SpaceOAR™ Hydrogel

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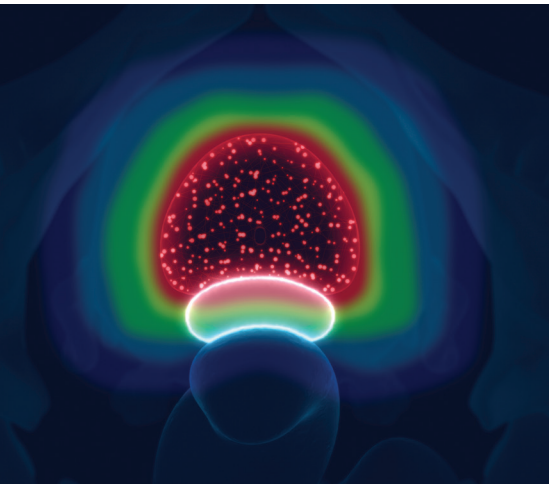
Expanding the Utilization of Rectal Spacer Hydrogel for Larger Prostate Glands (>80cc): Feasibility and Dosimetric Outcomes



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Limitations of this report include:

- Study was retrospective in nature
- The SpaceOAR Hydrogel pivotal study did not evaluate glands >80cc so the results may not be comparable
- This study was not designed or powered to make definitive claims about the benefits of a spacer
- These results may not be achieved with other large gland protocols
- The pivotal study done for SpaceOAR Hydrogel utilized fractionation schedules of 79.2Gy over 44 fractions

"Hydrogel placement is feasible in large glands >80cc, even when including a subgroup of patients with prostates >100cc (100.1-186.6 cc) with very favorable dosimetric outcomes which are in line with benchmark published results with smaller glands."

78Gy over 39 fractions was not the method used in the SpaceOAR™ Hydrogel single-blind Phase III trial performed to evaluate dosimetric and clinical effects of SpaceOAR Hydrogel. IG-IMRT delivered at 79.2 Gy in 1.8-Gy fractions was the method used.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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URO-1141303-AA DEC 2021

33 patients with localized prostate cancer with glands exceeding 80cc were treated at a single institution using intensity-modulated radiotherapy (IMRT, n=15) and proton therapy (n=18) from 2017 to 2019. 16 patients received conventional fractionation and 17 received hypofractionation. Previous prospective multi-institutional studies only included prostates <80cc.[1] The mean separation was 9.9 mm (range, 6.6 - 19.4 mm) for glands measuring >80 to 100 cm^3 and 8.8 mm (range, 4.7 - 12.3 mm) for glands >100 cm^3. Patients were assessed weekly using common terminology criteria for adverse events (CTCAE).

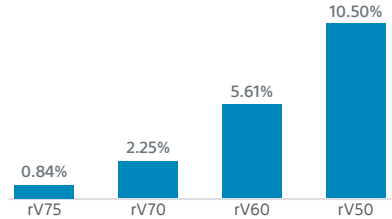
Dosimetric outcomes

Conventional fractionation (78 Gy/39 fractions)							
	Pts	rV75		rV70		rV60	rV50
All	16	0.84%	(0-2.7)	2.25%	(0-4.7)	5.61% (1.7-9.5)	10.5% (2.39-15.2)
P + SV	4	0.75%	(0.06-1.77)	2%	(0.75-4.4)	5.47% (2.5-9.5)	10.1% (6.4-15.2)
P + SV + Lns	12	0.87%	(0-2.7%)	2.3%	(0-4.7)	5.66% (1.7-8.9)	10.7% (2.3-14.9)
P + SV (IMRT)	2	0.58%	(0.06-1.1)	1.61%	(0.93-2.3)	4.95% (4.5-5.4)	9.45% (9.4-9.5)
P + SV (PT)	2	0.93%	(0.09-1.77)	2.57%	(0.75-4.4)	6% (2.5-9.5)	10.8% (6.4-15.2)

Moderate hypofractionation (70 Gy/28 fractions)							
	Pts	rV65		rV63		rV60	rV50
All P + SV	17	1.67%	(0-5.8)	2.3%	(0.1-6.7)	3.4% (0.4-9.6)	8.6% (3.3-15.7)
P + SV (IMRT)	9	1.16%	(0-4.6)	1.65%	(0.1-5.8)	2.5% (0.3-7.8)	6.9% (2.46-15)
P + SV (PT)	8	2.24%	(0.7-5.8)	3.1%	(1.3-6.7)	4.48% (2.4-9.6)	10.5% (4.9-15.7)

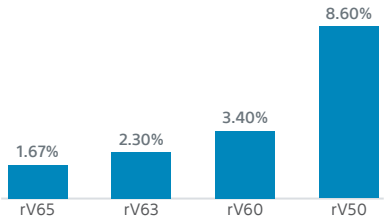
Abbreviations: IMRT = intensity modulated radiation therapy; (P + SV) = prostate plus seminal vesicles; (P + SV + Lns) = prostate plus seminal vesicles plus lymph nodes; PT = proton therapy; Pts = patients.

Conventional fractionation (78 Gy/39 fractions)
All patients (n=16)



Mean value and range, rV75 = 0.84% (range, 0 - 2.7), rV70 = 2.25% (range, 0 - 4.7), rV60 = 5.61% (range, 1.7 - 9.5), rV50 = 10.5% (range, 2.39 - 15.2)

Moderate hypofractionation (70 Gy/28 fractions)
All P + SV (n=17)



Mean value and range, rV65 = 1.67% (range, 0 - 5.8), rV63 = 2.3% (range, 0.1 - 6.7), rV60 = 3.4% (range = 0.4 - 9.6), rV50 = 8.6% (range, 3.3 - 15.7)

Link to full article:
https://www.advancesradonc.org/article/S2452-1094(21)00009-9/fulltext

1. Mariados N, Sylvester J, Shah D, et al. Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys*. 2015;92(5):971-977.