

## Original Research Article

# RADIATION-INDUCED CYSTITIS AND PROCTITIS FOLLOWING DEFINITIVE RADIOTHERAPY WITH OR WITHOUT CONCURRENT CHEMOTHERAPY IN CARCINOMA CERVIX: A SINGLE-INSTITUTION RETROSPECTIVE COHORT STUDY

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**ABSTRACT**

**Background:** Definitive radiotherapy, with or without concurrent chemotherapy, is central to the treatment of carcinoma cervix. Pelvic irradiation can injure the bladder and rectum and lower quality of life. **Aim:** To measure the incidence, severity and time to onset of radiation-induced cystitis and proctitis.

**Materials and Methods:** Retrospective single-institution cohort of patients with histologically confirmed carcinoma cervix treated with definitive pelvic radiotherapy (50 Gy in 25 fractions with weekly concurrent chemotherapy, followed by high-dose-rate intracavitary brachytherapy, 7 Gy per fraction for 3 weekly fractions), in 2023 to 2025, with at least 6 months of follow-up. Toxicity was identified from documented investigations and graded by CTCAE v5.0. Incidence is given with Wilson 95% confidence intervals (CI).

**Results:** Of 85 patients (median age 50 years; median follow-up 13 months; 88.2% treated with conventional two-dimensional radiotherapy), 17 developed proctitis (20.0%; 95% CI 12.9 to 29.7) and 8 developed cystitis (9.4%; 95% CI 4.8 to 17.5). Grade 2 or higher toxicity occurred in 15 of 17 proctitis cases and 4 of 8 cystitis cases; grade 3 occurred in 6 and 1. Median time to onset was 11 months (IQR 10 to 14) for proctitis and 10.5 months (IQR 5 to 14) for cystitis, with cases from 1 to 17 months. Toxicity was more frequent in stage III disease than in stage II or IVA combined (38.9% vs 12.9%; exploratory Fisher P = 0.014). Toxicity rates did not differ significantly between conventional 2D radiotherapy and other techniques, or between chemotherapy agents, though these subgroup comparisons were underpowered.

**Conclusion:** Proctitis was more frequent and more severe than cystitis, and onset was spread over at least the first 17 months. Careful dose planning for the bladder and rectum and follow-up beyond the first year are needed. Prospective studies with dosimetric data should identify modifiable risk factors.

**Keywords:** Carcinoma cervix; radiation proctitis; radiation cystitis; definitive radiotherapy; CTCAE; late toxicity.

**INTRODUCTION**

Definitive radiotherapy, with or without concurrent chemotherapy, is a cornerstone of treatment for carcinoma cervix. The bladder and rectum lie next to the cervix, so pelvic irradiation exposes both organs

to dose. Gastrointestinal and genitourinary toxicities are the most common side effects, and proctitis and cystitis are the leading examples. Both can affect quality of life long after treatment ends.

Published rates vary widely. Chronic radiation proctitis is usually described as developing three

months or more after treatment, with a median onset of roughly 8 to 12 months.<sup>[1]</sup> Late hemorrhagic cystitis can appear years later; in a series of 1,784 women treated for stage IB cervical cancer, it occurred in 6.5%, with a median onset of about three years.<sup>[2]</sup> Prospective image-guided programmes report low but real severe late morbidity: in EMBRACE-I, the 5-year actuarial rate of grade 3 to 5 events was 8.5% for the gastrointestinal tract and 6.8% for the genitourinary tract.<sup>[3]</sup> Technique matters. In randomised studies, intensity-modulated radiotherapy (IMRT) reduced gastrointestinal toxicity compared with conventional or three-dimensional conformal radiotherapy,<sup>[4,5]</sup> and higher rectal dose is linked to more severe late rectal morbidity.<sup>[6]</sup>

Most of this evidence comes from centres with advanced imaging and planning. Local data help units plan treatment, counsel patients and set follow-up schedules. Earlier work has examined risk factors for these toxicities.<sup>[7]</sup> and cystitis and proctitis in an earlier series from this institution.<sup>[8]</sup> We therefore reviewed patients treated at our institution to determine the incidence, severity and time to onset of radiation-induced cystitis and proctitis after definitive radiotherapy with or without concurrent chemotherapy.

## MATERIALS AND METHODS

### Study design and population

This was a single-institution retrospective cohort study in the Department of Radiation Oncology, State Cancer Institute, Gauhati Medical College, Guwahati. It is reported in line with the STROBE guideline for observational studies.<sup>[9]</sup> We included patients with histologically confirmed carcinoma cervix who were treated with definitive radiotherapy, with or without concurrent chemotherapy, in 2023 to 2025.

### Eligibility

Patients were eligible if they met all of the following: a minimum follow-up of 6 months; definitive pelvic radiotherapy with or without chemotherapy; and available demographic, disease, treatment and follow-up data. Disease stage was recorded using the FIGO 2018 staging system.<sup>[10]</sup> Variables analysed were age, histology, human papillomavirus (HPV) status, FIGO stage, external beam radiotherapy (EBRT) technique and concurrent chemotherapy agent.

### Treatment

Patients received EBRT by conventional two-dimensional (2D) technique, three-dimensional

conformal radiotherapy (3DCRT) or intensity-modulated radiotherapy (IMRT), to a dose of 50 Gy in 25 fractions with once-weekly concurrent chemotherapy. This was followed by high-dose-rate intracavitary brachytherapy, delivered as 7 Gy per fraction for 3 weekly fractions. Concurrent chemotherapy was cisplatin or carboplatin, given once weekly.

### Toxicity assessment

Cystitis and proctitis were identified from documented, relevant investigations. Cystitis was assessed by cystoscopy and a routine urine profile; proctitis was assessed by colonoscopy or sigmoidoscopy, alongside routine blood investigations to assess the patient's general condition. Severity was graded using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.<sup>[11]</sup> Time to onset was recorded in months from completion of radiotherapy; in our experience, symptoms of these late toxicities most often appeared 6 months to 1 year after treatment completion, though earlier and later onset also occurred (Table 2).

### Statistical analysis

Data were summarised descriptively, with counts and percentages for categorical variables and medians with interquartile range (IQR) or range for continuous variables. Incidence was the number of patients with the toxicity divided by the 85 patients in the cohort, with 95% CI by the Wilson score method.<sup>[12]</sup> Toxicity in patients treated with conventional 2D radiotherapy was compared with that in all other patients, and toxicity by FIGO stage group and by chemotherapy agent were each compared, using Fisher's exact test (two-sided,  $P < 0.05$ ). These comparisons were exploratory. No adjustment for confounders or multiple testing was made because of the small number of events. Analyses were performed in R, version 4.6.0 (R Foundation for Statistical Computing, Vienna, Austria).

## RESULTS

### Patient characteristics

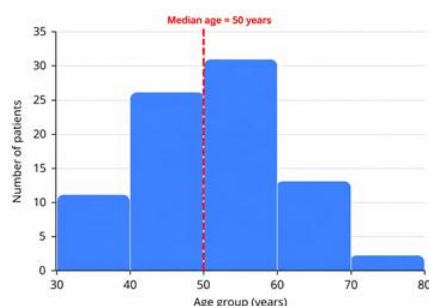
The cohort had 85 patients. Median age was 50 years and median follow-up was 13 months. Most patients were between 40 and 60 years old (Figure 1). Squamous cell carcinoma was the most common histology (76 patients, 89.4%). Most patients (75, 88.2%) received conventional 2D EBRT, while 7 (8.2%) received IMRT and 3 (3.5%) received 3DCRT (Table 1).

**Table 1: Patient and treatment characteristics (N = 85)**

| Characteristic            | Value     |
|---------------------------|-----------|
| Age, years, median        | 50        |
| Follow-up, months, median | 13        |
| <b>Histology, n (%)</b>   |           |
| Squamous cell carcinoma   | 76 (89.4) |
| Adenocarcinoma            | 6 (7.1)   |

|                                       |           |
|---------------------------------------|-----------|
| Adenosquamous carcinoma               | 2 (2.4)   |
| Small cell neuroendocrine carcinoma   | 1 (1.2)   |
| <b>HPV status, n (%)</b>              |           |
| Positive                              | 12 (14.1) |
| Negative                              | 73 (85.9) |
| <b>EBRT technique, n (%)</b>          |           |
| Conventional 2D                       | 75 (88.2) |
| IMRT                                  | 7 (8.2)   |
| 3DCRT                                 | 3 (3.5)   |
| <b>Concurrent chemotherapy, n (%)</b> |           |
| Cisplatin                             | 66 (77.6) |
| Carboplatin                           | 9 (10.6)  |
| None                                  | 10 (11.8) |

EBRT, external beam radiotherapy; HPV, human papillomavirus; IMRT, intensity-modulated radiotherapy; 3DCRT, three-dimensional conformal radiotherapy.



**Figure 1: Age distribution of the cohort. The dashed line marks the median age of 50 years.**

### Incidence and severity

In total, 25 patients (29.4%; 95% CI 20.8 to 39.8) developed cystitis or proctitis, and 60 (70.6%)

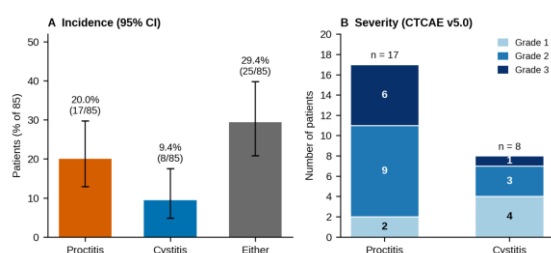
developed neither. Proctitis occurred in 17 patients (20.0%; 95% CI 12.9 to 29.7) and cystitis in 8 (9.4%; 95% CI 4.8 to 17.5) (Table 2, Figure 2). No patient had both toxicities. The intervals overlap, so the size of the gap between the two should be read with caution.

Proctitis was mostly moderate to severe: 2 cases were grade 1, 9 were grade 2 and 6 were grade 3, so 15 of 17 (88.2%; 95% CI 65.7 to 96.7) were grade 2 or higher. Cystitis was milder: 4 cases were grade 1, 3 were grade 2 and 1 was grade 3, so 4 of 8 (50.0%; 95% CI 21.5 to 78.5) were grade 2 or higher. Across the whole cohort, grade 2 or higher proctitis affected 17.6% of patients and grade 3 proctitis 7.1%; the corresponding figures for cystitis were 4.7% and 1.2%. No grade 4 or 5 events were recorded.

**Table 2: Incidence, severity and time to onset of toxicity**

| Toxicity  | n (% of 85; 95% CI)  | G1 | G2 | G3 | Grade ≥2, n (% of cases) | Onset, months: median (IQR; range) |
|-----------|----------------------|----|----|----|--------------------------|------------------------------------|
| Proctitis | 17 (20.0; 12.9–29.7) | 2  | 9  | 6  | 15 (88.2)                | 11 (10–14; 2–17)                   |
| Cystitis  | 8 (9.4; 4.8–17.5)    | 4  | 3  | 1  | 4 (50.0)                 | 10.5 (5–14; 1–17)                  |

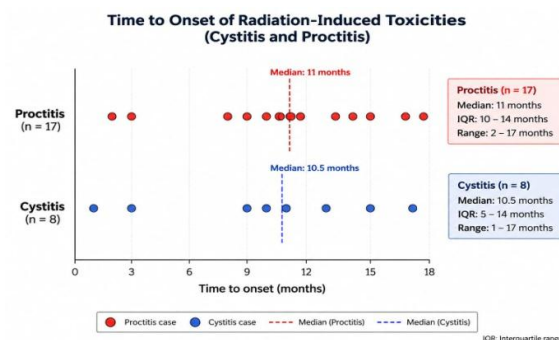
G1 to G3, grade 1 to 3 by CTCAE v5.0. CI, Wilson 95% confidence interval. IQR, interquartile range. Either toxicity: 25 of 85 (29.4%; 95% CI 20.8–39.8).



**Figure 2: A, Incidence of proctitis, cystitis and either toxicity with 95% confidence intervals. B, Number of patients by CTCAE grade. n gives the total for each toxicity.**

### Time to onset

Median time to onset was 11 months for proctitis (IQR 10 to 14; range 2 to 17) and 10.5 months for cystitis (IQR 5 to 14; range 1 to 17). Cases were spread across the whole period, from the first month to month 17 (Figure 3). Some cases therefore arose after the median follow-up of 13 months.



**Figure 3: Time to onset of radiation-induced proctitis (n = 17) and cystitis (n = 8). Each dot is one patient; dashed lines mark the medians.**

### Distribution by stage, technique and chemotherapy

The cohort included 6 patients with stage IIA disease, 22 with IIB, 7 with IIIA, 10 with IIIB, 27 with IIIC1, 10 with IIIC2 and 3 with IVA (54 patients, 63.5%, had stage III disease in all). Toxicity was concentrated in this stage III group: 21 of its 54 patients (38.9%) developed cystitis or proctitis,

against 4 of the 31 patients with stage II or IVA disease (12.9%). This difference was significant on exploratory testing (Fisher's exact test,  $P = 0.014$ ), though it was not adjusted for other factors and should be read alongside the limitations below (Table 3, Figure 4A).

By EBRT technique, all 8 cystitis cases and 15 of 17 proctitis cases arose in the 75 patients treated with conventional 2D radiotherapy, and 2 proctitis cases arose in the 7 patients treated with IMRT; no toxicity occurred in the 3 patients treated with 3DCRT (Table 3, Figure 4B). Toxicity rates did not differ significantly between conventional 2D radiotherapy and all other techniques combined ( $n = 10$ ): proctitis

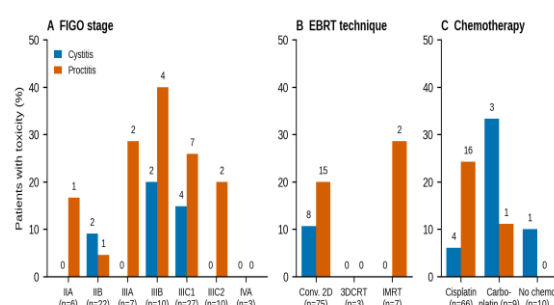
20.0% versus 20.0% ( $P = 1.00$ ) and cystitis 10.7% versus 0% ( $P = 0.59$ ). With only 10 patients in the comparison group, this test has very little power.

Most patients received cisplatin (66, 77.6%); 9 (10.6%) received carboplatin and 10 (11.8%) received no concurrent chemotherapy. Toxicity occurred in 20 of 66 cisplatin patients (30.3%), 4 of 9 carboplatin patients (44.4%) and 1 of 10 patients who received no chemotherapy (10.0%) (Table 3, Figure 4C). Neither difference reached significance (cisplatin versus no chemotherapy,  $P = 0.27$ ; cisplatin versus carboplatin,  $P = 0.46$ ), and both comparisons involved very small groups.

**Table 3: Toxicity by FIGO stage, EBRT technique and concurrent chemotherapy, n (% of patients in that group)**

| Group                          | Patients  | Cystitis       | Proctitis        | Either, n (%)    |
|--------------------------------|-----------|----------------|------------------|------------------|
| <b>FIGO stage</b>              |           |                |                  |                  |
| IIA                            | 6         | 0 (0.0)        | 1 (16.7)         | 1 (16.7)         |
| IIB                            | 22        | 2 (9.1)        | 1 (4.5)          | 3 (13.6)         |
| IIIA                           | 7         | 0 (0.0)        | 2 (28.6)         | 2 (28.6)         |
| IIIB                           | 10        | 2 (20.0)       | 4 (40.0)         | 6 (60.0)         |
| IIIC1                          | 27        | 4 (14.8)       | 7 (25.9)         | 11 (40.7)        |
| IIIC2                          | 10        | 0 (0.0)        | 2 (20.0)         | 2 (20.0)         |
| IVA                            | 3         | 0 (0.0)        | 0 (0.0)          | 0 (0.0)          |
| <b>EBRT technique</b>          |           |                |                  |                  |
| Conventional 2D                | 75        | 8 (10.7)       | 15 (20.0)        | 23 (30.7)        |
| 3DCRT                          | 3         | 0 (0.0)        | 0 (0.0)          | 0 (0.0)          |
| IMRT                           | 7         | 0 (0.0)        | 2 (28.6)         | 2 (28.6)         |
| <b>Concurrent chemotherapy</b> |           |                |                  |                  |
| Cisplatin                      | 66        | 4 (6.1)        | 16 (24.2)        | 20 (30.3)        |
| Carboplatin                    | 9         | 3 (33.3)       | 1 (11.1)         | 4 (44.4)         |
| None                           | 10        | 1 (10.0)       | 0 (0.0)          | 1 (10.0)         |
| <b>All patients</b>            | <b>85</b> | <b>8 (9.4)</b> | <b>17 (20.0)</b> | <b>25 (29.4)</b> |

No patient had both cystitis and proctitis, so the 'either' column is their sum. Groups below 10 patients (3DCRT, IVA) give unstable percentages. Fisher's exact test (exploratory): stage III versus stage II/IVA,  $P = 0.014$ ; conventional 2D versus other techniques, cystitis  $P = 0.59$  and proctitis  $P = 1.00$ ; cisplatin versus no chemotherapy,  $P = 0.27$ ; cisplatin versus carboplatin,  $P = 0.46$ .



**Figure 4: Percentage of patients with cystitis and proctitis by FIGO stage (A), EBRT technique (B) and concurrent chemotherapy (C). Labels give the number of patients with each toxicity; n in the axis labels is the number of patients in that group**

## DISCUSSION

### Principal findings

In this cohort of 85 women treated with definitive radiotherapy, nearly three in ten (29.4%) developed radiation proctitis or cystitis. Proctitis was about twice as common as cystitis (20.0% versus 9.4%) and more severe: 15 of 17 cases were grade 2 or higher and 6 were grade 3, against 4 of 8 and 1 for cystitis.

The confidence intervals are wide, as expected for a cohort of this size, and they overlap.

### Comparison with published series

Reported rates of chronic radiation proctitis after pelvic radiotherapy range from about 2% to 20%.<sup>[13]</sup> A recent Brazilian record review of 226 women treated for cervical cancer found confirmed proctitis in 25.7%.<sup>[13]</sup> Our 20.0% falls at the upper end of the commonly quoted range and below that review. For cystitis, the large series of women with stage IB disease reported 6.5%.<sup>[2]</sup> Our 9.4% is somewhat higher, although the populations differ in stage, technique and era, and our interval is wide.

For severe events, 7.1% of our patients had grade 3 proctitis and 1.2% had grade 3 cystitis. In EMBRACE-I, which used MRI-guided adaptive brachytherapy, the 5-year actuarial rates of grade 3 to 5 events were 8.5% (gastrointestinal) and 6.8% (genitourinary).<sup>[3]</sup> Our crude grade 3 proctitis rate is of similar size to the gastrointestinal figure. Our genitourinary rate is lower, which may reflect shorter follow-up, because bladder toxicity tends to appear later. These comparisons are only approximate, because grading systems, endpoints, follow-up and treatment methods differ.

### Timing of toxicity

Median onset was close to 11 months for both toxicities, and cases ranged from 1 to 17 months. Our proctitis timing agrees with the usual median of 8 to 12 months for chronic proctitis,<sup>[1]</sup> and with a Korean series in which lower gastrointestinal toxicity peaked about 12 months after radiotherapy.<sup>[14]</sup> Our cystitis timing is earlier than in earlier reports, in which bladder toxicity first peaked at about 24 months and kept appearing beyond 36 months,<sup>[14]</sup> and hemorrhagic cystitis had a median onset near three years.<sup>[2]</sup> A short observation window can explain part of this gap. With a median follow-up of 13 months, only events that occur early can be counted, so the median onset we report is likely to be lower than the true value, especially for cystitis. Longer follow-up of this cohort is likely to add cases.

### Technique and dose

Nearly nine in ten patients (88.2%) were treated with conventional 2D radiotherapy, and this technique accounted for all cystitis cases and 15 of 17 proctitis cases. That share mostly reflects how many patients were treated this way, and we found no significant difference in toxicity between 2D and other techniques. Only 10 patients were treated otherwise, so this test could not detect even a large difference. The two proctitis cases among 7 IMRT patients show that IMRT does not remove the risk.

External evidence points in the same direction as the poster's conclusion on dose optimisation. In an Indian randomised study of 44 women with locally advanced cervical cancer, whole-pelvis IMRT gave less grade 2 or higher acute gastrointestinal toxicity than conventional pelvic radiotherapy (31.8% versus 63.6%) and less chronic gastrointestinal toxicity (13.6% versus 50%).<sup>[4]</sup> In the PARCER trial of postoperative radiotherapy, the 3-year cumulative incidence of grade 2 or higher late gastrointestinal toxicity was 21.1% with image-guided IMRT and 42.4% with 3D conformal radiotherapy.<sup>[5]</sup> Dose to the rectum also matters directly. In EMBRACE, higher rectal dose was associated with more severe late rectal morbidity,<sup>[6]</sup> and earlier work on cervical cancer linked bladder and rectal dose to complications.<sup>[15]</sup> We had no dose-volume data, so we could not test this in our cohort. Recording rectal and bladder dose-volume parameters is the most useful next step.

### Stage and chemotherapy

With patient denominators now available for each subgroup, toxicity was significantly more common in stage III disease than in stage II or IVA disease combined (38.9% versus 12.9%;  $P = 0.014$ ). Larger or nodal disease often calls for larger fields or boosts, which may raise dose to the bladder and rectum, and prior work has linked FIGO stage to the risk of these toxicities.<sup>[7]</sup> This association is exploratory: it was not adjusted for EBRT technique, chemotherapy, field size or follow-up time, and multiple subgroup comparisons were made without correction, so it should be treated as hypothesis-generating rather than confirmatory.

Toxicity was numerically more frequent with carboplatin (44.4%) than with cisplatin (30.3%) or no chemotherapy (10.0%), but neither comparison reached significance and the carboplatin and no-chemotherapy groups held only 9 and 10 patients respectively. Cisplatin was the usual concurrent agent (77.6% of the cohort), so its case count reflects how often it was used more than any specific effect. These small, unbalanced groups mean the chemotherapy comparison is unable to support a conclusion either way, and it should be revisited once more patients have accrued.

### Clinical implications

Three points follow. First, careful planning to limit dose to the bladder and rectum is worthwhile, given the frequency and severity of proctitis, and particularly for patients with stage III disease. Second, follow-up should not stop at the first post-treatment visit. New rectal bleeding, urgency, or blood in the urine at any point in the first year and later should prompt assessment. Third, counselling before treatment can include the fact that these toxicities are not rare and can appear many months after radiotherapy.

### Strengths and limitations

Strengths include the use of one grading system (CTCAE v5.0) for both organs, a minimum follow-up requirement, and reporting of onset time and full subgroup denominators alongside incidence. Limitations are important. The study is retrospective and single-institution, so selection and documentation bias are possible, and mild or unrecorded cases may have been missed because toxicity was identified from documented investigations. Follow-up was short for late toxicity. Incidence is a crude proportion rather than a time-to-event estimate, so it will rise with longer follow-up; a cumulative incidence analysis is the better method once follow-up matures. Numbers are small in several subgroups, especially 3DCRT ( $n = 3$ ), IVA ( $n = 3$ ), carboplatin ( $n = 9$ ) and no chemotherapy ( $n = 10$ ), and the stage and chemotherapy comparisons were not adjusted for one another or for technique. No dose-volume data were available. Larger, prospective, multicentre studies with standardised planning, dose constraints and toxicity assessment are needed to validate these findings.

## CONCLUSION

After definitive radiotherapy for carcinoma cervix, proctitis (20.0%) was more frequent than cystitis (9.4%) in this cohort. Of 17 proctitis cases, 9 were grade 2 and 6 were grade 3. Toxicity was significantly more common in stage III disease than in earlier or IVA-stage disease, an exploratory finding that should be confirmed prospectively. The findings support careful planning and dose optimisation for the organs at risk. Onset times varied widely, which supports long-term surveillance beyond the immediate post-treatment period.

Prospective studies with dosimetric data are needed to identify modifiable risk factors so that treatment-related morbidity can be reduced and quality of life improved.

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