

CLINICAL SUMMARY

Early Tolerance and Tumor Control Outcomes with High-dose Ultrahypofractionated Radiation Therapy for Prostate Cancer.

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Limitations of this report include:

- Study was retrospective in nature
- The SpaceOAR™ Hydrogel pivotal study did not use SBRT so the results may not be comparable
- Short follow-up time and additional events could alter the conclusions
- Study was not designed or powered to make definitive claims about rectal spacer benefit
- These results may not be achieved with other SBRT protocols
- Rectal spacer placement was ubiquitous after 2016 unless contraindicated – data may be confounded by an underlying effect of time period.

References

Zelefsky MJ, Pinitpatcharalert A, Kollmeier M, et al. Early Tolerance and Tumor Control Outcomes with High-dose Ultrahypofractionated Radiation Therapy for Prostate Cancer. *Eur Urol Oncol.* 2019;S2588-9311(19)30147-6.

Disclaimers

SBRT 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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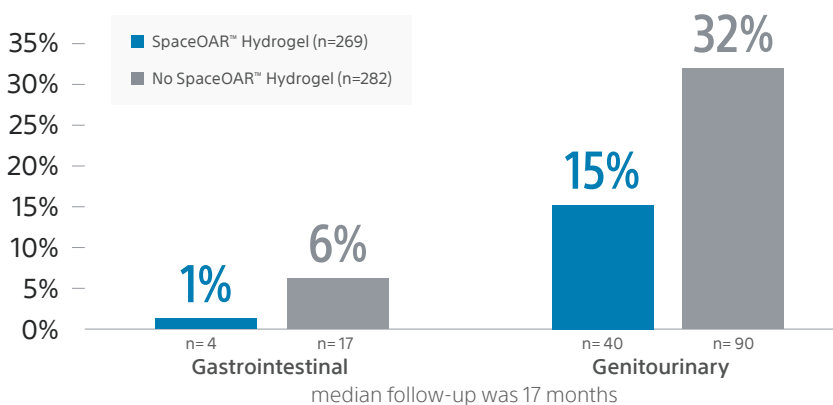
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In a retrospective analysis entitled Early Tolerance and Tumor Control Outcomes with High-Dose Ultrahypofractionated Radiation Therapy for Prostate Cancer, a total of 551 prostate cancer patients received dose-escalated SBRT (40 Gy over 5 fractions). 269 of the 551 patients received a hydrogel spacer.

Percentage of Late Toxicities with and without SpaceOAR™ Hydrogel



“The use of a hydrogel rectal spacer was significantly associated with reduced late GI toxicity and lower odds of developing late GU toxicity”.

Link to full article:

[https://euoncology.europeanurology.com/article/S2588-9311\(19\)30147-6/fulltext](https://euoncology.europeanurology.com/article/S2588-9311(19)30147-6/fulltext)

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