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Incidence of Chronic Radiation Proctitis and Its Impact on Quality of Life in Patients Receiving Radiotherapy for Prostate Cancer: A Prospective Observational Study

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ABSTRACT

Background: Chronic radiation proctitis is a recognized late complication of pelvic radiotherapy in patients treated for prostate malignancy. Although most cases are mild, persistent bowel symptoms can significantly impair quality of life. Early identification and assessment of symptom burden are important for improving long-term patient care.
Aim: To determine the incidence of chronic radiation proctitis in patients receiving radiotherapy (RT) for prostate cancer and to evaluate its impact on quality of life.
Materials and Methods: This prospective observational study was conducted in the Department of Radiation Oncology of a tertiary care hospital including patients treated from August 2021 to September 2024. A total of 39 patients with histologically confirmed prostate malignancy receiving pelvic radiotherapy were included. Patients were followed up clinically for the development of chronic radiation proctitis. Radiation toxicity was graded using the Radiation Therapy Oncology Group (RTOG) criteria. Quality-of-life assessment included bowel frequency, toilet dependence, daily activity limitation, and sexual life impairment. Data were documented in excel sheet and analyzed using SPSS version 25.0.
Results: The majority of patients belonged to the 61–70 years age group, with a mean age of 66.4 ± 5.8 years. Chronic radiation proctitis was observed in 15 patients (38.5%). Grade 1 toxicity was the most common presentation (25.6%), followed by Grade 2 toxicity (10.3%), while Grade 3 toxicity was uncommon (2.6%). Most patients developed symptoms within 8–12 months after completion of radiotherapy. Increased stool frequency (73.3%) and toilet dependence (53.3%) were the predominant symptoms. Mild-to-moderate impairment in quality of life was observed in the majority of affected patients.
Conclusion: Chronic radiation proctitis is a relatively common late complication following radiotherapy for prostate cancer, predominantly presenting as low-grade toxicity. Despite its mild severity in most cases, it significantly affects bowel habits and quality of life, highlighting the importance of regular follow-up and early supportive management.

Keywords: *Prostate cancer, Radiotherapy, Chronic radiation proctitis, Quality of life, Radiation toxicity, Pelvic irradiation.*

INTRODUCTION

Prostate cancer is one of the most common malignancies affecting elderly men worldwide and represents a major public health concern due to its increasing incidence and long-term survivorship burden. Radiotherapy (RT) plays a central role in the management of prostate cancer, either as definitive treatment or as adjuvant therapy or even for palliation or salvage depending upon the stage of the disease[1]. Advances in radiation delivery techniques have significantly improved tumor control and survival outcomes; however, radiation-induced toxicity to adjacent pelvic organs remains an important clinical

challenge. Among these complications, chronic radiation proctitis is a notable late adverse effect that can adversely affect patient quality of life[2]. Chronic radiation proctitis refers to persistent inflammatory and ischemic injury to the rectal mucosa occurring months to years after pelvic irradiation. The rectum is particularly vulnerable because of its fixed anatomical position adjacent to the prostate gland. Radiation exposure leads to mucosal ischemia, fibrosis, obliterative endarteritis, and progressive epithelial damage, resulting in symptoms such as rectal bleeding, diarrhoea, urgency, mucus discharge, tenesmus, and fecal incontinence[3]. Although severe complications are uncommon with modern radiotherapy techniques, even mild chronic symptoms can significantly interfere with social functioning, emotional well-being, and daily activities.

The reported incidence of chronic radiation proctitis varies widely in literature, ranging from 5% to 20%,[4] depending on radiation dose, treatment technique, duration of follow-up, and criteria used for toxicity assessment[5]. The degree of rectal mucosal injury is proportional to the technique of RT used , the total dose prescribed ,the dose per fraction delivered and the absolute volume of rectum irradiated[6]. Role of genetic variants in the development of RT-induced rectal toxicity has been documented[7]. Several nomograms have shown individual patient risk factors like use of anti-hypertensives ,anti-coagulants, hormonal therapy, or; presence of comorbid conditions like diabetes or hemorrhoids, and a history of pre-RT abdominal surgery have shown predictive values for chronic radiation proctitis in prostate cancer patients[8,9]. Incorporation of modern techniques of RT like intensity - modulation, image-guidance can help increase the therapeutic ratio[10-12] by sparing rectum while safely maximizing prostate doses, however long-term outcomes are yet unclear.Most patients develop symptoms within the first year after completion of radiotherapy, particularly between 8 and 12 months. Grade 1 and Grade 2 toxicities constitute the majority of cases, whereas severe Grade 3 or Grade 4 complications are relatively rare[13]. Elderly patients and those with comorbid conditions such as diabetes mellitus and vascular disease may be at increased risk of developing chronic rectal toxicity.

Several studies have evaluated gastrointestinal complications following pelvic radiotherapy in prostate cancer patients. Andreyev highlighted that chronic gastrointestinal symptoms after pelvic irradiation are frequently underreported and undertreated despite their substantial impact on quality of life[14]. Krol et al., in a systematic review, demonstrated that bowel dysfunction and rectal bleeding remain common long-term complications even with improved radiation techniques[5]. Henson et al. further reported that bowel frequency disturbances, urgency, and social embarrassment are major contributors to quality-of-life deterioration among prostate cancer survivors receiving radiotherapy[15]. With increasing survival rates in prostate cancer patients, assessment of treatment-related morbidity has become equally important as oncological outcomes. Despite improvements in conformal radiotherapy and image-guided techniques, chronic radiation proctitis continues to affect a subset of patients and may lead to persistent bowel dysfunction and psychological distress. Data regarding the incidence and quality-of-life impact of chronic radiation proctitis in the Indian population remain limited. Therefore, the present study was undertaken to evaluate the incidence, severity, and temporal pattern of chronic radiation proctitis in patients receiving radiotherapy for prostate malignancy and to assess its influence on patient quality of life.

AIM AND OBJECTIVES

Aim of the Study

To evaluate the incidence of chronic radiation proctitis in patients receiving radiotherapy for prostate malignancy and to assess its impact on quality of life.

Objectives of the Study

1. To determine the incidence and grading pattern of chronic radiation proctitis among patients receiving radiotherapy for prostate cancer.
2. To assess the time of onset and clinical presentation of chronic radiation proctitis following completion of radiotherapy.
3. To evaluate the impact of chronic radiation proctitis on quality of life, including bowel frequency, toilet dependence, and sexual life impairment.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of Radiation Oncology at a tertiary care teaching hospital over a period of three years, from August 2021 to September 2024. The study was designed to evaluate the incidence of chronic radiation proctitis in patients receiving radiotherapy for prostate malignancy and to assess its impact on quality of life following treatment.

Study Population

The study included patients diagnosed with histopathologically confirmed carcinoma prostate who underwent pelvic radiotherapy during the study period. Patients were recruited consecutively after obtaining written informed consent. Since carcinoma prostate predominantly affects elderly men, the study population mainly consisted of male patients in the age group of 55–75 years.

Inclusion Criteria

- Patients aged more than 18 years with histologically confirmed prostate malignancy.
- Patients receiving external beam radiotherapy for prostate cancer with curative or adjuvant intent.
- Patients available for follow-up for at least 12 months after completion of radiotherapy.

Exclusion Criteria

- Patients with pre-existing inflammatory bowel disease or chronic gastrointestinal disorders.
- Patients with prior pelvic irradiation.
- Patients with recurrent malignancy receiving palliative radiotherapy.
- Patients with rectal involvement due to direct tumor extension.
- Patients who were lost to follow-up during the study period.

Sample Size Calculation

The sample size was estimated based on the expected incidence of chronic radiation proctitis among patients undergoing pelvic radiotherapy for prostate cancer. Previous studies have reported the incidence of chronic radiation-induced proctitis ranging between 5% and 20%. Considering an anticipated incidence of 12%, the minimum required sample size was calculated using the standard formula for estimation of proportion:

$$n = \frac{Z^2 pq}{d^2}$$

Where:

- n= required sample size
- Z= standard normal deviate at 95% confidence interval = 1.96
- p= anticipated prevalence/incidence = 12% (0.12)
- q= 1 − p = 0.88
- d= allowable absolute error = 10% (0.10)

Substituting the values:

$$n = \frac{(1.96)^2 \times 0.12 \times 0.88}{(0.10)^2}$$

$$n = \frac{3.84 \times 0.1056}{0.01}$$

$$n = 40.5$$

Thus, the calculated sample size was approximately 40 patients. Based on feasibility and availability of eligible patients during the study period, a final sample size of 39 patients was included in the study.

Sampling Technique

A consecutive sampling method was employed, wherein all eligible patients satisfying the inclusion criteria during the study period were recruited until the required sample size was achieved.

Study Procedure

All patients underwent detailed clinical evaluation at baseline prior to initiation of radiotherapy. Demographic details including age, comorbidities, tumor characteristics, treatment details, radiation dose, fractionation schedule, and concurrent therapies were documented using a structured proforma. Patients received external beam radiotherapy according to institutional protocols. Radiation treatment details including total dose, number of fractions, treatment duration, and technique employed were recorded. Following completion of radiotherapy, patients were followed up periodically in the outpatient department. Clinical assessment for symptoms suggestive of chronic radiation proctitis was performed at regular intervals, particularly between 8 and 12 months post-radiotherapy, as chronic proctitis is commonly reported during this period.

Assessment of Chronic Radiation Proctitis

Patients were evaluated for symptoms including:

- Increased stool frequency
- Rectal bleeding
- Tenesmus
- Mucus discharge
- Urgency
- Pain during defecation

- Toilet dependence

Severity of radiation toxicity was graded according to the Radiation Therapy Oncology Group (RTOG)/European Organization for Research and Treatment of Cancer (EORTC) late radiation morbidity scoring criteria. Toxicity grades were categorized as:

- Grade 1 – mild symptoms
- Grade 2 – moderate symptoms requiring medical management
- Grade 3 and above – severe complications requiring procedural or surgical intervention

Quality of Life Assessment

Quality of life was assessed using a structured questionnaire during follow-up visits. Parameters evaluated included:

- Frequency of stools
- Degree of toilet dependence
- Interference with daily activities
- Social embarrassment
- Sexual life impairment

Patients were categorized according to the severity of quality-of-life impairment based on symptom burden and functional limitation.

Outcome Measures

The primary outcome measure was the incidence of chronic radiation proctitis among patients receiving radiotherapy for prostate malignancy.

Secondary outcome measures included:

- Time interval between completion of radiotherapy and onset of proctitis symptoms
- Severity grading of radiation proctitis
- Association between chronic proctitis and quality-of-life impairment

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) software version 25.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation. Association between categorical variables was assessed using Chi-square test or Fisher's exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all study participants prior to enrollment. Confidentiality of patient information was strictly maintained throughout the study in accordance with ethical guidelines and the Helsinki Declaration of 1975 as revised in 2024.

RESULTS

Table 1: Age Distribution of Study Participants (n = 39)

Age Group (Years)	Number of Patients	Percentage (%)
55–60	8	20.5
61–65	11	28.2
66–70	12	30.8
71–75	6	15.4
>75	2	5.1
Total	**39**	**100.0**

Mean age: 66.4 ± 5.8 years

Table 2: Incidence and Severity of Chronic Radiation Proctitis (n = 39)

Radiation Proctitis Grade	Number of Patients	Percentage (%)
No Proctitis	24	61.5
Grade 1	10	25.6
Grade 2	4	10.3
Grade 3	1	2.6
Total	**39**	**100.0**

Overall incidence of chronic radiation proctitis: 15 patients (38.5%)

Table 3: Time of Onset of Chronic Radiation Proctitis Following Radiotherapy (n = 15)

Time of Symptom Onset	Number of Patients	Percentage (%)
<6 months	2	13.3
6–8 months	3	20.0
8–12 months	8	53.3
>12 months	2	13.3
Total	**15**	**100.0**

Most patients developed symptoms of chronic radiation proctitis within 8–12 months following completion of radiotherapy.

Table 4: Clinical Manifestations of Chronic Radiation Proctitis (n = 15)

Clinical Symptoms	Number of Patients	Percentage (%)
Increased stool frequency	11	73.3
Rectal bleeding	7	46.7
Tenesmus	5	33.3
Mucus discharge	4	26.7
Toilet dependence	8	53.3
Pain during defecation	3	20.0
Sexual life impairment	6	40.0

Multiple responses were observed among study participants.

Table 5: Quality of Life Impairment Among Patients with Chronic Radiation Proctitis (n = 15)

Quality of Life Parameter	Mild Impairment n (%)	Moderate Impairment n (%)	Severe Impairment n (%)
Stool frequency disturbance	6 (40.0)	4 (26.7)	1 (6.6)
Toilet dependence	5 (33.3)	2 (13.3)	1 (6.6)
Daily activity limitation	4 (26.7)	3 (20.0)	1 (6.6)
Sexual life impairment	3 (20.0)	2 (13.3)	1 (6.6)

Overall, most patients experienced mild-to-moderate quality-of-life impairment secondary to chronic radiation proctitis, with bowel frequency disturbances and toilet dependence being the most commonly affected domains.

DISCUSSION

Radiotherapy remains one of the standard treatment modalities for localized and locally advanced prostate cancer. Although technological advances in radiation delivery have reduced treatment-related complications, chronic radiation proctitis continues to be an important late adverse effect affecting bowel function and quality of life. The present study evaluated the incidence, severity, temporal onset, and quality-of-life impact of chronic radiation proctitis among patients receiving pelvic radiotherapy for prostate malignancy. In the present study, the majority of patients belonged to the age group of 61–70 years, with a mean age of 66.4 ± 5.8 years. This finding is consistent with the epidemiological profile of prostate cancer reported in previous studies. Zelefsky et al. observed a mean age of approximately 68 years among prostate cancer patients receiving radiotherapy, reflecting the predominance of disease in elderly males[13]. Similarly, Krol et al. reported that prostate cancer-related rectal toxicity is most frequently observed in older patients undergoing definitive pelvic irradiation[5].

The overall incidence of chronic radiation proctitis in the present study was 38.5%. Although this appears slightly higher than rates reported in some Western literature, the majority of patients developed only low-grade toxicity. Variability in incidence across studies may be attributed to differences in radiation techniques, dose fractionation, follow-up duration, and scoring systems used for toxicity assessment. Krol et al., in their systematic review, documented chronic gastrointestinal toxicity rates ranging from 5% to 20% after prostate radiotherapy[5]. However, Andreyev emphasized that bowel symptoms following pelvic irradiation are frequently underreported, which may underestimate the true clinical burden[14]. The relatively higher incidence in the present study may also be related to prolonged follow-up and detailed symptom-based assessment. Grade 1 toxicity constituted the majority of cases (25.6%), followed by Grade 2 toxicity (10.3%), while severe Grade 3 toxicity was uncommon (2.6%). These findings are comparable with those reported by Zelefsky et al., who demonstrated that most rectal toxicities following conformal radiotherapy were mild and manageable conservatively, with severe complications occurring infrequently[13]. Similarly, Henson et al. reported that low-grade chronic bowel dysfunction remains more common than major rectal complications in long-term survivors of pelvic radiotherapy[15]. The low incidence of severe toxicity observed in the present study may reflect improved radiotherapy planning and adherence to dose constraints.

The temporal pattern observed in this study showed that most patients developed symptoms within 8–12 months following completion of radiotherapy. This observation correlates with previous reports indicating that chronic radiation proctitis commonly manifests within the first year after pelvic irradiation[16]. Denton et al. reported that late rectal toxicity usually develops several months after completion of treatment due to progressive ischemic and fibrotic changes in the rectal mucosa[3]. The delayed onset highlights the importance of long-term follow-up in prostate cancer survivors receiving radiotherapy. Among clinical manifestations, increased stool frequency was the most common symptom, followed by toilet dependence and rectal bleeding. Similar findings were observed by Henson et al., who identified bowel urgency, increased stool frequency, and social inconvenience as the most prevalent late gastrointestinal symptoms affecting quality of life after pelvic radiotherapy[15]. Andreyev also reported that bowel dysfunction and urgency substantially impair routine activities and psychosocial well-being in affected individuals[14]. The occurrence of toilet dependence in more than half of symptomatic patients in the present study underscores the functional burden associated with chronic radiation proctitis.

Quality-of-life assessment in the present study demonstrated predominantly mild-to-moderate impairment, particularly in bowel habits, daily activity, and sexual life. Previous studies have similarly highlighted the association between chronic bowel symptoms and deterioration in overall quality of life among prostate cancer survivors[17]. Sanda et al. reported that bowel dysfunction and sexual impairment significantly contribute to long-term dissatisfaction after prostate cancer treatment[18]. Even low-grade symptoms may negatively influence emotional health, social confidence, and daily functioning, particularly in elderly patients. Overall, the findings of the present study are in agreement with previous literature demonstrating that chronic radiation proctitis is a relatively common but predominantly low-grade late complication of pelvic radiotherapy. Despite advances in radiotherapy techniques, bowel-related quality-of-life impairment persists in a considerable proportion of patients. Early recognition, regular follow-up, and timely supportive management may help reduce symptom severity and improve long-term patient outcomes.

Limitations of the Study

The present study has certain limitations that should be considered while interpreting the findings. The study was conducted in a single tertiary care center with a relatively small sample size of 39 patients, which may limit the generalizability of the results to the broader population. The follow-up duration, although adequate for identifying most cases of chronic radiation proctitis, may not have captured very late-onset rectal toxicities occurring several years after radiotherapy.

CONCLUSION

Chronic radiation proctitis is a relatively common late complication among patients receiving pelvic radiotherapy for prostate malignancy. In the present study, the majority of affected patients developed low-grade toxicity, with symptoms most commonly appearing within 8–12 months following treatment. Increased stool frequency, toilet dependence, and rectal discomfort were the predominant manifestations contributing to impairment in quality of life. Although severe toxicity was uncommon, even mild-to-moderate symptoms significantly affected daily activities and psychosocial well-being in a subset of patients. The findings emphasize the importance of regular long-term follow-up, early recognition of bowel symptoms, and timely supportive management in patients undergoing radiotherapy for prostate cancer. Improved radiation techniques and patient-centered quality-of-life assessment may help minimize treatment-related morbidity and enhance long-term survivorship outcomes.

DECLARATIONS

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Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Author Contributions

Rasi.S: Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft preparation, Writing – review & editing. K.L. Jayakumar: Methodology, Resources, Supervision, Validation, Critical revision of manuscript. All authors read and approved the final manuscript.

Availability of Data and Materials

The datasets generated and/or analysed during the current study are not publicly available due to institutional data protection policies but are available from the corresponding author on reasonable request, subject to approval by the Institutional Ethics Committee.

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