Technology Guidance

SpaceOAR systems

for rectum protection during prostate cancer treatment

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 SpaceOAR systems (SpaceOAR and SpaceOAR Vue Systems) for rectum protection during prostate cancer treatment.

Funding status

SpaceOAR systems are not recommended for subsidy in patients with the abovementioned indications.

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Factors considered to inform the recommendations

1. Technology evaluation

1.1. The MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of the SpaceOAR and SpaceOAR Vue Systems (hereafter referred to as SpaceOAR systems) for rectum protection in patients with prostate cancer undergoing radiation therapy (RT). The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for SpaceOAR systems was considered in line with their registered indications.

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 second most common cancer in males in Singapore, accounting for 15.4% of all cancers. 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, resulting in adverse side effects such as rectal bleeding, urinary leakage, diarrhoea, and faecal incontinence.

2.2. The SpaceOAR systems are absorbable polyethylene glycol (PEG) hydrogel tissue spacers. When injected between the rectum and prostate, the hydrogel creates a temporary space between the two organs to reduce radiation to the rectum during RT. The tissue spacer can be introduced under general or local anaesthesia. It remains in place during RT and is fully absorbed by the body over approximately six months.

2.3. The Committee noted that, at the time of the evaluation the SpaceOAR systems were the only tissue spacers registered in Singapore with the Health Science Authority (HSA) for use in patients with prostate cancer undergoing RT.

Overall benefit of technology

3.1. The Committee acknowledged that the main comparator for patients with prostate cancer undergoing RT was no spacer, which is the current standard of care. The evidence base comprised three health technology assessment (HTA) reports.

3.2. The Committee noted that SpaceOAR systems were associated with major complications such as pulmonary embolisms. Of note, one study based on the Food and Drug Administration (FDA)'s Manufacturer and User Facility Device Experience (MAUDE) database revealed 85 reports on SpaceOAR systems, with 59 reports (69%) of severe or medically-significant adverse events (AE), including one death. The Committee noted that the reported complications could be due to the underlying prostate cancer, the SpaceOAR systems injection process, or RT. It was also noted that the risk for AE associated with the SpaceOAR systems could differ by individual patient clinical characteristics, such as presence of co-morbidities.

3.3. For effectiveness the Committee agreed that, when compared to no spacer, SpaceOAR systems had similar or favourable effect on rectal radiation dose, gastrointestinal or genitourinary toxicity, and quality of life (QoL). Although SpaceOAR systems reduced radiation dose to the rectum compared to no spacer, it was unclear if the observed reductions were clinically important and would result in improved patient relevant outcomes, such as reduction in acute or long-term toxicity or improvement in bowel, urinary and sexual QoL. This is in view of limitations in the evidence, particularly bias arising from high attrition rates (up to 37%) in studies reporting long-term toxicity.

3.4. The Committee noted that certain patient subgroups may derive greater benefits from SpaceOAR, such as the elderly with cardiovascular comorbidities or patients on anticoagulants. The latter group was more likely to develop bleeding complications from radiation-induced proctitis three to five years after radiation treatment. Although the Committee acknowledged the greater need for radiation shielding in these patient groups, the safety profile of SpaceOAR systems remained a concern.

Cost effectiveness

4.1. The Committee noted that SpaceOAR systems had mixed cost-effectiveness results based on five published economic evaluations. The most recent economic evaluations, published by Norwegian Institute for Public Health (NIPH) and McGill University Health System (MUHS) in 2021 and 2018 respectively, concluded that SpaceOAR systems were not cost-effective. Three other economic evaluations on hydrogel rectal spacers (not specific to SpaceOAR systems) yielded mixed results, with some evidence showing that hydrogel rectal spacers may deliver better value-for-money in some specific sub-populations. The key drivers of cost-effectiveness were care settings (ambulatory vs hospital care) and certain clinical characteristics (e.g. good baseline erectile function). Across the economic studies, a key limitation was uncertainty of the effectiveness of SpaceOAR systems.

4.2. The Committee noted that the two economic evaluations published by NIPH and MUHS were potentially more applicable to the Singapore context due to their use of longer-term follow-up data, and the specific use of SpaceOAR systems rather than general hydrogel rectal spacers within their analyses. Based on this, the Committee concluded that SpaceOAR systems would unlikely be cost-effective in the local context.

4.3. Currently, SpaceOAR systems are reimbursed in two reference countries (Australia and France). SpaceOAR systems are only used in the UK with special arrangements for clinical governance, consent, and audit or research. They are not reimbursed in Canada and Norway.

4.4. The Committee noted that the prevailing local prices for the SpaceOAR systems were significantly higher than in Australia.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be <SG$1 million, based on the projection of approximately 482 eligible patients in Singapore who would benefit from Government subsidy for SpaceOAR systems.

Organisational feasibility

6.1. The Committee noted that administration of SpaceOAR systems 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 that adequate training is of particular importance given the possibility of embolisms from hydrogel being accidentally misplaced into blood vessels.

Recommendations

7.1. Based on available evidence, the Committee recommended not to subsidise SpaceOAR systems for rectum protection during prostate cancer treatment in view of safety concerns, limited clinical evidence and mixed cost-effectiveness and reimbursement status in ACE's reference jurisdictions.