CLINICAL SUMMARY

SpaceOAR™ Hydrogel

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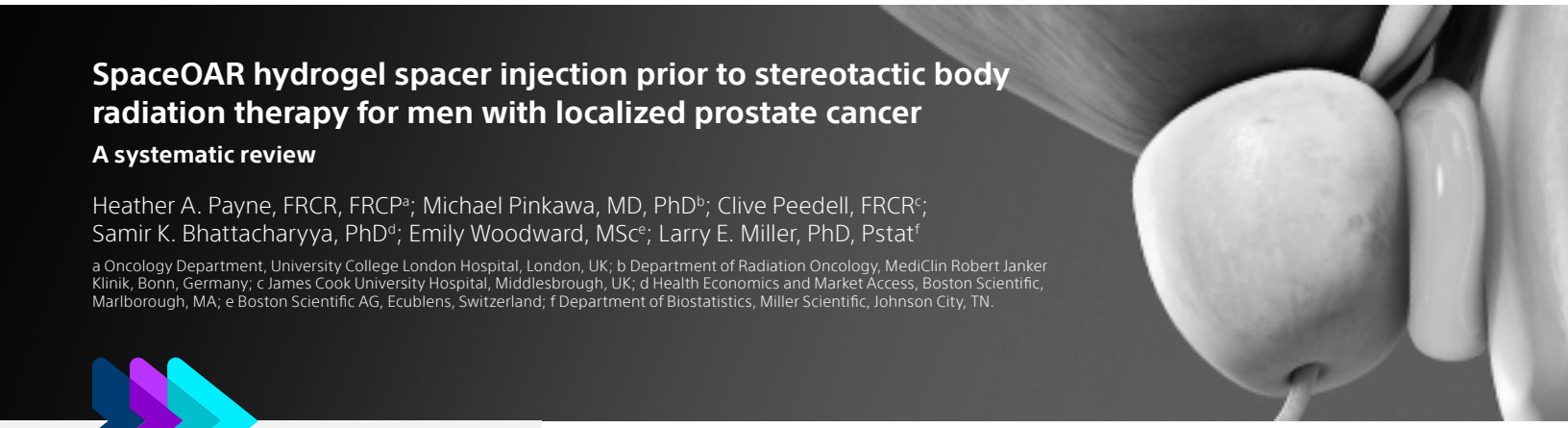

SpaceOAR hydrogel spacer injection prior to stereotactic body radiation therapy for men with localized prostate cancer

A systematic review

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Limitations of this report include:

- There are no randomized trials comparing various rectal spacer strategies with SBRT.
- SBRT protocols varied considerably among studies and patient characteristics were inconsistently reported.
- Late GI toxicity and FFBF data were available over mid-term follow-up only, and therefore, the long-term outcomes in patients treated with the hydrogel spacer prior to SBRT remain unknown.
- This review did not investigate the effect of hydrogel spacer placement on toxicities in adjacent organs such as the bladder or penile bulb.
- None of the included studies reported bowel-related quality of life. Whether patients receiving SBRT realize an overall improvement in healthy utility following hydrogel spacer placement remains unclear.

A growing consensus suggests that stereotactic body radiation therapy (SBRT) is similarly as effective as conventionally fractionated radiotherapy. The SpaceOAR hydrogel rectal spacer placed between the prostate and rectum reduces radiation-induced rectal injury in patients receiving conventionally fractionated radiotherapy, but spacer efficacy with SBRT is unclear.

Systematic searches of Medline, Embase, and the Cochrane Center Register of Controlled Trials for studies in men who received the SpaceOAR hydrogel spacer prior to SBRT (>5.0 Gy fractions) for localized prostate cancer were performed.

In 11 studies with 780 patients, SBRT protocols ranged from 7 to 10 Gy per fraction with total dose ranging from 19 to 45 Gy. Perirectal distance achieved with the rectal spacer ranged from 9.6 to 14.5 mm (median 10.8 mm). **Compared to controls receiving no spacer, SpaceOAR placement reduced the radiation delivered to the rectum by 29% to 56% across a dosimetric profile curve.**

Early follow-up found grade 2 GI complications were reported in 7.0% of patients and no early grade 3+ GI complications were reported. Over 16 months median follow-up, freedom from biochemical failure ranged from 96.4% to 100%.

		Gastrointestinal toxicity				FFBF	
Study	Perirectal distance (mm)	Early grade 2	Early grade 3	Late grade 2*	Late grade 3*	Rate	Follow-up* (mo)
Alongi, 2013[14]	—	—	0/8	0/[5]	0/[5]	8/8	[11]
Chen, 2020[15]	—	18/250	0/250	10/250	1/250	241/250	36
Cuccia, 2020[16]	9.9	0/10	0/10			—	—
Hwang, 2019[17] Hwang, 2018[18]	9.6	2/50	0/50	0/50	0/50	50/50	20
Jones, 2017[19] Folkert, 2017[20]	11.7	1/44	0/44	—	0/44	44/44	12
King, 2018[21]	—	0/6	0/6	—	—	—	—
Ogita, 2019[22]	—	7/40	0/40	—	—	—	—
Pryor, 2019[23] Wilton, 2017[24]	—	—	0/80	—	—	—	—
Ruggieri, 2014[25]	14.5	—	—	—	—	—	—
Saito, 2020[26]	—	—	—	—	—	—	—
Zelefsky, 2019[27]	—	—	—	3/269	—	—	—

FFBF = freedom from biochemical failure

*Brackets denote estimated values.

Table 3 – Summary of key outcomes in studies of stereotactic body radiation therapy and rectal hydrogel spacer for treatment of prostate cancer.

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