

Bowel toxicity after IMRT for prostate cancer with a spacer gel

– a matched-pair comparison

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Background & Purpose

The application of a hydrogel spacer is an innovative technique to protect the rectal wall during prostate cancer radiotherapy. Clinical effects are not well known. The aim of the study was to compare acute bowel quality of life changes after intensity modulated radiotherapy (IMRT) with a spacer gel in comparison to low and high dose radiotherapy without a spacer gel.

Methods & Materials

A group of 84 patients (28 in each group) has been surveyed prospectively before RT (time A), at the last day of RT (time B) and 2-3 months after RT (time C) using a validated questionnaire (Expanded Prostate Cancer Index Composite; only patients who responded to all questionnaires were included). The multi-item scale scores were transformed lineary to a 0-100 scale, with higher scores representing better quality of life. Score changes were calculated for the individual domains and additionally for each bowel bother item. Mean changes/differences of at least 5 points were defined as clinically relevant. The median dose to the prostate in the spacer subgroup (SP) was 78Gy in 2Gy fractions. The SpaceOAR™ maintains space for 70.2Gy in 1.8Gy fractions (LD) and IMRT up to 76Gy in 2Gy fractions (HD), respectively. Pairs were matched according to following criteria: age, prostate volume (larger volumes in subgroups without spacer accepted), bowel bother score before RT, prognostic risk subgroup and use of antiandrogens.

Results

Baseline mean bowel bother scores were 96 points in all subgroups (Table 1). Similar mean changes (SP: 16, 3DCRT: 14, IMRT: 17 points) resulted at the end of radiotherapy. The smallest difference resulted in the spacer subgroup 2-3 months after radiotherapy (SP: 2, 3DCRT: 8, IMRT: 6 points; Table 2). Bowel bother scores have not been significantly different in comparison to baseline levels only in the spacer subgroup. The percentage of patients reporting moderate/big bother with specific symptoms did not increase for any item (urgency, frequency, diarrhoea, incontinence, bloody stools, pain; Table 3).

Table 1. Baseline characteristics (* p=0.03 for comparison spacer vs. 70.2Gy)

	spacer	3DCRT 70.2Gy	IMRT 76Gy
patient age (years); mean/median (range)	72/73 (56-81)	72/74 (54-78)	73/74 (53-80)
prostate volume (cm ³); mean/median (range)	61/48 (25-180)	52/45 (22-122)	52/48 (18-120)
neoadjuvant hormonal therapy; n (%)	7 (25)	7 (25)	7 (25)
PSA (ng/ml); median (range)	8 (2-83)	8 (4-29)	7 (4-41)
biopsy Gleason score <7; n (%)*	16 (57)	23 (82)	17 (61)
clinical T-stage ≤2a; n (%)	25 (89)	22 (79)	24 (86)
prognostic risk group	low risk; n (%)	10 (36)	10 (36)
	intermediate risk; n (%)	13 (46)	13 (46)
	high risk; n (%)	5 (18)	5 (18)
bowel bother score before RT; median (range)	96/100 (54-100)	96/100 (64-100)	96/100 (61-100)

Fig. 1. Median rectal dose-volume histogram

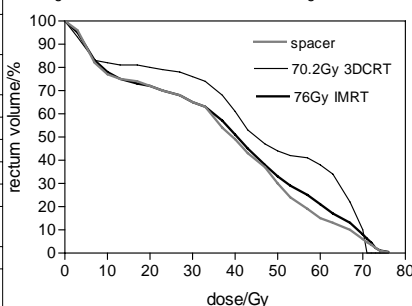


Fig. 2. Example for isodose distributions

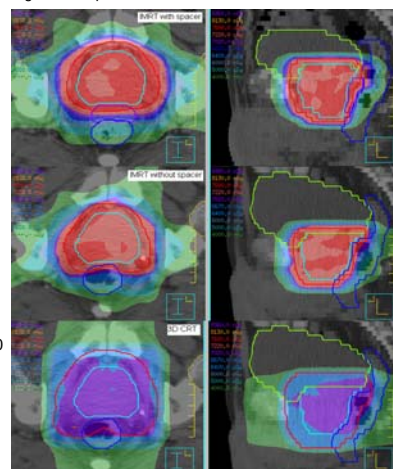


Table 2. Mean function and bother scores (quartiles in brackets)

		time A	change time B	change time C	significant differences	
					A vs. B	A vs. C
urinary function score	spacer	97 (100;100;100)	10 (0;6;20)	1 (0;0;0)	yes	no
	70.2Gy3DCRT	95 (94;100;100)	12 (0;11;20)	4 (0;0;7)	yes	no
	76Gy IMRT	95 (94;100;100)	10 (0;8;20)	5 (0;0;6)	yes	no
urinary bother score	spacer	90 (89;96;100)	17 (5;16;30)	4 (-3;2;7)	yes	no
	70.2Gy3DCRT	85 (75;89;100)	22 (4;18;39)	2 (-7;0;7)	yes	no
	76Gy IMRT	88 (86;91;100)	18 (0;14;22)	6 (-3;2;11)	yes	yes
bowel function score	spacer	96 (96;96;100)	15 (4;12;25)	3 (0;0;10)	yes	no
	70.2Gy3DCRT	93 (86;96;100)	10 (1;7;17)	4 (-4;0;4)	yes	no
	76Gy IMRT	94 (93;96;100)	14 (4;14;24)	3 (-4;0;7)	yes	no
bowel bother score	spacer	96 (96;100;100)	16 (0;10;28)	2 (0;0;6)	yes	no
	70.2Gy3DCRT	96 (96;100;100)	14 (0;11;28)	8 (0;0;14)	yes	yes
	76Gy IMRT	96 (96;100;100)	17 (2;14;29)	6 (0;0;4)	yes	yes

Table 3. Percentage of patients reporting big or moderate bother with specific symptoms

		time A	time B	time C	significant differences	
					A vs. B	A vs. C
rectal urgency	spacer	7	19	7	no	no
	70.2Gy3DCRT	0	22	7	yes	no
	76Gy IMRT	4	21	7	yes	no
frequent bowel movements	spacer	4	19	4	no	no
	70.2Gy3DCRT	0	19	4	yes	no
	76Gy IMRT	0	21	7	yes	no
watery bowel movements	spacer	0	10	0	no	no
	70.2Gy3DCRT	0	7	7	no	no
	76Gy IMRT	4	7	4	no	no
uncontrolled bowel movements	spacer	0	14	0	yes	no
	70.2Gy3DCRT	0	4	4	no	no
	76Gy IMRT	0	4	7	no	no
bloody stools	spacer	0	11	0	no	no
	70.2Gy3DCRT	0	0	4	no	no
	76Gy IMRT	0	4	0	no	no
abdominal/pelvic/rectal pain	spacer	4	11	0	no	no
	70.2Gy3DCRT	4	11	11	no	no
	76Gy IMRT	7	7	4	no	no

Conclusions

Moderate bowel quality of life changes can be expected during radiotherapy irrespectively of the spacer application or the total dose. Advantages following radiotherapy with a hydrogel spacer can be expected a few weeks after treatment and presumably in the long term.