SpaceOAR™ Hydrogel

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Phase II study of stereotactic body radiotherapy with hydrogel spacer for prostate cancer: acute toxicity and propensity score-matched comparison

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Limitations of this report include:

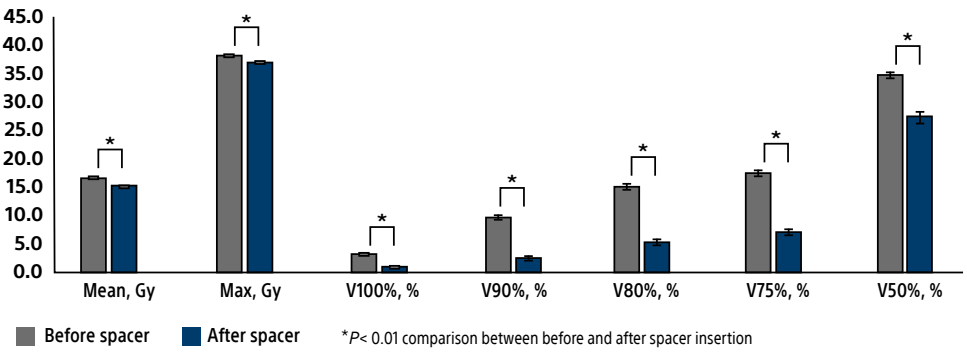
- Relatively small sample size
- Single institutional design
- Short follow-up duration
- As this is a single-arm study, precise comparisons without a spacer could not be made. Therefore, propensity score-matched analysis was conducted using retrospectively collected data from patients who received SBRT without the spacer in the institution. Although unknown confounders cannot be excluded, propensity score-matching can reduce the bias due to its confounding variables.

Safety and efficacy of SBRT in combination with a hydrogel spacer was evaluated in a prospective single-center, single-arm phase II study including 40 patients, all receiving a hydrogel spacer insertion followed by SBRT. Propensity score-matched analyses was used for comparison of patients with hydrogel spacers with those without spacers.

Primary endpoint: Physician-assessed acute gastrointestinal (GI) toxicity within 3 months after SBRT completion

Secondary endpoints: Physician-assessed acute genitourinary (GU) toxicity, patient-reported outcomes evaluated by the EPIC and FACT-P questionnaires, and dosimetric comparison.

Dosimetric comparison of rectum doses before and after spacer insertion.

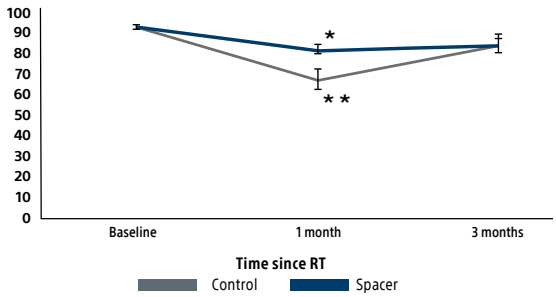


"A hydrogel spacer significantly reduced the dose to the rectum."

"The EPIC bowel summary score was significantly better in the spacer group at 1 month."

Link to full article:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8199395/pdf/13014_2021_Article_1834.pdf

Time course of patient-reported outcomes: EPIC Bowel domain score***



*P < 0.05 comparison between the spacer group and the control group by T-test.
**P < 0.05 comparison between the spacer group and the control group by two-way repeated ANOVA. ***after propensity score matching, EPIC: Expanded Prostate Cancer Index Composite

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.

SpaceOAR Hydrogel is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Hydrogel to reduce the radiation dose delivered to the anterior rectum. SpaceOAR Hydrogel contains polyethylene glycol (PEG). Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events. As with any medical treatment, there are some risks involved with the use of SpaceOAR Hydrogel. Potential complications associated with SpaceOAR Hydrogel include, but are not limited to: pain associated with SpaceOAR Hydrogel injection, pain or discomfort associated with SpaceOAR Hydrogel, local inflammatory reactions, infection (including abscess), urinary retention, urgency, constipation (acute, chronic, or secondary to outlet perforation), rectal tenesmus/muscle spasm, mucosal damage, ulcers, fistula, perforation (including prostate, bladder, urethra, rectum), necrosis, allergic reaction (localized or more severe reaction, such as anaphylaxis), embolism (venous or arterial embolism is possible and may present outside of the pelvis, potentially impacting vital organs or extremities), syncope and bleeding. The occurrence of one or more of these complications may require treatment or surgical intervention.

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