

### **Publication Summary**



# Delphi study to identify consensus on patient selection for hydrogel rectal spacer use during radiation therapy for prostate cancer in the UK

Payne H et al. BMJ Open. 2022, Jul 20; doi: 10.1136/bmjopen-2021-060506

## **BACKGROUND**

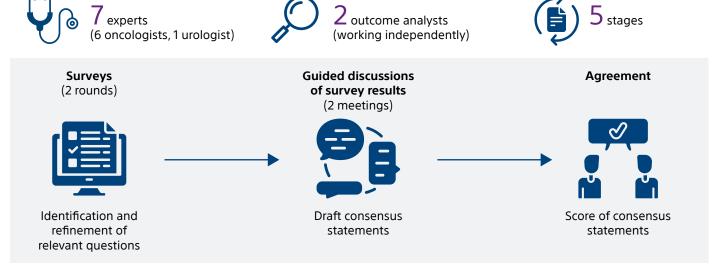


- Hydrogel spacers can help reduce rectal toxicity during radiotherapy (RT) for prostate cancer<sup>1,2</sup>
- Patient access to hydrogel spacers is limited in the United Kingdom (UK), so it is necessary to understand which patients should be prioritised for their use

The present Delphi study aimed to identify expert consensus on patient prioritisation for rectal hydrogel spacer use during radical RT for the treatment of prostate cancer in the UK.

## **METHODS**

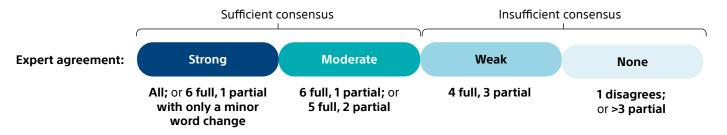
Consensus was reached through the Delphi methodology.



Note: The Delphi technique is an iterative, multistage process in which the opinions of a set panel of experts are synthesised into consensus statements through a series of increasingly specific questionnaires and feedback.

All experts were experienced in using hydrogel spacers.

### Consensus scoring:



Grade 1/2:

100% agreement

Grade 3:

86% agreement

Grade 4:

71% agreement

### 10 statements found sufficient consensus:

Too many patients experience rectal toxicity despite meeting rectal dose constraints

### **TOXICITY**



Certain Grade 1 toxicity-related AEs\* can significantly impact a patient's quality of life



In eligible patients, spacers significantly reduce rectal radiation dose and toxicity-related adverse events (AEs)



Curative treatments should aim to minimise toxicity and risk of side effects

### PATIENT SELECTION



Spacers are beneficial in eligible patients with T1–T2 disease. In patients with higher-grade tumours, the benefits of spacer use should be evaluated on a case-by-case basis by a team experienced in spacer use



Spacer use should be considered in patients receiving long-term anticoagulant therapy (e.g. direct oral anticoagulants<sup>†</sup>) who can safely pause their anticoagulation

### PATIENT CARE



Patients should have the opportunity to participate in the discussion around spacer use



Patient-reported outcomes should be considered alongside a grading system-based toxicity evaluation



Eligible patients with certain comorbidities<sup>‡</sup> and/or longer expected overall survival likely benefit more from spacers (agreement: 6 full/1 partial)



All eligible patients undergoing RT should have equal access to spacers, independent of socio-economic factors (agreement: 5 full/2 partial)

# MODERATE CONSENSUS

### Strengths

- Scientific rigour through applying the established Delphi technique
- An experienced and diverse expert panel

### Limitations

- All experts in the panel are experienced users of hydrogel spacers
- A panel size of only seven individuals, whose experiences may not reflect those of other spacer users

### CONCLUSION

- The use of hydrogel spacers is potentially advantageous for all patients undergoing radical RT for prostate cancer, particularly for those with diabetes, inflammatory bowel disease and/or those receiving anticoagulant therapy
- These recommendations may help prioritise and equalise spacer access for patients in the UK

### **REFERENCES**

- 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:** 971–7.
- 2. Hamstra DA, Mariados N, Sylvester J et al. Continued benefit to rectal separation for prostate radiation therapy: Final results of a phase III trial. Int J Radiat Oncol Biol Phys. 2017; 97: 976–85.

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This study was funded by Boston Scientific. The panellists were reimbursed for their time commitment during the Delphi process at local market rates.

\*Bowel frequency/urgency, flatulence, diarrhoea, radiation cystitis or proctitis, and rectal bleeding or mucus.

'All patients receiving a direct oral anticoagulant (DOAC) can potentially pause their anticoagulation safely, except for those with cardiac stent or prosthetic valve replacement. Thus, the reason for the DOAC prescription is key in deciding on suitability for spacer use.

\*Diabetes, inflammatory bowel disease (ulcerative colitis and Crohn's disease) or receiving anticoagulants.

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. URO-989608-AB MAR 2022

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