Technology Guidance

Hydrogel Rectal Spacers

for rectum protection during radiation therapy for prostate cancer

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has not recommended subsidy for hydrogel rectal spacers for rectum protection during radiation therapy for prostate cancer.

Funding status

Hydrogel rectal spacer systems are not recommended for subsidy in patients with the abovementioned indications.

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Factors considered to inform the recommendations

Technology evaluation

1.1. At the March 2025 meeting, the MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of hydrogel rectal spacers for rectum protection in patients with prostate cancer undergoing radiation therapy (RT). The evaluation focused on three Health Sciences Authority (HSA) registered implants, the SpaceOAR, SpaceOAR Vue and Barrigel Systems. Previously, in March 2023, a model-specific evaluation of SpaceOAR (Document Number 19/2023/RR) was presented to the Committee, as it was the only HSA registered rectal spacer at that time. MTAC gave a negative subsidy recommendation to SpaceOAR due to safety concerns, limited clinical evidence, and mixed cost-effectiveness. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for hydrogel rectal spacers was considered in line with its registered indication.

1.2. The evidence was used to inform the Committee's deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Overall benefit of the technology for the patient and/or the system;
- Cost-effectiveness (value for money), which considers the incremental benefit and cost of the technology compared to existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology; and
- Organisational feasibility, which covers the potential impact of adopting the technology, especially barriers for diffusion.

1.3. Additional factors, including social and value judgments, may also inform the Committee's deliberations.

Clinical need

2.1. Prostate cancer is the most common cancer in males in Singapore, accounting for 16.8% of cancer diagnoses nationally (6,912 cases) between 2017 to 2021. Common treatment options for prostate cancer include surgery to remove the prostate, RT with or without hormone therapy, chemotherapy, or active surveillance in certain patients. When used to treat prostate cancer, RT can damage neighbouring healthy tissues or organs, especially the rectum which is in close proximity to the prostate gland. This may result in adverse effects such as rectal bleeding, urinary leakage, diarrhoea, faecal incontinence, proctitis and ulceration of the rectal mucosa.

2.2. Hydrogel rectal spacers consist of biodegradable hydrogels and are injected into the

perirectal space creating a temporary implant that increases the space between the prostate and rectum, potentially reducing radiation received by the rectum during RT. In Singapore, hydrogel rectal spacers are injected during fiducial marker placement. Fiducial markers are metal seeds placed in a patient's body prior to RT to help doctors identify the precise locations requiring radiation delivery.

2.3. The Committee heard that SpaceOAR and SpaceOAR Vue (hereafter referred to as SpaceOAR systems) are polyethylene glycol (PEG)-based, while Barrigel is hyaluronic acid (HA)-based. While both spacer types function similarly, the material differences between the SpaceOAR systems and Barrigel result in differences in sculpting time and reversibility. The SpaceOAR systems are injected as two precursor solutions, which solidify and form a soft hydrogel within 10 seconds, after which removal or repositioning is not possible. SpaceOAR Vue has an additional iodine molecule added to its structure to allow visibility on computed tomography (CT) scans. Barrigel is reversible and injected as a pre-formed gel and remains soft and pliable indefinitely, allowing for repositioning.

2.4. The main comparator is standard of care, which involves RT without additional interventions to reduce the risk of RT-related side effects. The secondary comparators were other types of rectal spacers, such as biodegradable balloons.

2.5. The Committee noted that clinical practice guidelines on the management of prostate cancer did not publish any specific recommendation statements on the use of hydrogel rectal spacers for rectum protection during prostate cancer treatment. The 2022 American Urological Association (AUA) and American Society for Radiation Oncology (ASTRO) joint guideline asserts, as a "clinical principle", that clinicians should optimise the therapeutic ratio of external beam radiation therapy for prostate cancer, with hydrogel rectal spacers as one of the options to consider in this optimisation process.

Overall benefit of technology

3.1. The Committee agreed with the choice of comparators and acknowledged that the evidence base comprised four health technology assessment (HTA) reports (Australia, United Kingdom, Europe, Canada) and six primary studies. The Committee noted evidence for safety was further supplemented by local data provided by the Health Sciences Authority (HSA) and an overseas database from the US Food and Drug Association (FDA) Manufacturer and User Facility Device Experience (MAUDE). The Committee further noted there was no evidence available comparing the SpaceOAR systems and Barrigel.

3.2. The Committee noted that a recent update from the FDA MAUDE database indicated continuous safety concerns and an upward trend in complication rates associated with the SpaceOAR Systems from 2018 and 2022. Placement issues were frequently reported, with embolisms being a possible major complication. On the other hand, safety data for Barrigel was limited. The Committee considered anecdotal experience

from local clinicians regarding safe use of hydrogel rectal spacers in Singapore as a result of having adequate training to ensure user competency and putting monitoring protocols in place to manage gel misplacement. However, due to a lack of systematic tracking of outcome data at an institutional and national level, the Committee considered that there was insufficient evidence to draw definitive conclusions on the safety of hydrogel rectal spacers in the local setting.

3.3. For clinical effectiveness, the Committee considered that there was insufficient evidence to show hydrogel rectal spacers are superior to no intervention. While hydrogel rectal spacers significantly reduced rectal radiation compared to no spacer, the clinical meaningfulness of such reductions is uncertain. SpaceOAR Systems may reduce long-term rectal toxicity and may improve long-term bowel and sexual quality of life, while the effect on genitourinary toxicity and overall quality of life is unclear. Long-term outcomes for Barrigel were not available. The Committee also noted that evidence comparing rectal dosimetry between hydrogel rectal spacers and other types of rectal spacers is mixed and inconclusive.

3.4. The Committee heard that the use of hydrogel rectal spacers may benefit certain subgroups of patients who are at greater risk of suffering from rectal toxicity and bleeding given the rising age of patients with prostate cancer, high prevalence of co-existing medical conditions (e.g. coronary artery disease, or neurovascular ischemia), and increasing use of blood thinners coupled with shorter fractionated radiotherapy schedules. However, the Committee noted that at present, there is no published evidence to reliably identify specific patient subgroups who would benefit most from hydrogel rectal spacer use.

3.5. The Committee acknowledged that there were few ongoing trials on hydrogel rectal spacers for rectum protection during prostate cancer treatment, and that the clinical evidence base is not expected to change substantially.

Cost effectiveness

4.1. The Committee considered the cost-effectiveness of hydrogel rectal spacers for rectum protection during prostate cancer treatment based on one published HTA economic evaluation (by Norwegian Institute of Public Health, NIPH) and five published economic studies from Australia, Canada, the Netherlands and the United States of America. While overall results were mixed, with incremental cost effectiveness ratios ranging from USD$9,627 to USD$341,068 per quality-adjusted life year gained (QALY), the Committee noted higher quality and more recent studies including the HTA economic evaluation by NIPH (2021) and cost utility analysis by Jones et al. (2021) found that hydrogel rectal spacers were not cost effective, largely due to marginal improvements in incremental QALYs, reflecting the uncertainty in the evidence base regarding the benefits of hydrogel rectal spacers. No local cost-effectiveness study was identified.

4.2. The Committee noted that SpaceOAR is currently reimbursed in Australia, France and South Korea, while SpaceOAR Vue and Barrigel are reimbursed only in Australia. Reimbursement in these jurisdictions is not limited to certain high-risk patient subgroups, potentially due to the aforementioned lack of published evidence to identify such subgroups. The Committee also noted that on average, local prices for hydrogel rectal spacers remain higher than those of overseas jurisdictions.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be <SG$2 million based on the projection of approximately 650 eligible patients in Singapore who would benefit from Government subsidy for hydrogel rectal spacers.

Organisational feasibility

6.1. The Committee noted that administration of hydrogel rectal spacers would require clinicians with training and experience in transperineal interventional procedures, as well as the involvement of radiation oncologists and genitourinary oncologists. The Committee acknowledged the importance of having adequate training and monitoring protocols in place to ensure local safety of hydrogel rectal spacers.

Recommendations

7.1. Based on available evidence, the Committee recommended not listing hydrogel rectal spacers on the MOH Implant Subsidy List (ISL) for rectum protection during radiation therapy for prostate cancer, given its safety concerns, lack of robust evidence demonstrating clinically meaningful benefits, and mixed cost-effectiveness compared to standard of care.

VERSION HISTORY

Guidance on hydrogel rectal spacers
for rectum protection during radiation therapy for prostate cancer

This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance (SpaceOAR systems for rectum protection during prostate cancer treatment)**
   Date of Publication 14 Aug 2023

2. **Guidance updated due to an evidence update to provide a holistic assessment of available hydrogel rectal spacer options as a product group on the ISL**
   Date of Publication 28 Nov 2025

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About the Agency

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As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

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Agency for Care Effectiveness, Ministry of Health
Email: ACE_HTA@moh.gov.sg