



Study of quality of life in locally advanced carcinoma rectum patients treated with neoadjuvant chemoradiation

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ABSTRACT:

AIM:

To assess quality of life among the study population before, during and after 1 month of neoadjuvant chemoradiation treatment by using EORTC questionnaire.

Material & Methods:

Twenty five patients, who were eligible to receive neoadjuvant chemoradiation were considered for study. External beam Radiation therapy was delivered using IMRT on a linear accelerator with a total dose of 50.4Gy was delivered in 28 fractions and treated 5 days/week. Concurrent chemotherapy is administered using tablet capecitabine administered per orally, at a dose of 825 mg/m² twice daily. QOL is assessed using EORTC QLQ-30 and QLQ CR29 questionnaires at first, third and sixth weeks of treatment.

RESULTS:

Quality of life was assessment showed a functional scale mean scores of physical, role and emotional functions also returned to before treatment values at one month follow up. Global health scale improved at one month follow up. Most of the other symptoms like nausea & vomiting, pain, diarrhea, dysuria and constipation most of which were high during treatment had fallen back to baseline at one month follow up.

Conclusions:

From the present study it could be concluded that carcinoma rectum patients treated with neoadjuvant concurrent chemoradiation tolerated the treatment well and can be opted for locally advanced stages where upfront surgery is not possible. Quality of life of treated patients, though dipped during treatment, most of the domains returned to baseline scores at one month follow up.

KEYWORDS: carcinoma rectum, neoadjuvant chemoradiation, quality of life study, locally advanced carcinoma rectum

I. INTRODUCTION:

Rectal cancer is the third most common malignancy and the second in cancer mortality, colorectal cancer (CRC) induces estimated 1.9 million incidence cases and 0.9 million deaths worldwide in 2020. Cancer incidence and mortality rates have been higher in economically higher countries. This may be because of consumption of a high fat and red meat diet, with resulting obesity. Curative treatment for rectal adenocarcinoma is surgical resection. Surgery was the only treatment in the 1980s. However, the majority of patients presents with deeply invasive locally advanced tumors that are adherent to adjoining structures, which require more extensive transabdominal surgery. Management varies greatly depending on the stage and location of the tumor within the rectum. Multimodal therapy is optimal to reduce recurrence risk and improve survival.

Neoadjuvant chemoradiation has been utilized to promote tumor regression; The combination of radiotherapy and capecitabine enhances antitumor activity. Capecitabine acts as a radiosensitizer and increases the effectiveness of radiotherapy. As a result, Neoadjuvant long-course RT plus radiation sensitization with a fluoropyrimidine (eg. capecitabine, fluorouracil) followed by a treatment break of approximately 8 weeks before surgical excision and concluding with adjuvant chemotherapy, has been a standard of care in rectal cancer.

In light of this, a present study was conducted in our institution to evaluate quality of life in locally advanced carcinoma rectum patients treated with neoadjuvant chemoradiation.



II. MATERIALS & METHODOLOGY

STUDY GROUP

It is a hospital based observational prospective study. This study is initiated after obtaining approval from the Institutional ethical committee. Histopathologically confirmed cases of carcinoma rectum presented to the Department of Radiation Oncology, NRI Medical College & General Hospital, Chinakakani, Guntur are included in the study. The sample size is taken as 25 based on convenience sampling method. The study was conducted from April 2021 to September 2022. The clinical findings and stage of all patients were discussed in a multidisciplinary tumor board composed of Radiation Oncologists, Surgical Oncologists, Medical Oncologists, and Radiologists. Patients who were planned for neoadjuvant chemoradiation were the study group. All patients were decided according to the termed inclusion and exclusion criteria.

INCLUSION CRITERIA:

1. Age : 18 – 75 years
2. ECOG: performance status 0-2 on a scale of 0-4
3. Histopathological confirmed locally advanced adenocarcinoma.
4. Hematological parameters within normal limits , renal and liver function tests within normal range.

EXCLUSION CRITERIA:

1. Any prior treatment received for the tumor.
2. Patients who do not give informed consent
3. Metastatic carcinoma rectum.
4. Patients who received upfront surgery for carcinoma rectum

STUDY DESIGN

Histologically proven cases of locally advanced carcinoma rectum patients who had given consent and met inclusion criteria and who doesn't have any exclusion criteria.



Staging and metastatic workup, including routine investigations like CBC, BGT, RFT, LFT and chest X Ray



CT simulation, target volume delineation and plan evaluation



Total dose of 50.4Gy in 28 fractions each of 1.8Gy along with tablet capecitabine , for 5 days a week



QOL is assessed in the study group using EORTC QLQ-30 and QLQ CR29 questionnaires at first, third and sixth weeks of treatment.

TREATMENT

External beam Radiation therapy was delivered using IMRT on a linear accelerator with 6 MV / 15 MV photons .As per our institution protocol, a total dose of 50.4Gy was delivered in 28 fractions and treated 5 days/week. Concurrent chemotherapy is administered using oral capecitabine 825 mg/m² twice daily.

QUALITY OF LIFE (QOL):

EORTC QLQ-C30

The QLQ-C30 is composed of multi-item scales as well as single-item measures. This questionnaire includes three symptom scales, five functional scales, six single items and a global health status/ QoL scale. Each of these multi-item scales incorporates a different set of items i.e. no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to 100. The principle for scoring these scales is the 46 same in all cases. The average of the items that contribute to the scale is estimated; this is the raw score. Linear transformation is done to standardize the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms(1).

EORTC QLQ-CR29

The scoring of EORTC QLQ-CR29 is similar to EORTC QLQ-C30. There are three multi item scales and six single item scales. In general, the higher the scores the worse is the problem (except sexual activity and sexual enjoyment).

Data was analyzed by obtaining rates and proportions. Chi-square test and t test was used to find the significance. This whole analysis was done using SPSS software version 26(2).

III. RESULTS

In this present study a total of 25 patients were taken.



AGE DISTRIBUTION:

Out of 25 patients, the median age is 56 years. Patients were ranging between 30 years to 76 years. 36 percent of patients lie between 51-60 years .

SEX DISTRIBUTION:

This study group of a total 25 patients, 11 were females and 14 were males. 56% of patients in the study were male and 44% were females.

SOCIAL AND ECONOMIC DISTRIBUTION:

8% of study group were from APL card holders. Rest of 92% of them were from BPL card holders. 8% of patients were skilled labours and rest of the 92% of them were unskilled labours. 80 % patients were illiterates , 12% of patients studied primary education and 8% of them have completed a degree . 88% of patients hailed from rural region and 12% of them were from urban area.The mean BSA was 1.6kg/m2.

ECOG PERFORMANCE STATUS:

The patients are categorized according to ECOG performance status. 68% of patients scored a performance status score of “one” which is strenuous physical activity restricted; fully ambulatory and able to carry out light work. 32% of them i.e 8 of them scored a performance status of “two”.

COMORBIDITIES

QUALITY OF LIFE:

EORTC QLQ-C30:

Global health status / QoL: In the present study, quality of life was statistically significant between Pre treatment and during treatment (p=0.008) . QOL trended upwards at 1 month follow up.It was also statistically significant(P=0.03) between during treatment and 1 month Follow up after treatment and reached pretreatment state.

A total of 10 patients had hypertension and 7 patients had diabetes i.e 40% of patients had hypertension and 28% of patients had diabetes.

DISTRIBUTION ACCORDING TO HPE:

Well differentiated adenocarcinoma was the commonest histology in the study group seen in 18 patients i.e 72% . Moderately differentiated adenocarcinoma seen in 4 patients i.e in 16% and poorly differentiated adenocarcinoma seen in 2 patients which is 8%. The least common histology being signet ring cell adenocarcinoma in one of the patients and accounts for 4 % of the total study group.

STAGE WISE DISTRIBUTION OF PATIENTS:

The most common stage of presentation was IIIB in 56% of patients . Descending order of presentation was III B, II A, III A, II B and III C. The distribution according to percentages were 56%, 28% , 8% , 4% and 4% respectively.

NEOADJUVANT CHEMORADIATION DOSE

All patients were treated with 6 MV/15 MV beam energy on linear accelerator and by IMRT/RAPIDArc technique. As per our institution protocol, all the patients were irradiated with a total dose of 50.4Gy in 28 fractions for 5 days/week. All the patients were given concurrently , tablet capecitabine per orally at a dose of 825 mg/m2 during the radiation treatment days.

Time	global health score Mean (29,30)	SD	Comparison between before and during treatment	Comparison between during and after treatment
Pre treatment	55.66	7.5	P -value	P -value
During treatment	49.33	8.64		
At 1 month FU	55	9.31		

Table no. 1: Global health status scores



Functional scales

Physical functioning : In this study, physical functioning was statistically significant between pre treatment and during treatment ($p=0.0001$) . It was also statistically significant($P=0.01$) between during treatment and 1 month Follow up and trended upwards at 1 month follow up.

Time	PHYSICAL(1-5)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	90.4	7.47	P -value	P -value
During treatment	77.06	6.96	0.0001	0.01
At 1 month FU	82.66	8.06		

Table no.2:Physical functioning scores

Role functioning (6,7): In the present study, role functioning deteriorated during treatment phase but rapidly attained pre treatment value at 1 month follow up. It was statistically significant between Pre treatment and during treatment ($p=0.0001$) . It was also statistically significant($P=0.0001$) between during treatment and 1 month follow up.

Time	Role functioning (6,7)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	94	8.16	P -value	P -value
During treatment	66	24.28	0.0001	0.0001
At 1 month FU	92.66	10.84		

Table no.3: Role functioning scores

Emotional functioning:

In the present study, emotional functioning decreased during treatment might be because of fear of newly diagnosed chronic disease. But it has reached pre treatment value at 1 month follow up. It was statistically significant between Pre treatment and during treatment ($p=0.0008$) . It was also statistically significant($P=0.007$) between during treatment and 1 month follow up.

Time	Emotional functioning(21-24)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	96.33	4.85	P -value	P -value
During treatment	87.66	11.05	0.0008	0.007
At 1 month FU	94.66	5.83		

Table no.4:Emotional functioning scores



Cognitive functioning(20,25)

In this study, the cognitive functioning has not deteriorated much in terms of score values, it was also not statistically significant between pre treatment and during treatment (P=0.19) and between during treatment and at 1 month follow up (P=0.12)

Time	Cognitive functioning(20,25)	SD	Comparison between before and during treatment	Comparison between during treatment and at 1 month FU
Pre treatment	94.66	7.93	P -value	P -value
During treatment	90.66	12.8	0.19	0.12
At 1 month FU	95.33	7.63		

Table no.5 Cognitive functioning scores

Social functioning(26,27)

Social functioning had fallen down during treatment compared to pre-treatment and was statistically significant (P=0.015) and has reached almost near pretreatment value at 1 month follow-up. The Comparison between during treatment and at 1 month follow up was statistically significant (P=0.32).

Time	Social functioning(26,27)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	88	11.3	P -value	P -value
During treatment	77.33	17.92	0.015	0.32
At 1 month FU	82	15.15		

Table no.6: Social functioning scores

Symptom scales / items: The higher the score, the worse the symptom.

Fatigue(10,12,18): Even though fatigue score was less, it was statistically significant pretreatment vs during treatment (P=0.0001) and statistically insignificant during treatment vs at 1 month follow up (P=0.09)

Time	Fatigue(10,12,18)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	4.88	6.51	P -value	P -value
During treatment	16.88	12.47	0.0001	0.093
At 1 month FU	11.55	9.34		

Table no.7: Fatigue score

NAUSEA & VOMITING (14,15):

Nausea was higher during treatment phase in comparison to pre treatment, during and at 1 month follow up. It was statistically significant when compared between before vs during treatment (P=0.001) and during vs at 1 month follow up (P=0.01)



Time	NAUSEA & VOMITING (14,15)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	10.66	10.62	P -value	P -value
During treatment	24	16.01		
At 1 month FU	13.33	13.6	0.001	0.014

Table no.8:Nausea & vomiting scores

PAIN(9,19):Pain score raised during treatment and was statistically significant compared to pretreatment (P=0.003) and reduced compared to baseline before treatment scores and were statistically significant (P=0.0006).

Time	PAIN(9,19)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	32	17.95	P -value	P -value
During treatment	50	23.57		
At 1 month FU	28.66	17.02	0.003	0.0006

Table no.9:Pain scores

DYSPNOEA(8)

Dyspnea scores were stable throughout all the phases. Comparison between before vs during treatment and during vs at 1 month follow up was statistically insignificant with P being one.

Time	DYSPNOEA(8)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	4	11.05	P -value	P -value
During treatment	4	11.05		
At 1 month FU	4	11.05	1	1

Table no.10:Dyspnoea scores



INSOMNIA(11)

Insomnia score had a slight increase during treatment but was statistically insignificant compared to pre treatment (P=23). It had no statistical significance when compared between during and at one month follow up(P=12).

Time	INSOMNIA(11)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	8	14.52	P -value	P -value
During treatment	13.33	16.66	0.23	0.12
At 1 month FU	6.66	13.6		

Table no.11:Insomnia scores

LOSS OF APPETITE(13)

There was higher degrees of loss of appetite during treatment and improved at 1 month follow up. The scores were statistically significant when compared between pre and during treatment (P=0.02) and during vs at 1 month follow up (P=0.009).

Time	LOSS OF APETITE(13)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	24	18.05	P -value	P -value
During treatment	36	19.05	0.02	0.009
At 1 month FU	22.66	15.86		

Table no.12:Loss of appetite scores

CONSTIPATION(16): score of constipation decreased during treatment and was statistically insignificant compared to pretreatment values (P=0.08) and scores were still less at one month follow-up, the decrease was statistically significant (P=0.01) compared to during treatment values.

Time	CONSTIPATION(16)	SD	Comparison between before and during treatment	Comparison between during treatment and at 1 month FU
Pre treatment	45.33	23.33	P -value	P -value
During treatment	33.33	25.45	0.08	0.011
At 1 month FU	17.33	16.99		

Table no.13:Constipation scores



DIARRHEA(17)

Diarrhea scores were highest during treatment and were statistically significant compared to pretreatment values(P=0.0013) . Scores reduced at one month follow up and were statistically significant when compared to during treatment scores (P=0.0001).

Time	DIARRHEA(17)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	24	18.05	P -value	P -value
During treatment	42.66	20.45	0.0013	0.0001
At 1 month FU	18.66	16.88		

Table no.14:Diarrhea scores

DIARRHEA(17)

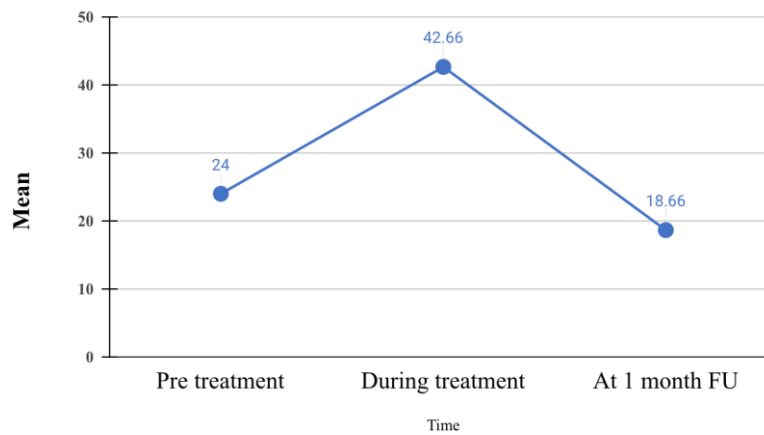


Fig no.15:Diarrhea scores

FINANCIAL DIFFICULTY(28)

As most of the patients were BPL card holders , financial difficulty raised in the treatment time and it was significant compared to pretreatment value (P=0.0008) . Financial difficulty was still present at 1 month follow up but was statistically insignificant compared to during treatment.(P=0.12).

Time	FINANCIAL DIFFICULTY(28)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	9.33	15.86	P -value	P -value
During treatment	28	20.81	0.0008	0.12
At 1 month FU	18.66	21.68		

Table no.16:Financial difficulty scores



EORTC QLQ-CR 29

Functional scales

ANXIETY (ANX) (43) : Anxiety score was maximum in pre-treatment phase and slightly reduced during treatment. It was slightly increased at 1 month follow up . Comparison between before and during treatment was statistically significant (P=0.001). Comparison between during and at 1 month follow up was also statistically significant (P=0.015).

Time	ANXIETY (ANX) (43)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	80	21.51	P -value	P -value
During treatment	53.33	23.57	0.001	0.015
At 1 month FU	69.33	21.34		

Table no.17:Anxiety scores

WEIGHT (WEI) (44)

Weight scores reduced during treatment and attained almost similar score at 1 month follow up. Comparison between before and during treatment was statistically significant (t P=0.001)and comparison between during and post treatment 1 month follow up was also statistically significant(P=0.015)

Time	WEIGHT (WEI) (44)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	88	18.95	P -value	P -value
During treatment	77.33	18.55	0.001	0.015
At 1 month FU	80	19.24		

Table no.18:Weight scores

BODY IMAGE(45-47)

Body images scores dipped during treatment and raised to baseline at one month follow up. Comparison between before vs during treatment (P=0.34) and between during and at one month follow up(P=0.15) were statistically insignificant.

Time	BODY IMAGE(45-47)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	80	19.51	P -value	P -value
During treatment	75.11	16.75	0.34	0.15
At 1 month FU	80.88	10.88		

Table no.19:Body image scores



SYMPTOMS DOMAIN

URINARY FREQUENCY(UF) (31,32)

Urinary frequency scores were low during all the phases of treatment and follow up , except that it has raised slightly during treatment compared to pretreatment values but was statistically insignificant (P=0.14). It had fallen to baseline at 1 month follow up and statistically insignificant compared to during treatment phase (P=0.23).

Time	URINARY FREQUENCY(UF) (31,32)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	6.66	8.33	P -value	P -value
During treatment	11.33	13.36	0.14	0.23
At 1 month FU	7.33	9.71		

Table no.20:Urinary frequency scores

URINARY INCONTINENCE (UI) (33)

Urinary incontinence scores were also low at all phases . Mild increase in the scores were seen during treatment and were statistically insignificant compared to before treatment values(P=0.39). The scores reversed to baseline at one month follow up but were still statistically insignificant. (P=0.69).

Time	URINARY INCONTINENCE (UI) (33)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	2.66	9.22	P -value	P -value
During treatment	5.33	12.47	0.39	0.69
At 1 month FU	4	11.05		

Table no.22:urinary incontinence scores

cystitis(34)

cystitis scored raised during treatment and reduced at 1 month follow up. The raise during treatment was statistically significant (P=0.001) compared to pre-treatment. The scores reduced at 1 month follow up and were statistically significant (P=0.001) compared to during treatment.

Time	cystitis(DY) (34)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	5.33	12.47	P -value	P -value
During treatment	36	12.34	0.001	0.001
At 1 month FU	10.66	15.86		

Table no.23:cystitis scores



ABDOMINAL PAIN (AP) (35)

The abdominal pain score was highest during treatment and attained near pretreatment values. Comparison between before and during treatment was statistically significant ($P=0.005$). Comparison between during and at 1 month follow up was also statistically significant ($P=0.048$).

Time	ABDOMINAL PAIN (AP) (35)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	9.33	15.27	P -value	P -value
During treatment	28	28.34		
At 1 month FU	14.66	16.88	0.0056	0.048

Table no.24:Abdominal pain score

BUTTOCK PAIN (BP)(36)

Buttock pain score was minimal pre-treatment but raised during treatment and the raise was statistically significant ($P=0.003$). The score reduced at one month follow up but has not attained pre treatment value and was statistically insignificant compared to 1 month follow up ($P=0.13$).

Time	BUTTOCK PAIN (BP)(36)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	2.66	9.22	P -value	P -value
During treatment	17.33	21.77		
At 1 month FU	9.3	15.27	0.003	0.13

Table no.25:Buttock pain score

BLOATING(BF)(37)

Bloating score was greatest during treatment and has neared the baseline value at one month follow up. The comparisons between before and during treatment ($P=0.0034$), between and one month follow up ($P=0.014$) were statistically significant

Time	BLOATING(BF)(37)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	8	14.52	P -value	P -value
During treatment	25.33	24.11		
At 1 month FU	10.66	15.86	0.0034	0.014

Table no.26:Bloating score

BLOOD AND MUCUS IN STOOLS (BMS)(38,39)

Blood and mucus in stools scores were maximum during treatment. The scores were higher even in the pre-treatment phase also but were highest during treatment. The comparison between before and during



treatment was statistically insignificant ($P=0.22$) and the fall of score at one month follow-up was statistically significant when compared to during treatment means. ($P=0.018$).

Time	BLOOD AND MUCUS IN STOOLS (BMS)(38,39)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	20.66	21.12	P -value	P -value
During treatment	28.66	24.3		
At 1 month FU	14	17.79	0.22	0.018

Table no.27:Blood and mucus in stools scores

DRY MOUTH(DM) (40)

The dry mouth score was minimal at all the phases of assessment. There were slightly increased scores during treatment. Scores compared between before vs during and during vs at one month follow up were all statistically insignificant. ($P=0.11$)

Time	DRY MOUTH(DM) (40)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	5.33	12.47	P -value	P -value
During treatment	12	16.32		
At 1 month FU	5.33	12.47	0.11	0.11

Table no.28:Dry mouth score

HAIR LOSS(HL)(41)

Hair loss score was very minimal at all the points of assessments. Maximum score was seen during treatment and was statistically insignificant compared to pretreatment scores ($P=0.16$). The scores had dipped down at one month's follow up but were still statistically insignificant. ($P=0.69$)

Time	HAIR LOSS(HL)(41)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	1.3	6.66	P -value	P -value
During treatment	5.33	12.47		
At 1 month FU	4	11.05	0.16	0.69

Table no.29:Hair loss score

TASTE (TA) (42)



Taste scores were very minimal at all the stages of measurements. Maximum score was seen during treatment and was statistically significant compared to pretreatment scores (P=0.048). The scores had graphed down at one month's follow up but were still statistically insignificant. (P=0.21)

Time	TASTE (TA) (42)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	4	11.05	P -value	P -value
During treatment	12	16.32	0.048	0.21
At 1 month FU	6.66	13.6		

Table no.30:Taste

FLATULENCE(FL)(49)

Flatulence score was almost stable at all the stages of evaluation. Both the comparisons were statistically insignificant. Value between before and during treatment, during and at one month follow up.

Time	FLATULENCE(FL)(49)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	10.66	15.86	P -value	P -value
During treatment	13.33	16.66	0.56	0.38
At 1 month FU	9.33	15.27		

Table no.31:Flatulence

FECAL INCONTINENCE (FI) (50)

Fecal incontinence scores were maximum during treatment and has attained the before treatment baseline values. Both comparisons were statistically insignificant.

Time	FECAL INCONTINENCE (FI) (50)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	5.33	15.75	P -value	P -value
During treatment	13.33	19.24	0.11	0.59
At 1 month FU	10.66	15.86		

Table no.32:Fecal incontinence

SORE SKIN (SS) (51)

Sore skin scores were highest during treatment and slightly reduced at one month follow up. Comparison between pre and during treatment was statistically significant (P=0.0001). The fall at one month follow up was also statistically significant (P=0.003) compared to during treatment.



Time	SORE SKIN (SS) (51)	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	2.66	9.22	P -value	P -value
During treatment	32	24.49	0.0001	0.0003
At 1 month FU	9.33	15.27		

Table no.33:Sore skin

STOOL FREQUENCY (SF) 52,53

Stool frequency scores were maximum during treatment. The comparison between before vs during treatment was statistically significant (P=0.06) and comparison between during vs 1 month follow up (P=0.017)

Time	STOOL FREQUENCY (SF) 52,53	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	23.33	20.41	P -value	P -value
During treatment	34.66	21.47	0.06	0.017
At 1 month FU	22	14.2		

Table no.34:Stool frequency

EMBARRASSMENT (EMB) 54

Embarrassment scores were almost equal at all the points of assessment. comparison between before vs during(P=0.24) and during and at one month follow up(P=0.22) was statistically insignificant

Time	EMBARRASSMENT (EMB) 54	SD	Comparison between before and during treatment	Comparison between during treatment and at one month FU
Pre treatment	20	25.45	P -value	P -value
During treatment	28	22.93	0.24	0.22
At 1 month FU	20	23.57		

Table no.36:Embarrassment

IV. DISCUSSION

A study entitled “ Study of quality of life in locally advanced carcinoma rectum patients treated with neoadjuvant chemoradiation.” was undertaken at the Department of Radiation Oncology, NRI Medical College and General Hospital, from April 2021 to September 2022.

The present study is an observational study proposed to measure toxicities, response and quality of life (QOL) in locally advanced carcinoma rectum patients presented to the department of radiation oncology, NRI medical college and general hospital.



Twenty five patients, who were eligible to receive neoadjuvant chemoradiation were considered for study. External beam Radiation therapy was delivered using IMRT on a linear accelerator with 6 MV / 15 MV photons. As per our institution protocol, a total dose of 50.4Gy was delivered in 28 fractions and treated 5 days/week. Concurrent chemotherapy is administered using tablet capecitabine administered per orally, at a dose of 825 mg/m² twice daily. Twelve percent of the study population had to withhold concurrent capecitabine due to grade 3 diarrhea at 4th week of concurrent chemoradiotherapy with tablet capecitabine was withheld in 12% of patients.

In this study the median age group was 56 years, the majority of them were between 51-60 years of age. Slight male preponderance was seen, 56% males and 44% females. 92% of them were from low socioeconomic class and were unskilled laborers. Few of them (8%) were skilled laborers and literates. The mean BSA was 1.6 m². 68% of patients had a performance score of one. 40% of patients had hypertension and 28% of patients had diabetes. The patient characteristics were consistent with a study conducted by **Veknateshan et al**, where 41-60 years was the commonest age group with 45.6% of patients, males being 72.2% of study and 70% of them scoring a performance score of one (3).

96% of patients' histology was adenocarcinoma and the rest of 4% patients were signet ring cell adenocarcinoma. The commonest presenting feature was blood in stools which was seen in 92% of patients, next being altered bowel habits in 80% of patients, abdominal pain in 16% of patients, incomplete stool evacuation in 12% of patients and least symptom was unexplained weight loss in 8%. 68% of patients had presented with blood in stools with altered bowel habits.

QUALITY OF LIFE

In this present study, global health status/quality of life mean score was 49.33 during treatment. It reached the baseline at one month's follow up. The decrease of score during treatment and flip back to baseline at one month follow up were statistically significant. ($p=0.008$ and 0.03 respectively). All the functional scales except cognitive functioning were statistically reduced during treatment and raised back to baseline at one month follow up. The mean scores of our study population measured during treatment were 77.06 for physical functioning, 66 for role functioning, 87.66 for emotional functioning, 90.66 for cognitive

functioning and 77.33 for social functioning. The mean scores of physical and social functioning were similar to another study done by **Stephanie Hui-Su Lim et al**, where their mean scores for physical and social functioning were 80.8 and 78.6 respectively. The same studies' results depicted a similar range of global health status/QOL mean score of 58.2 - 82.1 (4). The mean score for role functioning in our study was 66 and was consistent with another study with a mean of 67.51 done by **Jumanah T. Qedai**(5).

The symptom scales fatigue, nausea & vomiting and pain were statistically increased during treatment compared to baseline but has come down to baseline at one month follow up. The mean scores during treatment were 16.88 for fatigue, 24 for nausea & vomiting and 50 for pain. The nausea & vomiting and pain score values were similar to study done by **Stephanie et al** and were 16.8 and 35.5 respectively. The individual item scores includes dyspnea, insomnia, loss of appetite, constipation, diarrhea and financial difficulty. The dyspnea mean score was less and is stable throughout the points of the assessment and were statistically insignificant. The mean scores of loss of appetite, constipation, diarrhea and financial difficulty showed a statistically significant increase from baseline and are 36($P=0.02$), 33.33($P=0.08$), 42.66($P=0.0013$) and 28($P=0.0008$) respectively. The financial difficulty remained almost the same even at one month's follow up. This burden of financial difficulty remaining elevated after completion of treatment was also depicted in another study by **Herman JM et al**, (6). Rest of the scores of loss of appetite, constipation and diarrhea reached the pre treatment values at one month follow-up. Out of these individual symptoms the scores of loss of appetite, diarrhea were higher depicting the symptoms of the rectal cancer and also the toxicities of chemoradiation. The mean scores of loss of appetite, constipation and financial difficulty were similar to a study by **Jummanah T et al** and were 35.59, 34.46 and 30.7 respectively(5).

From the cancer specific questionnaire QLQ CR- 29, the functional mean scores of anxiety, weight and body image were 53.33, 77.33 and 75.11 respectively. The decrease from baseline of mean scores of anxiety and weight were statistically significant. Anxiety score increased during treatment and returned to baseline at one month follow up. Body image score slightly dipped during treatment and raised back to pre treatment values at one month follow up. The rise and fall of the value during treatment and at one month follow



up were statistically not significant. Sexual interest of men and women were not in this study.

In our study, of the individual symptom scores, the symptoms which showed a statistically significant reduced mean score from baseline were dysuria, abdominal pain, buttock pain, bloating, sore skin and stool frequency. Rest of the symptoms like urinary frequency, urinary incontinence, dry mouth, hair loss, flatulence, fecal incontinence and embarrassment scores were statistically insignificant compared to baseline and the mean scores were low. Of the urinary symptoms like urinary frequency, urinary incontinence and dysuria, the symptom with highest mean score was dysuria. Score of dysuria reduced at one month follow up and is statistically significant ($P=0.001$). Urinary incontinence and frequency symptoms were low and raised slightly during treatment but came back to baseline at one month treatment and were statistically insignificant. Buttock pain, abdominal pain and bloating mean scores increased from baseline and were 28, 17.33 and 25.33 with mean values of $P=0.0056, 0.003$ and 0.0034 respectively. Buttock pain hasn't come to baseline mean scores at one month's follow up. Stool frequency and sore skin mean scores during treatment were 34.66 ($P=0.06$) and 32 (0.0001).

The mean scores of QLQ-CR29 of this present study were similar with study conducted by **Herman JM et al**, which reported that dysuria (13.33, $P<0.0001$) and urinary frequency (11.82, $P=0.0006$) were significant among the urinary symptoms and that these symptoms returned to baseline after treatment. None of the measures of anorectal function decreased during treatment, with bowel problems (-9.30, $P=0.0032$), blood and mucus in stool (-16.38, $P<0.0001$), and bowel frequency (-14.49; $P=0.0032$). Improvements were seen throughout the first month after treatment compared to pretreatment values. Other symptoms that worsened during treatment were chemotherapy-related side effects (12.33, $P < 0.0001$), skin pain (24.22, $P < 0.0001$) and buttock pain (15.34, $P = 0.0179$), all of which Relapsed after treatment at baseline. In contrast, hair loss (10.00, $P=0.0029$) and taste (15.99, $P=0.0005$) remained below baseline after therapy (36). **Guren MG et al**, in their study reported a similar outcome of increased stool frequency and diarrhea during treatment in 54% of their patients and is almost similar to our present study (7). As stated by Herman JM et al, overall quality of life for many of these symptoms was transient, and almost all

gastrointestinal, urinary, and fatigue symptom scores appeared to have returned to baseline by 1 month after treatment.

V. SUMMARY

This study was conducted in the Department of Radiation Oncology NRI Medical College, Guntur from April 2021 to November 2022. It was a hospital based observational prospective study initiated after obtaining approval from the Institutional ethical committee. After taking informed consent from the patients, all the patients were staged with thorough history taking, clinical examination, blood examination, chest X ray and ultrasound of abdomen pelvis. After initial staging all patients who were eligible for the study underwent a computed tomography (CT) scan of the abdomen and pelvis. External beam radiation therapy was delivered using a linear accelerator with 15 MV photons. A dose of 60 Gy is delivered in 25 to 30 fractions, using IMRT /RapidArc technique treated weekly 5 days and along with concurrent chemotherapy with oral capecitabine 825 mg/m² twice daily.

Quality of life was assessed by EORTC QLQ C30 and QLQ CR29 in the first, third weeks and at one month follow-up. Functional scale mean scores of physical, role and emotional functions also returned to before treatment values at one month follow up. Global health scale improved at one month follow up. Most of the other symptoms like nausea & vomiting, pain, diarrhea, dysuria and constipation most of which were high during treatment had fallen back to baseline at one month follow up.

VI. CONCLUSION

From the present study it could be concluded that carcinoma rectum patients treated with neoadjuvant concurrent chemoradiation tolerated the treatment well and can be opted for locally advanced stages where upfront surgery is not possible. Quality of life of treated patients, though dipped during treatment, most of the domains returned to baseline scores at one month follow up.

REFERENCES:

- [1]. aronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, de Haes JCJM, Kaasa S, Klee MC, Osoba D, Razavi D, Rofe PB, Schraub S, Sneeuw KCA, Sullivan M, Takeda F. The European Organisation for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international



- clinical trials in oncology. *Journal of the National Cancer Institute* 1993; 85: 365-376.
- [2]. Fayers PM, Aaronson NK, Bjordal K, Groenvold M, Curran D, Bottomley A, on behalf of the EORTC Quality of Life Group. *The EORTC QLQ-C30 Scoring Manual (3rd Edition)*. Published by: European Organisation for Research and Treatment of Cancer, Brussels 2001.
- [3]. Venkatesan, Kannan & Anand, Vivek & Bajpai, Ranjeet & Kabre, RohitSantosh & Kapadia, Asha & Almel, Sachin & Shaikh, Muzammil & Babu, Vinay & Kolse, Ajay & Nagrajan, Ganesh & Lala, Murad & krishna, Smruti & Jagannath, P & Deshpande, Sudesh. (2020). A single-institution retrospective analysis of outcomes for locally advanced rectal cancer treated with neoadjuvant chemoradiotherapy. *Journal of Radiation and Cancer Research*. 11. 81. 10.4103/jrcr.jrcr_26_20.
- [4]. Lim SH, Ip E, Ng W, Chua W, Asghari R, Roohullah A, Descallar J, Henderson C, Spring K, de Souza P, King MT. Health-Related Quality of Life during Chemoradiation in Locally Advanced Rectal Cancer: Impacts and Ethnic Disparities. *Cancers (Basel)*. 2019 Aug 28;11(9):1263. doi: 10.3390/cancers11091263. PMID: 31466306; PMCID: PMC6770309.
- [5]. Qedair, Jumanah T; Al Qurashi, Abdullah A; Alamoudi, Saeed; Syed Sameer Aga; Hakami, Alqassem Y. *International Journal of Surgical Oncology*; New York Vol. 2022, (2022). DOI:10.1155/2022/4745631
- [6]. Herman JM, Narang AK, Griffith KA, Zalupski MM, Reese JB, Gearhart SL, Azad NS, Chan J, Olsen L, Efron JE, Lawrence TS, Ben-Josef E. The quality-of-life effects of neoadjuvant chemoradiation in locally advanced rectal cancer. *Int J Radiat Oncol Biol Phys*. 2013 Jan 1;85(1):e15-9. doi: 10.1016/j.ijrobp.2012.09.006. Epub 2012 Oct 9. PMID: 23058059; PMCID: PMC3578309.
- [7]. Guren MG, Dueland S, Skovlund E, Fosså SD, Poulsen JP, Tveit KM. Quality of life during radiotherapy for rectal cancer. *Eur J Cancer*. 2003 Mar;39(5):587-94. doi: 10.1016/s0959-8049(02)00741-4. PMID: 12628837.