

Impact of Hydrogel Spacer Placement on Urinary and Bowel Function After Intensity-Modulated Radiation Therapy for Localized Prostate Cancer

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Hypothesis / aims of study

Intensity-modulated radiation therapy (IMRT) is an effective treatment for localized prostate cancer with excellent tumor control. However, late adverse events such as radiation-induced proctitis and cystitis remain clinically significant issues. Since 2019, a hydrogel spacer has been utilized at our institution. In this study, we evaluated the impact of hydrogel spacer use on urinary and bowel function.

Study design, materials and methods

Patients with localized prostate cancer who underwent IMRT at our institution between April 2015 and March 2022 were retrospectively analyzed. Patients were divided into two groups: those without spacer placement (Group A) and those with spacer placement (Group B). Patient characteristics, radiation techniques and dose, use of androgen deprivation therapy (ADT), and adverse events were compared between the two groups. ADT was administered to high-risk patients, starting 6 months before radiotherapy and continuing for 2 years after treatment.

Urinary and bowel functions were assessed using the Expanded Prostate Cancer Index Composite (EPIC) before treatment and at 3, 6, 12, 24, and 36 months after radiotherapy. Statistical analyses were performed using the Mann–Whitney U test, chi-square test, and Wilcoxon signed-rank test, with a significance level set at $p < 0.05$. All analyses were conducted using EZR, a graphical user interface for R.

Results

Of the 168 patients treated during the study period, 116 patients (93 in Group A and 23 in Group B) with available EPIC data were included in the analysis. Significant differences between the groups were observed in baseline PSA levels (11.6 ng/mL in Group A vs. 8.10 ng/mL in Group B, $p = 0.03$), the proportion of hypofractionated radiotherapy (12 vs. 23 patients, $p < 0.01$), NCCN risk classification ($p = 0.008$), and the use of ADT ($p = 0.007$).

Radiation cystitis occurred in 11 patients (11.8%) in Group A and 3 patients (13.0%) in Group B. Hyperbaric oxygen therapy was required in 3 patients in Group A and 1 patient in Group B. Radiation proctitis was observed only in Group A (9 patients, 9.7%), including 2 patients who required endoscopic hemostasis, while the remaining cases were managed conservatively.

In EPIC assessments, Group A showed significant declines at 24 months in urinary summary, urinary function, and urinary incontinence scores compared with baseline. Additionally, at 36 months, significant declines in bowel summary and bowel bother scores were observed. In contrast, Group B did not show significant deterioration in either urinary or bowel function at any time point.

Interpretation of results

The hydrogel spacer increases the distance between the prostate and rectum, thereby reducing rectal radiation dose and mitigating radiation-induced rectal toxicity.

In our study, radiation proctitis was observed only in the non-spacer group, and deterioration in bowel function was also limited to this group, which is consistent with previous reports.

Regarding urinary function, the direct effect of the spacer is considered limited. However, in this study, the non-spacer group showed a long-term decline in urinary incontinence-related scores. This may be attributable to the impact of rectal toxicity on quality of life or confounding factors such as differences in ADT use and radiation techniques.

This study has several limitations, including its retrospective design, differences in baseline characteristics and treatment modalities between groups, and the relatively small sample size. In particular, temporal bias due to the introduction of the spacer and the influence of hypofractionated radiotherapy should be considered.

Limitation

All patients in the treatment group received hypofractionated radiotherapy, and significant between-group differences were also observed in radiation dose, NCCN risk classification, and the proportion of patients receiving androgen deprivation therapy. Therefore, the present results may have been influenced by these differences in treatment background.

Concluding message

Hydrogel spacer placement may reduce the incidence of radiation-induced proctitis and contribute to the long-term preservation of bowel function. Further prospective studies with larger sample sizes and appropriate adjustment for treatment-related factors are warranted to validate these findings.

Table1 Patient’s Characteristics

	Group A	Group B	p-value
Number of patients	93	23	
Age, years, median, IQR	72.00 (67.00, 74.00)	73.00 (69.50, 77.00)	0.318
Body mass index, kg/m ² , median, IQR	23.40 (22.20, 25.10)	24.10 (22.10, 25.75)	0.368
PSA, ng/mL, median, IQR	11.60 (6.85, 25.20)	8.10 (6.01, 9.36)	0.03
Prostate volume, ml, median, IQR	25.00 (18.00, 34.00)	22.20 (19.60, 33.00)	0.879
Clinical T stage, n, %			0.844
1	5 (5.4)	2 (8.7)	
2	41 (44.1)	11 (47.8)	
3	44 (47.3)	10 (43.5)	
4	3 (3.2)	0 (0.0)	
Gleason grade, n, %			0.134
1	3 (3.2)	1 (4.3)	
2	16 (17.2)	5 (21.7)	
3	11 (11.8)	7 (30.4)	
4	34 (36.6)	4 (17.4)	
5	29 (31.2)	6 (26.1)	
NCCN risk group, n, %			0.008
Low	1 (1.1)	0 (0.0)	
Intermediate	11 (11.8)	9 (39.1)	
High	81 (87.1)	14 (60.9)	
Hypofractionated irradiation, n, %	12 (12.9)	23 (100.0)	<0.001
Radiation dose, Gy, median, IQR	78.00 (74.00, 78.00)	70.00 (70.00, 70.00)	<0.001
Neoadjuvant hormone therapy, n, %	81 (87.1)	14 (60.9)	0.007
Adjuvant hormone therapy, n, %	77 (82.8)	14 (60.9)	0.044
Radiation cystitis, n, %	11 (11.8)	3 (13.0)	0.873
Radiation proctitis, n, %	9 (9.7)	0 (0.0)	0.12
PSA recurrence, n, %	2 (2.2)	0 (0.0)	0.478
Radiographic recurrence, n, %	2 (2.2)	0 (0.0)	0.478
Radiation induced secondary malignancy, n, %	2 (2.2)	0 (0.0)	0.478

Fig 1 Longitudinal changes in EPIC scores

