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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[1,2]
- 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.

7 experts
(6 oncologists, 1 urologist)

2 outcome analysts
(working independently)

5 stages

Surveys
(2 rounds)

Identification and refinement of relevant questions

Guided discussions of survey results
(2 meetings)

Draft consensus statements

Agreement

Score of consensus statements

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:

	Sufficient consensus		Insufficient consensus	
Expert agreement:	**Strong**	**Moderate**	**Weak**	**None**
	All; or **6 full, 1 partial with only a minor word change**	**6 full, 1 partial;** or **5 full, 2 partial**	**4 full, 3 partial**	**1 disagrees;** or **>3 partial**

RESULTS

Most experts agreed that hydrogel spacers reduce post-RT rectal toxicity of any grade:

Grade 1/2:	Grade 3:	Grade 4:
100% agreement	**86%** agreement	**71%** agreement

10 statements found sufficient consensus:

TOXICITY

- Too many patients experience rectal toxicity despite meeting rectal dose constraints
- 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†) 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

STRONG CONSENSUS

- Eligible patients with certain comorbidities‡ 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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*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.

NOTE: 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; needle penetration of the bladder, prostate, rectal wall, rectum or urethra; injection of SpaceOAR Hydrogel into the bladder, prostate, rectal wall, rectum or urethra; local inflammatory reactions; infection; injection of air, fluid or SpaceOAR Hydrogel intravascularly; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; and rectal urgency

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