete response was observed in 25.5% of patients, while pathological complete response (pCR) was achieved in 21.6% of cases. These findings are comparable to published literature reporting pCR rates generally ranging between 15% and 30% following neoadjuvant chemoradiotherapy. Bunjo and Sammour (2025) reviewed landmark neoadjuvant therapy trials and concluded that pCR remains one of the strongest surrogate markers for favourable oncological outcomes [(2)]. Similarly, Qin and Wang (2018) emphasized that successful tumour downstaging and pathological response after neoadjuvant therapy are closely associated with improved disease control and facilitate optimal surgical management [(3)].

Recurrence developed in 21.6% of patients during follow-up, with distant recurrence (63.6%) occurring more frequently than local recurrence (36.4%). The median recurrence time was 13 months, indicating that recurrence predominantly occurred within the initial years following treatment. These findings support the importance of intensive postoperative surveillance during the early follow-up period. Airoldi et al. (2025) emphasized that although advances in multimodality therapy have substantially reduced local recurrence, distant metastasis continues to represent the principal cause of treatment failure in patients with locally advanced rectal cancer [(1)]. Therefore, prolonged follow-up and early detection of recurrence remain essential components of patient management.

The survival outcomes observed in the present study were favourable. The overall cohort demonstrated a 3-year overall survival of 84.3%, an estimated 5-year overall survival of 76.5%, a 2-year disease-free survival of 78.4%, and a 3-year disease-free survival of 70.6%. Patients who achieved pCR experienced significantly superior survival compared with among patients without pCR. These differences were statistically significant. Marco et al. (2018) similarly demonstrated that patients achieving excellent pathological response following chemoradiotherapy and consolidation chemotherapy experienced superior long-term survival [(6)]. Airoldi et al. (2025) also highlighted pathological complete response as an important prognostic indicator associated with improved survival and lower recurrence risk [(1)].

Baseline carcinoembryonic antigen (CEA) levels showed a significant association with pathological complete response in the present study. Patients achieving pCR had significantly lower median baseline CEA levels than those without pCR (p=0.038). Although CEA alone cannot determine treatment response, lower pretreatment CEA levels have frequently been associated with better tumour regression following neoadjuvant therapy. Qin and Wang (2018) noted that clinical and biochemical parameters, including pretreatment CEA, may assist in predicting tumour response and guiding individualized treatment strategies [(3)].

Multivariate Cox regression analysis identified node-positive disease, R1 resection margin, and failure to achieve pathological complete response as independent predictors of poorer disease-free survival. These findings are biologically plausible because residual nodal disease reflects persistent tumour burden, while positive surgical margins increase the risk of local recurrence. Furthermore, patients who fail to achieve complete pathological response are more likely to harbour residual microscopic disease, resulting in inferior long-term outcomes. Bunjo and Sammour (2025) and Airoldi et al. (2025) similarly reported that pathological response, nodal status, and complete surgical resection remain among the most important determinants of long-term survival following multimodality treatment for locally advanced rectal cancer [(1,2)].

Overall, the findings of the present study demonstrate that neoadjuvant chemoradiotherapy followed by chemotherapy and surgery provides satisfactory pathological response and encouraging survival outcomes in patients with locally advanced rectal cancer. The favourable survival observed among patients achieving pathological complete response further reinforces the importance of optimizing neoadjuvant treatment strategies and achieving complete oncological resection. These findings are consistent with contemporary international evidence and support the continued implementation of multidisciplinary treatment protocols for the management of locally advanced rectal cancer in tertiary care centres in India.

CONCLUSION

Neoadjuvant chemoradiotherapy followed by chemotherapy and curative surgery resulted in favourable oncological outcomes in patients with locally advanced rectal cancer treated at our tertiary care centre. A pathological complete response was achieved in 21.6% of patients and was associated with significantly improved overall survival and disease-free survival. The overall cohort demonstrated encouraging survival outcomes, the 3-year overall survival was 84.3%, with an estimated 5-year overall survival of 76.5%. Disease-free survival was 78.4% at two years and 70.6% at three years. Distant recurrence was more common than local recurrence, emphasizing the need for vigilant postoperative surveillance. Lower baseline CEA levels were significantly associated with pathological complete response, while node-positive disease, R1 resection margin, and failure to achieve pathological complete response were identified as independent predictors of poorer disease-free survival. These findings support the effectiveness of a multidisciplinary treatment approach and highlight the prognostic importance of pathological response and complete surgical resection in improving long-term outcomes in locally advanced rectal cancer.

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