

CLINICAL SUMMARY

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

Michael J. Zelefsky^{a*}, Attapol Pinitpatcharalert^b, Marisa Kollmeier^a, Debra A. Goldman^c, Sean McBride^a, Daniel Gorovets^a, Zhigang Zhang^c, Melissa Varghese^a, Laura Happersett^d, Neelam Tyagi^d, Margie Hunt^d

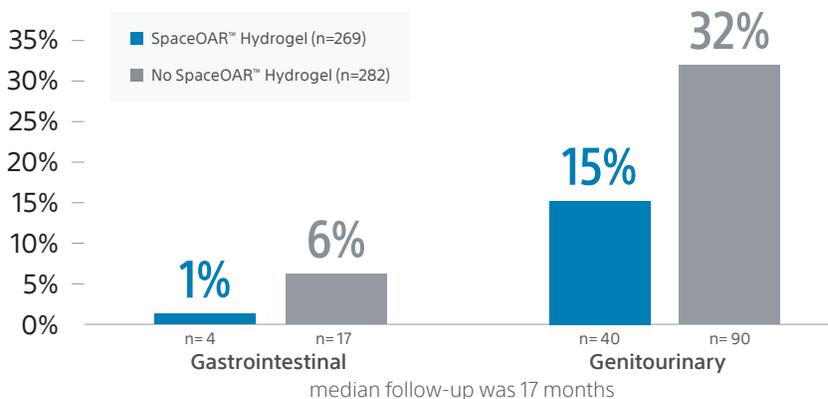
^a Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ^b Division of Radiation Oncology, Thammasat University Hospital, Pathumthani, Thailand; ^c Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer, New York, NY, USA; ^d Department of Medical Physics, Memorial Sloan Kettering Cancer, New York, NY, USA

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.

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)

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.

The content of this article/publication is under the sole responsibility of its author/publisher and does not represent the opinion of BSC.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service

All trademarks are the property of their respective owners.

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

© 2020 Boston Scientific Corporation or its affiliates. All rights reserved.

URO-793909-AA JUN 2020