Queensland Health

Prostate radiation therapy – rectal spacer use

Queensland Health Guideline

1. Purpose

This guideline provides recommendations regarding best practice to support the use of rectal spacers for prostate cancer patients receiving radiation therapy. It provides guidance on patient selection and clinical treatment criteria for determining the best application of rectal spacers in this patient cohort.

2. Scope

This guideline applies to Radiation Oncology and Urology physicians charged with the care and treatment of patients diagnosed with prostate cancer. More specifically, this guideline supports discussion of rectal spacer use with patients intending on receiving radiation therapy treatment. Compliance with this guideline is not mandatory, but sound reasoning must exist for departing from the recommended principles within a guideline.

3. Guideline for prostate radiation therapy – rectal spacer use

Determining which patients should receive a rectal spacer during their prostate cancer radiation therapy treatment is based on multiple factors. The following consensus statements have been reached through consultation with clinical specialists from across Queensland to provide guiding principles on their appropriate use, where clinical access to rectal spacer use is available. Rectal spacer use in this setting is still an active area of research with long term results still pending for some trials and studies. Therefore, the statements described may be subject to change following the publication of new evidence and should be understood within this context.

3.1. Overview

3.1.1. There is limited long-term outcome data demonstrating non-inferior cancer control when using rectal spacers in prostate radiotherapy.

3.1.2. There is insufficient published evidence of clear and definitive clinical treatment indicators (eg. Treatment modality, dose, fractionation) for use of rectal spacers in prostate radiotherapy patients.

3.1.3. There is insufficient published evidence of clear and definitive patient characteristic indicators (eg. co-morbidities, age) to unequivocally identify who should receive a rectal spacer as part of their prostate radiotherapy treatment.

3.1.4. Where clear evidence-based indicators for rectal spacer use are unavailable or are limited, physician discretion may be used to recommend rectal spacer use in accordance with the remaining guidelines in this document.

3.1.5. When rectal spacers are employed, the aim is to reduce the incidence of ≥Grade 2 gastrointestinal toxicities in both the acute and late setting.

3.1.6. The risk reduction of rectal toxicity gained by using a rectal spacer is dependent on many patient and treatment factors and is therefore difficult to clearly define.

3.1.7. Placement of a rectal spacer should be performed by an experienced practitioner for consistent results.

3.2. Treatment Considerations

3.2.1. Rectal spacers are suitable for all treatment modality applications including external beam radiotherapy (EBRT) and brachytherapy, in addition to combined EBRT + brachytherapy regimes.

3.2.2. Rectal spacers should only be used in patients receiving definitive doses and not in the palliative setting. Rectal spacers have not been studied and are unlikely to be of benefit in these lower dose schedules.

3.2.3. Treatment fractionation alone is not an indicator for rectal spacer use.

3.2.4. Rectal spacers may be considered in the setting of moderate hypofractionation with dose escalation of dominant nodules (identified with MRI) located posteriorly, close to the anterior rectal wall.

3.2.5. Rectal spacers may be considered in the setting of ultra-hypo fractionation/stereotactic body radiotherapy (SBRT) particularly when the GTV is situated posteriorly close to the anterior rectal wall.

3.2.6. Access to an experienced physician with currency of skill who can insert rectal spacer is an important treatment consideration.

3.3. Patient Considerations

3.3.1. Rectal spacer use is not dependant on prostate cancer risk group.

3.3.2. Rectal spacer could potentially provide benefit in the salvage SBRT setting following previous EBRT failure. However, this should be considered in the context of risk associated with fibrosis or adhesions in the tissue plane from previous treatment (see point 4.3.9).

3.3.3. Rectal spacer should be used with caution in patients with extra-capsular extension (≥T3 disease). The location of the extra-capsular extension (eg. anterior or laterally) may still allow use of a rectal spacer in some circumstances.

3.3.4. Rectal spacer use should be considered for patients with bi-lateral prosthetic hips. This should be balanced with alternative options such as brachytherapy or surgery in these individuals.

3.3.5. Patient age and BMI are generally not considerations for determining rectal spacer use.

3.3.6. The life expectancy of a patient should be considered when deciding on rectal spacer use, however this is typically integrated with assessment of patient ECOG status and treatment intent.

3.3.7. Rectal spacer should only be considered for patients who are able to give informed consent following discussion of potential risk of insertion.

3.3.8. Rectal spacer can be considered in patients with risk factors associated with increased acute or late rectal toxicity such as:

- Long-term anticoagulation use
- Inflammatory bowel disease
- Pre-existing rectal or gastrointestinal disorders
- Disorders increasing vasculopathy
- Connective tissue diseases

3.3.9. Patient risk factors that can be considered contraindications for rectal spacer use include:

- High anaesthetic risk
- Previous treatments that may have caused fibrosis or adhesions of the tissue plane between the prostate and rectal wall (eg. pelvic surgery, cryotherapy, radiotherapy)
- Anticoagulation that cannot be stopped
- Active local infection in rectum
- Previous misplaced rectal spacer

3.4. Product Selection

3.4.1. Three commercially available rectal spacer products are currently available within Queensland for use in prostate radiation therapy. These include SpaceOAR™ Hydrogel (Boston Scientific, Massachusetts, USA), SpaceOAR Vue™ Hydrogel (Boston Scientific, Massachusetts, USA), and Barrigel® (Palette Life Sciences, Santa Barbara, USA).

3.4.2. Radio-opaque rectal spacer (SpaceOAR Vue™) may reduce the need for MRI scans in patients with contraindication to MRI or easily visible prostate apex on CT imaging.

3.4.3. Barrigel® rectal spacer provides the ability to be shaped in situations of spacer misplacement (has the potential to be hydralysed) and should be considered in all contexts, but especially in the setting of a very large prostate or salvage SBRT following failed EBRT.

3.5. Clinical Impact Considerations

3.5.1. T2 MRI imaging in the treatment position is recommended after placement of rectal spacer for volume delineation during planning. Refer to previous point (3.4.2) on use of radio-opaque rectal spacers for patients with contraindication to MRI.

3.5.2. Image guidance during treatment should follow standard prostate EBRT guidelines of soft tissue matching using daily CBCT with or without fiducial markers.

3.6. Risks & Limiting Factors

3.6.1. Insertion of a rectal spacer carries the risk of misplacement which can lead to lateral displacement of the target area or toxicities such as inadvertent intravascular insertion, rectal wall infiltration, pelvic abscess, rectal wall ulceration, tenesmus and pain.

3.6.2. Out-of-pocket cost and lack of public funding is a barrier to public patients accessing rectal spacer.

3.7. Outcome Review

3.7.1. For prostate cancer patients who have had a rectal spacer inserted it is recommended that clinician and patient reported outcome measures are used to record patient outcomes.

3.7.2. The following validated tools are recommended for collecting outcome information:

- CTCAE v4.0/v5.0
- Expanded Prostate cancer Index Composite (EPIC)

3.7.3. Recommended time-points for collecting outcome information include:

- 1-week post-insertion (ie. at planning appointment)
- On final fraction of radiation therapy treatment course
- At regular post-treatment follow-up appointment

4. Supporting Literature

1. Aminsharifi A, Kotamarti S, Silver D, Schulman A. Major Complications and Adverse Events Related to the Injection of the SpaceOAR Hydrogel System before Radiotherapy for Prostate Cancer: Review of the Manufacturer and User Facility Device Experience Database. Journal of Endourology. 2019;33(10).

2. Bahl A, Challapalli A, Jain S, Payne H. Rectal spacers in patients with prostate cancer undergoing radiotherapy: A survey of UK uro-oncologists. International Journal of Clinical Practice. 2021;75(8).

3. Björeland U, Notstam K, Fransson P, Söderkvist K, Beckman L, Jonsson J, et al. Hyaluronic acid spacer in prostate cancer radiotherapy: dosimetric effects, spacer stability and long-term toxicity and PRO in a phase II study. Radiation Oncology. 2023;18(1).

4. Cousins MM, Short E, Heckman P, Narayana V, Bryant AK, Hurley P, et al. Prostate radiotherapy in the setting of bilateral hip prostheses: All commonly used photon-based radiation approaches are feasible. Medical Dosimetry. 2021;46(4).

5. Folkert MR, Zelefsky MJ, Hannan R, Desai NB, Lotan Y, Laine AM, et al. A Multi-Institutional Phase 2 Trial of High-Dose SAbR for Prostate Cancer Using Rectal Spacer. International Journal of Radiation Oncology Biology Physics. 2021;111(1).

6. Gorovets D, Hopkins M, Kollmeier M, Moore A, Goel A, Shasha D, et al. Early outcomes of high-dose-rate brachytherapy combined with ultra-hypofractionated radiation in higher-risk prostate cancer. Brachytherapy. 2021;20(6).

7. Hall WA, Tree AC, Dearnaley D, Parker CC, Prasad V, Roach M, 3rd, et al. Considering benefit and risk before routinely recommending SpaceOAR. Lancet Oncol. 2021;22(1):11-3.

8. Hamstra DA, Daignault-Newton S, Bosch WR, Mariados NF, Sylvester JE, Gross ET, et al. Who Benefits From a Prostate Rectal Spacer?: Secondary Analysis of Dosimetry and Bowel Quality of Life From a Phase III Trial. International Journal of Radiation Oncology*Biology*Physics. 2018;102(3).

9. Magli A, Farneti A, Faiella A, Ferriero M, Landoni V, Giannarelli D, et al. Toxicity at 1 Year After Stereotactic Body Radiation Therapy in 3 Fractions for Localized Prostate Cancer. International Journal of Radiation Oncology Biology Physics. 2021;111(1).

10. Mariados NF, Orio PF, Schiffman Z, Van TJ, Engelman A, Nurani R, et al. Hyaluronic Acid Spacer for Hypofractionated Prostate Radiation Therapy. JAMA Oncology. 2023.

11. Miller LE, Efstathiou JA, Bhattacharyya SK, Payne HA, Woodward E, Pinkawa M. Association of the placement of a perirectal hydrogel spacer with the clinical outcomes of

men receiving radiotherapy for prostate cancer: A systematic review and meta-analysis. JAMA Network Open2020.

12. Morgan SC, Morton GC, Berlin A, Cheung P, Chung P, Ménard C, et al. Current topics in radiotherapy for genitourinary cancers: Consensus statements of the Genitourinary Radiation Oncologists of Canada. Canadian Urological Association Journal2020.

13. Newman NB, Rajkumar A, Cleary RK, Shinohara ET, Kirschner AN. Patient Reported Quality of Life Outcomes After Definitive Radiation Therapy With Absorbable Spacer Hydrogel for Prostate Cancer. Advances in Radiation Oncology. 2021;6(6).

14. Ogita M, Yamashita H, Nozawa Y, Ozaki S, Sawayanagi S, Ohta T, et al. Phase II study of stereotactic body radiotherapy with hydrogel spacer for prostate cancer: acute toxicity and propensity score-matched comparison. Radiation Oncology. 2021;16(1).

15. Payne HA, Jain S, Peedell C, Edwards A, Thomas JA, Das P, et al. Delphi study to identify consensus on patient selection for hydrogel rectal spacer use during radiation therapy for prostate cancer in the UK. BMJ Open. 2022;12(7).

16. Quinn TJ, Daignault-Newton S, Bosch W, Mariados N, Sylvester J, Shah D, et al. Who Benefits From a Prostate Rectal Spacer? Secondary Analysis of a Phase III Trial. Practical Radiation Oncology. 2020;10(3).

17. See AW, Bowden P, Wells G, Appu S, Lawrentschuk N, Liodakis P, et al. Dose-escalated radiotherapy to 82 Gy for prostate cancer following insertion of a peri-rectal hydrogel spacer: 3-year outcomes from a phase II trial. Radiation Oncology. 2022;17(1).

18. Seymour ZA, Hamstra DA, Daignault-Newton S, Bosch W, Michalski J, Gay HA, et al. Long-term follow-up after radiotherapy for prostate cancer with and without rectal hydrogel spacer: a pooled prospective evaluation of bowel-associated quality of life. BJU International. 2020;126(3).

19. Zelefsky MJ, Pinitpatcharalert A, Kollmeier M, Goldman DA, McBride S, Gorovets D, et al. Early Tolerance and Tumor Control Outcomes with High-dose Ultrahypofractionated Radiation Therapy for Prostate Cancer. European urology oncology. 2020;3(6).

5. Definitions

Optional – List of concise definitions of technical terms or acronyms used in this guideline.

Term	Definition / Explanation / Details	Source
BMI	Body Mass Index	
CBCT	Cone-Beam Computed Tomography	
ECOG	Eastern Cooperative Oncology Group	
EBRT	External Beam Radiotherapy	
GTV	Gross Tumour Volume	
MRI	Magnetic Resonance Imaging	
SBRT	Stereotactic Body Radiotherapy	

6. Document approval details

Document custodian

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Version control

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1.0	03/05/2023	Initial guideline drafted
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