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Long term clinical outcomes in patients with rectal adenocarcinoma treated at a Tertiary Care Centre in South India

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Abstract

Introduction: Treatment of rectal adenocarcinoma involves multi-disciplinary approach which includes radiation, surgery and chemotherapy. Our study aims to assess the clinical outcomes of patients with rectal adenocarcinoma treated in a tertiary care centre in South India.

Materials and methods: A retrospective content-based analysis was made of 131 patients diagnosed and treated for adenocarcinoma rectum in a tertiary care hospital during the period of 1st January 2014 to 31st December 2015. The primary objectives were to assess disease free survival (DFS) and overall survival (OS).

Results: Of the 131 patients, 82 were males and 49 were females with a median age of 59 years. Stage II and Stage III disease together contributed to 65.6% of study population. After a median follow up of 105.8 months, the 8-year overall OS and DFS were found to be 77.2% and 78.8% respectively. In the univariate analysis, stage of the disease and histology were found to be significant factors in determining the overall survival ($p<0.05$). Multivariate analysis showed poorly differentiated adenocarcinoma emerged as significant factor affecting overall survival. About 31 (23.6%) patients showed disease recurrence. Of the 31 patients, pelvic recurrence occurred in 26% patients and among the distant metastases, liver was the most common site (33%) followed by lung (22%).

Conclusion: The disease free survival and overall survival of our patients were comparable with the available published data.

Keywords: Rectal cancer, Histology, Young adults, Survival rates, Prognosis

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Introduction

Colorectal cancer (CRC) is the third most diagnosed cancer in recent years, and the second leading cause of cancer deaths globally. There exists a geographical variation among the rectal cancer incidence, with higher rates in the western countries but mortality is higher in developing and under developed countries. Colorectum ranks sixth among the most common sites of cancer incidence in India, contributing to more than 4% incidence in 2022 (1). As per the recent report from National Centre for Disease Informatics and Research (NCDIR), gastrointestinal (GI) cancers comprised 18% of overall cancer cases in the country of which rectal cancer was the third most common cancer with an overall incidence rate of 2.6% (2).

Rectal cancer had been primarily considered a disease of the elderly, which mostly occur after the fifth decade of life but younger people aged less than 50 years diagnosed with colorectal cancer have been on the rise recently (3). Most of the patients present with locally advanced disease having a 5-year survival of 73% as per National Cancer Institute's (NCI's) Surveillance, Epidemiology, and End Results (SEER) program and the Centers for Disease Control and Prevention's (CDC's) National Program of Cancer Registries (4). But the 5-year survival rate of locally advanced rectal cancer in India is 40% which is one of the lowest in the world (5).

The standard treatment in early-stage disease is primary surgery with or without adjuvant treatment. In locally advanced disease, the standard of care is neoadjuvant treatment followed by surgery with or without adjuvant chemotherapy. Assessment of survival is the strongest parameter in oncologic outcomes. The complexity of multidisciplinary approach and the subtle variability in clinical decision making warrants periodical scrutiny of treatment profiles.

A study by Patil et al., showed that most of the colorectal cancers presents at a younger age, with an aggressive histopathology, and with involvement of both rectum and anal canal (5). There have been only few epidemiological studies with respect to clinical outcomes of rectal cancer in India and with its wide cultural and socio-ethnic differences, it is imperative to assess the demographic and clinical profile that helps in strategic planning, early diagnosis and efficient treatment modalities. Hence this study aims to assess the clinical outcomes of patients with rectal cancer treated in a tertiary care centre in South India.

Materials and methods

A total of 131 patients were diagnosed and treated from June 1st 2014 to May 31st 2015 in a tertiary care hospital in South India. This is a retrospective analytical study with data obtained from the Medical Records in the hospital. It was based on content analysis where the clinical and histopathological staging, treatment and follow up details were collected from the case records using a structured proforma.

All rectal carcinoma patients with histology of adenocarcinoma during the study period were included in the study. Histology other than adenocarcinoma were excluded from the study. Informed consent was obtained from all patients and the study was approved by Institutional Review Board (No: 09/2016/04).

Statistical analysis

All patients (n = 131) were analysed and follow up data was updated until April 2023. The primary endpoints analysed were disease free survival (DFS) and overall survival (OS). DFS was defined as the period from the date of registration to the date of locoregional relapse, distant relapse or death, whichever occurred earlier. OS was defined as the period from the date of registration to the date of death from any cause. The statistical analysis was done using SPSS version 20. The data was analysed and results were tabulated using descriptive statistics. Continuous variables were expressed as mean and standard deviation, and categorical variables as counts and percentages. Survival curves were generated using the Kaplan-Meier method and statistical significance was assessed using the log-rank test. The risk for survival was assessed using cox regression analysis and a p-value < 0.05 was considered significant.

Results

Baseline characteristics

From June 1st 2014 to May 31st 2015, 131 patients with biopsy proven rectal adenocarcinoma were analysed in the present study. Baseline characteristics are shown in table 1. The median age of the population was 59 years ranging from 24 to 91 years. There were 82 males (62.59%) and 49 females (37.41%) included in the study. Mid rectal cancer (defined as tumors residing 5-10cm from anal verge) was the most common occurring in 51 patients (38.93%) closely followed by lower rectal cancer (defined as tumors residing <5cm from anal verge) diagnosed in 45 patients (34.36%) and upper rectal cancer (defined as tumors residing 10-15cm from anal verge) in 35 patients (26.71%). Majority had cT3 disease (38.16%) followed by cT2 (30.55%) and cT4 disease (16.03%). With respect to nodal status, 72 patients (54.96%) had node negative disease. Stage II and Stage III disease dominated the study population each contributing to 32.82% followed by stage I disease (27.49%).

High risk factors like obstruction, perforation, presence of LVE (lymphovascular emboli)/PNI (Perineural invasion) and inadequate nodal sampling, were present in 11 patients (8.39%). High-risk pathology like poorly differentiated carcinoma (2.29%), mucinous adenocarcinoma (12.21%) and presence of signet ring cells (9.92%) were observed.

Treatment characteristics

Prior to reporting at our centre, 32 patients (24.42%) received some form of oncological treatment elsewhere. Of the remaining 99 patients, 82 patients (82.82%) received neoadjuvant chemoradiation. Pathological Complete Response was seen in 8.39% patients. Pathologically node-negative disease was observed in 52.7% of patients. About 88 patients received adjuvant chemotherapy, of them 75% patients were treated with mFOLFOX-6 (5-Fluorouracil + Folinic acid + Oxaliplatin) and 14.7% patients were treated with CAPOX (Capecitabine + Oxaliplatin) regimen.

Table 1. Baseline Characteristics.

Characteristics	Number (n)	Percentage (%)
Age		
<40	10	7.6%
40-59	61	46.56%
60-79	55	42.04%
>80	5	3.8%
Sex		
Male	82	62.59%
Female	49	37.41%
Site of disease		
Upper	35	26.71%
Mid	51	38.93%
Lower	45	34.36%
Tumour characteristics		
T1	20	15.26%
T2	40	30.55%
T3	50	38.16%
T4	21	16.03%
Nodal Status		
N0	72	54.96%
N1	33	25.20%
N2	26	19.84%
Stage of the disease		
Stage I	36	27.49%
Stage II	43	32.82%
Stage III	43	32.82%
Stage IV	9	6.87%
High risk factors		
Obstruction	1	0.76%
Perforation	1	0.76%
LVE/PNI	4	3.05%
Inadequate Lymph Node sampling	5	3.81%
Histology		
Well Differentiated	21	16.04%
Moderately Differentiated	78	59.54%
Poorly differentiated	3	2.29%
Mucinous	16	12.21%
Signet ring cell	13	9.92%
Radiotherapy		
NACTRT	83	63.35%
Adjuvant CRT	17	12.97%
SCRT	3	2.22%
Palliative RT	6	4.58%

Abbreviations: LVE - lymphovascular emboli; PNI - Perineural invasion; NACTRT – Neoadjuvant chemoradiotherapy; CRT – chemoradiotherapy; SCRT – short course radiotherapy; RT – Radiotherapy.

The median follow up was 105.8 months (16.6 to 182.6 months). The 8-year OS and DFS was shown to be 77.2% and 78.8% respectively. Figure 1 shows the Kaplan Meier curves for 8-year DFS and OS in our study.

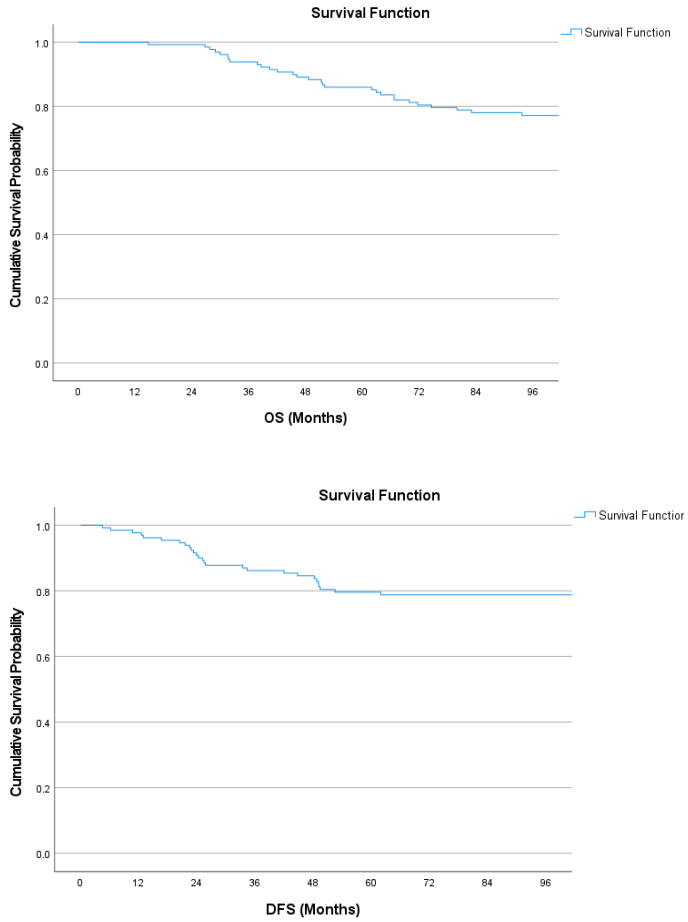

Figure 1. Kaplan Meier curves of 8-year DFS and OS.

Tables 2 and 3 show the cumulative survival probabilities of OS and DFS with respect to stage, sex, site of disease, histology, and various chemotherapy regimens respectively. Figure 2 shows the Kaplan Meier curves of OS with respect to stage, histology and nodal status.

Table 2. Survival probability with respect to OS.

Variables	Cumulative Survival Probability (%)		P-value
Stage	I	77.1	**0.009**
	II	90.1	
	III	71.9	
	IV	44.4	
Sex	Female	70.5	0.101
	Male	81.1	
Age	<50	72.1	0.371
	>=50	78.9	
Site	Lower	81.0	0.756
	Mid	76.2	
	Upper	74.1	
Histology	MD	76.2	**<0.001**
	PD	0.0 (all died)	
	WD	84.8	
Prior Treatment	Treated elsewhere	84.4	0.258
	No Treatment	74.7	
Pathological Nodal Status	Negative	83.6	0.063
	Positive	68.3	
Adjuvant Chemotherapy	CAPECITABINE	100.0	**0.043**
	CAPOX	61.5	
	FOLFOX	81.4	
Palliative Chemotherapy	CAPOX	66.7	**0.007**
	FOLFOX	0.0 (all died)	
	5-FU+LV	100.0	

Abbreviations: MD- Moderately Differentiated; WD- Well Differentiated; PD- Poorly Differentiated; 5FU + LV – 5-Flourouracil + Leucovorin; mFOLFOX-6 (5-Fluorouracil + Folinic acid + Oxaliplatin); CAPOX (Capecitabine + Oxaliplatin).

Table 3. Survival probability with respect to DFS.

Variables	Cumulative Survival Probability (%)		P-value
Stage	I	80.3	0.775
	II	80.8	
	III	73.7	
	IV	88.9	
Sex	Female	73.0	0.116
	Male	82.4	
Age	<50	75.4	0.434
	>=50	80.0	
Site	Lower	75.0	0.592
	Mid	77.3	
	Upper	85.7	
Histology	MD	73.8	0.391
	PD	66.7	
	WD	85.7	
Prior Treatment	Treated elsewhere	77.6	0.928
	No Treatment	79.2	
Pathological Nodal Status	Negative	75.0	0.473
	Positive	81.7	

Adjuvant Chemotherapy	CAPECITABINE	77.8	0.904
	CAPOX	76.2	
	FOLFOX	80.2	
Palliative Chemotherapy	CAPOX	66.7	0.459
	FOLFOX	0.0 (all died)	
	5-FU+LV	100.0	

Abbreviations: MD- Moderately Differentiated; WD- Well Differentiated; PD- Poorly Differentiated; 5FU + LV – 5-Flourouracil + Leucovorin; mFOLFOX-6 (5-Fluorouracil + Folinic acid + Oxaliplatin); CAPOX (Capecitabine + Oxaliplatin).

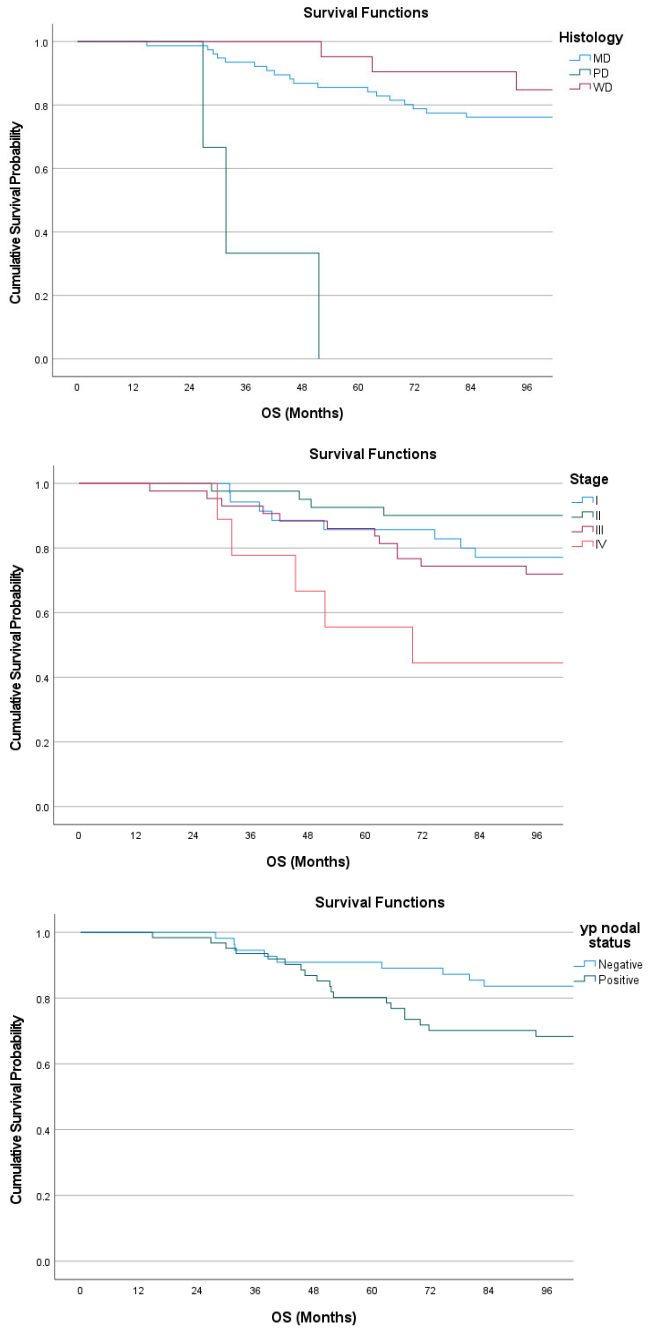

Figure 2. Kaplan Meir curves of OS with respect to Stage, Nodal status, and histology

Univariate analysis showed stage IV had worse outcomes compared to stage I (Hazard ratio (HR) 3.19; p = 0.042) and poorly differentiated adenocarcinoma had worse OS compared to moderately differentiated adenocarcinoma (HR 14.94; p = <0.001). Multivariate cox regression analysis showed poorly differentiated histology is associated with poor OS with an HR 9.47 (p = 0.003). Table 4 and 5 shows the univariate analysis with respect to OS and DFS respectively. Table 6 shows the multiple cox regression analysis affecting OS.

Figure 3 shows the pattern of recurrence after radical treatment with locoregional recurrence of 26% and among the distant sites, liver metastasis contributes to 33% followed by lung (22%), non-regional nodes (11%) and other sites (8%) which includes bone, brain and adrenals.

Discussion

Colorectal cancer has witnessed a staggering rise in its incidence and parallelly the evolution of surgical and chemoradiation techniques have improved the survival of the patients. In general, women tend to have lower incidence and higher survival in colorectal cancer (6). Losurdo et al., published a gender focussed analysis of long-term outcomes of colorectal cancer that revealed a higher 5-year (86.9% vs 80.5%) and 10-year survival (80% vs 73.3%) for women compared to men (7). This contrasts with our study where no statistically significant survival differences were seen between men and women.

Siegel et al., reported rising incidence rates of colorectal cancer in younger population (less than 50 years) in western countries over the last 2 decades (8). A retrospective analysis in an Indian population showed that around 21% of patients with colorectal cancer were less than 40 years (9). Hong et al., showed that the lowest 5-year OS and DFS were seen in age group less than 40 years (62.5% and 52.1% respectively) (10), similar to our study where a statistically non-significant trend of lower survival rates were seen in patients less than 50 years.

Table 4. Univariate Cox regression analysis of OS.

Variables	HR	95.0% CI for HR		Sig.
		Lower	Upper	
Age Group: ≥50 vs <50	0.70	0.32	1.54	0.374
SEX: Male vs Female	0.55	0.27	1.14	0.107
Stage: II vs I	0.41	0.12	1.36	0.145
Stage: III vs I	1.26	0.52	3.08	0.612
Stage: IV vs I	**3.19**	1.04	9.78	**0.042***
Pathological nodal status: Yes vs No	2.09	0.94	4.61	0.070
Adjuvant Chemotherapy: CAPECITABINE vs FOLFOX	0.00	0.00	0.00	0.981
Adjuvant Chemotherapy: CAPOX vs FOLFOX	2.68	0.94	7.60	0.065
Palliative Chemotherapy: FOLFOX vs CAPOX	233.29	0.00	69017143.65	0.396
Palliative Chemotherapy: 5-FU+LV vs CAPOX	0.05	0.00	487.19	0.520
Site: Mid vs Lower	1.34	0.55	3.28	0.522
Site: Upper vs Lower	1.39	0.54	3.60	0.500
No prior treatment vs Treated elsewhere	1.73	0.66	4.54	0.264
Histology: PD vs MD	**14.94**	4.13	54.06	**<0.001***
Histology: WD vs MD	0.54	0.16	1.85	0.329
Histology: Mucin vs MD+PD+WD	0.24	0.03	1.75	0.158
Histology: Signet vs MD+PD+WD	1.42	0.49	4.08	0.520

Abbreviations: MD- Moderately Differentiated; WD- Well Differentiated; PD- Poorly Differentiated; 5FU + LV – 5-Flourouracil + Leucovorin; mFOLFOX-6 (5-Fluorouracil + Folinic acid + Oxaliplatin); CAPOX (Capecitabine + Oxaliplatin).

Table 5. Univariate Cox regression analysis of DFS.

Variables	HR	95.0% CI for HR		Sig.
		Lower	Upper	
Age Group: ≥50 vs <50	0.72	0.32	1.65	0.436
SEX: Male vs Female	0.55	0.26	1.17	0.121
Stage: II vs I	1.00	0.36	2.75	0.994
Stage: III vs I	1.39	0.54	3.59	0.494
Stage: IV vs I	0.61	0.08	4.97	0.645
Pathological nodal status: Yes vs No	0.75	0.34	1.65	0.474
Adjuvant Chemotherapy: CAPECITABINE vs FOLFOX	1.16	0.26	5.15	0.844
Adjuvant Chemotherapy: CAPOX vs FOLFOX	1.32	0.38	4.62	0.669
Palliative Chemotherapy: FOLFOX vs CAPOX	1.41	0.09	23.57	0.809
Palliative Chemotherapy: 5-FU+LV vs CAPOX	0.00	0.00	0.00	0.981
Site: Mid vs Lower	0.88	0.38	2.03	0.767
Site: Upper vs Lower	0.58	0.20	1.67	0.314
No prior treatment vs Treated elsewhere	0.96	0.41	2.27	0.928
Histology: PD vs MD	1.86	0.25	13.94	0.548
Histology: WD vs MD	0.50	0.15	1.67	0.256
Histology: Mucin vs MD+PD+WD	0.51	0.12	2.16	0.360
Histology: Signet vs MD+PD+WD	0.32	0.04	2.37	0.265

Abbreviations: MD- Moderately Differentiated; WD- Well Differentiated; PD- Poorly Differentiated; 5FU + LV – 5-Flourouracil + Leucovorin; mFOLFOX-6 (5-Fluorouracil + Folinic acid + Oxaliplatin); CAPOX (Capecitabine + Oxaliplatin).

Table 6. Multiple Cox Regression analysis for Overall OS.

Variables	HR	95.0% CI for HR		Sig.
		Lower	Upper	
Stage: II vs I	0.54	0.16	1.82	0.316
Stage: III vs I	1.47	0.60	3.63	0.400
Stage: IV vs I	1.99	0.55	7.19	0.294
Histology: PD vs MD	**9.47**	2.10	42.72	**0.003***
Histology: WD vs MD	0.61	0.18	2.10	0.433

Abbreviations: MD- Moderately Differentiated; WD- Well Differentiated; PD- Poorly Differentiated.

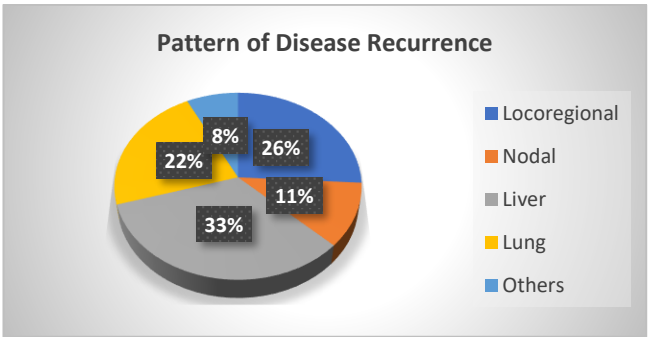

Figure 3. Pattern of disease recurrence.

Fang et al., reported a 5-year OS for stage I and II tumors (95.1% and 90.3% respectively) comparable to our study where stage II had the maximal overall survival due to lesser number of stage I patients (11). In the same study, the survival rates dropped down to 77.8% in stage III disease and only 34.9% for stage IV disease reiterating the fact of advanced tumour stage as a bad prognostic factor causing poor survival in patients with rectal cancer. The present study had only 9 cases with stage IV disease constituting just 6.87% of the total population, hence a higher DFS rate (88.9%) can be seen, but with no statistical significance.

Park et al., reported that the local relapse rates of upper rectal cancer were 3.5% and that of mid/lower rectal cancer group were 11.1% (12). The 5-year OS of upper and mid/lower rectal cancers in the same study were 78.8% and 73.3% respectively. This is in accordance with our study where lower rectal cancers had a relatively poor DFS rates compared to upper rectal tumors but not statistically significant. Generally, lower rectal tumors have a rich lymphatic drainage and vascular supply allowing for rapid and early metastases to distant sites.

Histologically, poorly differentiated carcinoma had the worst survival and well differentiated tumours had a better survival advantage. Most Western studies report a prevalence of 5–15% for mucinous histology and 1% for signet ring tumors (13,14). Vasudevan et al., reported an inferior overall survival for signet ring cell histology compared to mucinous adenocarcinoma (24 vs 38 months) and occurred more in younger population compared to older adults (11% vs 4%) (15). In another study by Patil et al., the proportion of signet ring cell histology was higher in patients aged less than 40 years compared to those above 40 years (22.9% vs 8.3%) (5). We observed lower overall survival (66.7%) for patients with signet ring histology identical to the published reports. In our multivariate analysis, poorly differentiated histology established itself as a single most prognostic factor affecting overall survival.

A German cohort study showed that rectal cancer patients treated in certified cancer care centres had a better overall survival compared to those treated in non-certified centres (5-year OS 65% vs 58.8%) owing to the high evidence-based practices and better sophistication in certified centres (16). The high-volume dedicated cancer centres significantly reduce in-hospital mortality rates owing to the better quality of oncologic practices as stated in standard guidelines. However, our study did not show a significant survival benefit for patients treated exclusively in our centre though DFS was slightly higher for patients treated at our centre (77.6% vs 79.2%).

Lymph node status was a single most important prognostic factor in determining the need for adjuvant chemotherapy. Pathologically node positive disease tends to have lower survival and frequent relapses. Diefenhardt et al., showed that 5-year OS of 86.1% for ypN0, 74.0% for ypN1, and 43% for ypN2 and concluded that persistent lymph node metastases after neoadjuvant therapy indicates an unfavourable phenotype of rectal cancer having higher risk for treatment failure thus offering poor survival rates (17). This was similar to our study where pathologically node positive population had lower 8-year OS compared to node negative population reiterating the importance of nodal status as a prognostic marker.

The benefit of adding oxaliplatin to standard 5-FU based chemotherapy was first demonstrated in the MOSAIC trial as it significantly improved 5-year DFS (73% versus 67%) and 5-year OS (79% vs 76%) (18). The phase II ADORE trial showed addition of oxaliplatin to 5-FU after chemoRT resulted in significantly higher 6-year DFS (68.2% vs 56.8%) and borderline significant 6-year OS (78.1% vs 76.4%) (19). Literature showed no direct comparisons between mFOLFOX-6 and CAPOX regime in rectal adenocarcinoma but the comparison reports from colon cancer studies showed no significant differences in terms of survival. Our study showed better outcomes with capecitabine and CAPOX regimes but the sample size was too small to draw a conclusion.

The 8-year OS and DFS rates of our study were consistent with majority of the colorectal cancer studies across the globe. Hong et al., conducted a retrospective analysis of colorectal adenocarcinoma and reported a five-year overall and disease-free survival of 79.5% and 69.9%, respectively (10). Various reports from different population groups showed similar survival rates – a Brazilian study showed 5-year OS of 60.3% (20); a Thailand single institution study (21) showed 5-year OS and DFS of 72% and 68% respectively and a South Australian study showed 5-year OS of 63% (22).

A noticeable observation from our study was that 25% of patients were under 50 years of age. In the past, rectal cancer was considered as a disease of the elderly but various Indian studies have reported a staggering rise in early onset rectal cancers (23,24). This has been consistent across the world where analysis of 143 million people from 20 European countries showed CRC incidence has increased by 7.9% per year among subjects aged 20–29 years, by 4.9% among those aged 30–39 years, and by 1.6% among those aged 40–49 years from 2004 to 2016 (25). Based on current data, it is estimated that within the next decade, 1 in 4 rectal cancers and 1 in 10 colon cancers will be diagnosed in individuals under 50 (26). The presence of distinct genetic profiles and hereditary factors might influence the development of early onset rectal cancers. Other factors like inflammatory bowel disease, obesity, insulin resistance, smoking, consumption of red meat and high fat diet, contribute to the risk of developing rectal cancer especially in early adulthood.

The stage of the disease at diagnosis, as shown to have significant effect on survival in our study, is crucial in determining the natural course of the disease in terms of risk of recurrence and cancer free survival. Hence the need for diagnosis at an early stage stands critical in the management of rectal adenocarcinoma. The presence of tertiary care and oncology centres in urban areas provide better health awareness to the urban population alone, leaving the rural and low socioeconomic classes in a brim who may present at advanced stages that significantly hamper the colorectal survival rates in our country.

Our study has limitations. Being a retrospective study with limited sample size, we were unable to assess toxicities of chemotherapy and radiotherapy. Periodical evaluation of tumor markers was not available from the records in half of the study population. We could not analyse the survival outcomes with radiological factors like mesorectal fascia involvement (MRF), extramural vascular invasion (EMVI) which was not routinely reported during the study period. Surgery done from different institutions were also included in the study hence clarity on total mesorectal excision could not be elicited.

Conclusion

The long-term clinical outcomes of our patients were comparable with the available published data all over the world. Larger prospective analysis of rectal cancer can provide valuable insights regarding the current trend of epidemiology, prognostic factors and survival of rectal cancer.

Author contribution

Conceptualizations, methodology, project administration, supervision, validation, review and editing of the original draft by **LA** and **RS**; Data curation by **AA**, **LA**, **RS**, **MPA**; Writing original draft by **AA**. Investigation by **LA**, **RS**, **SCD**, **SA**, **AS**, **GMH**; Formal analysis, software, and visualization by **AM**.

Ethics approval

The author declares no conflict of interest.

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