

THE RESPONSE TO PRE-OPERATIVE (NEO-ADJUVANT) CHEMOTHERAPY AND RADIOTHERAPY IN LOCALLY ADVANCED RECTAL CANCER.

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ABSTRACT

Assess pre-operative (neo-adjuvant) chemo-radiotherapy for locally advanced rectal cancer. Follow-up continues until November 2019. The research required appropriate biochemistry, pathology, radiography, and medical/surgical management. Since June 2019, outpatients are assessed. Rectal cancer research studied age, sex, diagnosis delay, mortality, treatment options, death causes, surgical complications, and hospital stay. Typical, pre-validated, semi-structured case record proformas recorded the data. CBC, biochemical profile, serological sample, upright abdominal X-ray, CT scan, transrectal, pelvic, or abdominal ultrasound. After staging, patients received chemotherapy (625 mg/m² capecitabine orally in 4 doses) and radiation (50.4 Gy in 28 parts) and were reevaluated for surgery after 4 weeks. Radiation was compared to dentate line distance. 30% pre-therapy lesions were 2–5 cm from the dentate line. 27.5% exhibited 5–10-cm dentate line lesions. Neoadjuvant chemotherapy altered distance. 25% exceeded 10cm. 6.48 (p=0.039). 1:10 men to women Participants averaged 59.87 and 14.56 years old. Neoadjuvant therapy increased the median lesion distance from the anal verge from 4.8 ±3.13 cm to 6.13 ± 2.11 cm. After neoadjuvant therapy, 52.5% of patients had anterior resection, 37.5% had LAR, and 10% had APR. However, more experience, higher-quality expertise, and more patients are needed to make the neoadjuvant method routine.

KEYWORDS: Chemotherapy, Radiotherapy, Colorectal cancer

INTRODUCTION

Locally, nearly 90% of patients arrive at an advanced stage due to socio-cultural factors such as a lack of knowledge, access to specialized care, the popularity of alternative medicine, and a lack of community-based screening programs. India has a low CRC age-standardized rate (ASR) of 7.2 per 100,000 men and 5.1 per 100,000 women. CRC patients, on the other hand, are numerous in a country of over a billion people. India has the lowest five-year CRC survival rate at less than 40%. The CONCORDE-2 study found that some Indian rectal cancer registries have declining five-year survival rates. This may indicate CRC diagnostic and therapy shortcomings.¹

Assessing this poor survival is urgent. Surgery is still the backbone of treatment, but APR-related anxiety about a permanent colostomy reduces compliance (abdomino-perineal resection). Preoperative radiation therapy significantly reduced pelvic recurrence in a large Dutch randomized trial. Follow-up evaluations of this experiment demonstrated that node-positive individuals receiving complete mesorectal resection (TME) alone have pelvic failure rates over 20%. Recently, the German Rectal Cancer Study found that preoperative chemoradiation improves pelvic control, sphincter preservation, and acute and chronic toxicity.² Preoperative or neoadjuvant therapy for locally advanced rectal cancer became common after this trial. Recent European trials have shown that combining chemotherapy with preoperative radiation therapy optimizes local disease management. Chemotherapy is radio sensitizing in this scenario.

AIM: To assess the efficacy of pre-operative (neo-adjuvant) chemo-radiotherapy in locally advanced rectal cancer patients.

SOURCE OF SAMPLE

Forty patients with locally advanced rectal cancer, also known as stage II and stage III rectal cancer, who were admitted to or attended the oncosurgery OPD at Krishna Hospital during the course of the study provided the information that was used to compile our study's findings. The source of the data was gathered by interviewing patients and the informant, as well as conducting in-depth clinical examinations and appropriate investigations. This information was then recorded in a case recording proforma that had been carefully constructed.

INCLUSION CRITERIA

1. Patients of any and every age group, of either gender.
2. Patients will be included in the study if they meet the criteria for having locally advanced (stages II and III) rectal cancer.

EXCLUSION CRITERIA

1. People with rectal cancer in stages I or IV will not be part of the study.
2. Patients who have surgery as their main form of treatment will not be part of the study.

STUDY DESIGN: A hospital-based descriptive study was the methodological approach taken for this research.

STUDY DURATION: Approximately two years, from November 2017 through November 2019, were analyzed in the study.

SAMPLE SIZE: The disease's prevalence in the general population and the attrition factor determined the sample size. The sample size was 40.

MATERIAL & METHOD

Patients were tracked until November 2019. The planned investigations required biochemistry, pathology, radiography, and medical and surgical management at the department and/or institution. Since June 2019, OPD patients have been evaluated. Rectal cancer age, sex, etiology, hospitalization delay, mortality, line of management, cause of death, post-operative problems, and hospital stay were examined. A standard, pre-validated, semi-structured case record proforma captured the data. Complete blood count, biochemical analysis, microbiology for serology, an erect abdominal X-ray, a CT scan, or an ultrasound (abdomen/pelvis/transrectal). Patients were staged, treated with concomitant chemotherapy (625 mg/m² capecitabine orally in 4 doses) and radiation (50.4 Gy administered in 28 fractions), and then reevaluated after 4 weeks to determine surgical options.

STATISTICAL ANALYSIS

Microsoft Excel 2016 spreadsheets entered the data. Tables and graphs were used to analyse frequency, central tendency, and dispersion. IBM SPSS 22.0 analyses data. Parametric significance tests (students' test) were used for normally distributed variables. Non-parametric tests examined categorical and nominal associations (chi-square test). The desired outcome was computed within 95% confidence limits. A P value of 0.05 indicated a significant difference between two observations.

BUDGET

Because only the investigations or procedures that had already been done or were already planned for the patient's care were mentioned and reported, this study did not add any extra costs.

RESULTS

Gender	Number of cases	Percent
Female	21	52.5
Male	19	47.5
Total	40	100

Table 1: Gender-Wise Distribution

In the current investigation, we found that the majority of the patients were girls (52.5%), while only 47.5% were men with the condition. There were approximately 1.10 males for every female.

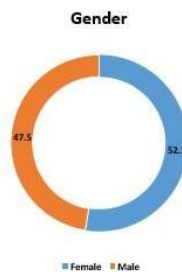


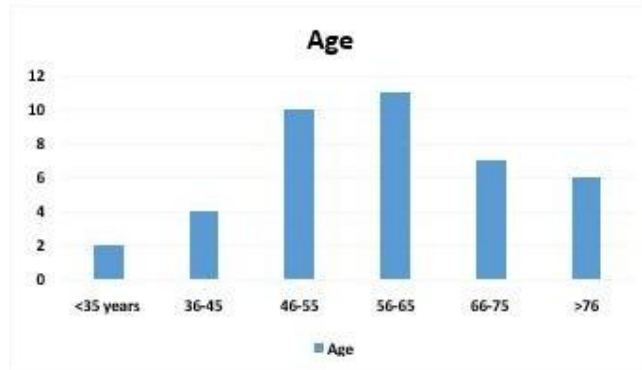
Figure 1: Distribution of study subjects based on gender

The current study included an analysis of the participants' age ranges. We found that 27.5% were

Distance from anal ring	Pre-therapy		Post-therapy	
	Number of cases	Percent	Number of cases	Percent
<2 cm	12	30	4	10
2-6	16	40	15	37.5
>6	12	30	21	52.5
Total	40	100	40	100
Mean distance	4.8 ± 3.13 cm		6.13 ± 2.11 cm	
Significance	Chi-square statistic is 6.48. The p-value is 0.039			

between the ages of 56 and 65, 25% were between the ages of 46 and 55, and 17.5% were between the ages of 66 and 76. In the table and graph that follow, we see a breakdown of the cases according to age group. In the study, participants averaged 59.87 ± 14.56 years of age.

Table 2: Distribution of study subjects according to their age.

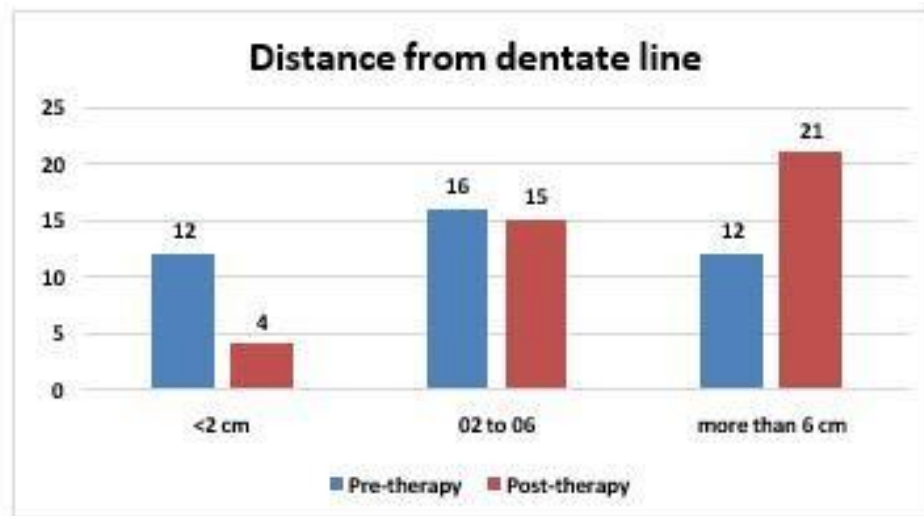


Graph 2: Distribution of study subjects according to their age.

In this study, we looked at how far away each study subject was from the dentate line before and after radiation. We saw that most of the lesions in the pre-therapy group were between 2 and 5 cm from the dentate line (30%). Another 27.5% of the lesions were between 5 and 10 cm from the dentate line. After neoadjuvant chemotherapy, there was a big change in the distance. Most of the distances were between 5 and 10 cm, and 25% of the distances were more than 10 cm. (The chi-square number is 6.48. The value of p is 0.039.

Age distribution	Number of cases	Percent
<35 years	2	5
36-45	4	10
46-55	10	25
56-65	11	27.5
66-75	7	17.5
>76	6	15
Total	40	100
Mean age	59.87 ± 14.56 years	

Table 3: Distance from dentate line.



Graph 3: Distance from dentate line.

DISCUSSION

Colorectal cancer is a common type of cancer all over the world, but most cases happen in developed countries. India has a low rate of CRC. The estimated rate of CRC over the last five years is 87 per 100,000 people. People think that the low number of CRC cases in the developing world is due to differences in diet and way of life.

The gender breakdown of the participants in this study was analyzed. It turned out that 52.5% were women and 47.5% were men. The ratio of males to females was roughly 1:10. The current study included an analysis of the participants' age ranges. We found that 27.5% were between the ages of 56 and 65, 25% were between the ages of 46 and 55, and 17.5% were between the ages of 66 and 76. In the table and graph that follow, we see a breakdown of the cases according to age group. In the study, participants averaged 59.87 ± 14.56 years of age.

Vivek Bansal et al. found that 78.8% were male and the rest were female, with a median age of 51 years.³ Prachi S. Patil et al. found 517 (65%) males and 283 (35% females).⁴ CRC patients averaged 47.2 years (range 11 years–85 years). Rectal cancer patients were younger than colon cancer patients (45.7 vs. 49.1 years, $p = 0.001$). The average age of diagnosis for 168 individuals with sporadic CRC in an eastern Indian study was 47.01 years, but for 220 cases of CRC detected through colonoscopy over a five-year period, the average age was 58.4 years. Another study conducted in central India with 233 individuals found that 39% of CRC patients were diagnosed at the age of 40 or younger. Men made up 65.6% of the participants in a study by Snita Sinukumar et al. at the time of presentation, the median age was 47 (range 18–77 years).⁵

The present study evaluated the distance from the dentate line before and after radiation treatment. The average distance of the lesion from the dentate line in the pre-irradiation group was 4.8 ± 3.13 cm and 6.13 ± 2.11 cm in the post-irradiation group (p value is 0.039). Following neo-adjuvant treatment, the distance was significantly increased. Research conducted by Vivek Bansal and colleagues found that the average distance of lesions from the dentate line was 3.8 cm.¹

CONCLUSION

They had a male-to-female ratio of 1:10. Participants in the study had an average age of 59.87 14.56 years. Following neoadjuvant treatment, there was a considerable rise in the median distance of the lesion from the anal verge, from 4.8 ± 3.13 cm to 6.13 ± 2.11 cm. Anterior resection was used to treat 52.5% of patients after neoadjuvant therapy; LAR was used to treat 37.5% of patients; and APR was performed in 10% of patients. To establish the neoadjuvant strategy as the standard of care, however, more experience is required, along with higher-quality expertise and a greater number of patients.

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