Percutaneous vertebral augmentation systems

for treating patients with vertebral compression fractures

Technology Guidance from the MOH Medical Technology Advisory Committee (MTAC)

Guidance Recommendations

The Ministry of Health's MTAC has not recommended subsidy for percutaneous vertebral augmentation systems (PVAS) for the treatment of patients with vertebral compression fractures (VCFs).

Subsidy status

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

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Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH MTAC ("the Committee") considered evidence presented for the technology evaluation on PVAS for VCFs. The evaluation was conducted in consultation with clinical experts in interventional radiology, neurosurgery, and orthopaedics from the public healthcare institutions.

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 covers 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;
- Organisational feasibility, which covers the potential impact of adopting technology, especially barriers for diffusion.

1.3 Additional considerations, such as ethical or social issues related to adoption of the technology, may also inform the Committee's deliberations.

Clinical need

2.1 VCFs occur when the vertebral body collapses, leading to loss of vertebral body height and potential kyphotic deformity of the spine. VCFs can cause severe debilitating back pain, limit physical function, and adversely affect quality of life (QoL). Subsequent kyphotic deformity of the spine is linked to poor cardiopulmonary function and appetite, and an increased risk of mortality in patients with VCFs. Once a VCF occurs, patients are at an increased risk of subsequent VCFs. VCFs are most commonly due to osteoporosis, but can also occur due to malignancies or trauma.

2.2 First-line management of VCFs is conservative treatment including analgesia, bed rest, physical therapy, or external bracing. For patients who failed conservative treatment(s), minimally invasive percutaneous techniques including percutaneous vertebroplasty (PVP), percutaneous balloon kyphoplasty (PKP) and PVAS are considered.

2.3 While PVP only uses bone cement, PKP uses a balloon catheter prior to cement to improve height restoration. PVAS additionally uses expandable stents to immobilise VCFs and further address loss of vertebral body height.

Clinical effectiveness and safety

3.1 The Committee acknowledged that the main comparators to PVAS were PVP and PKP.

3.2 The Committee noted that the evidence base comprised one health technology assessment report and a recent systematic review and network meta-analysis of randomised controlled trials (RCTs). Additionally, safety analysis was supplemented by one RCT and two case series.

3.3 The Committee noted PVAS was generally safe with no serious adverse events reported. Subsequent fracture rates were comparable between PVAS and its comparators (up to 13% versus up to 7%). Although cement leakage was reported in up to 44% of PVAS cases, most did not result in clinical sequelae.

3.4 The Committee noted that PVAS showed similar effectiveness to PVP and PKP in patient-reported outcomes such as pain relief, functional improvement, and QoL outcomes. Although PVAS demonstrated improvements in surrogate outcomes such as vertebral kyphotic angle, it was unclear on how these results would be translated into clinically meaningful benefit to patients.

3.5 The Committee noted that most of the evidence was limited to patients with VCFs due to osteoporosis, and focused on one out of the three locally available implant models.

Cost-effectiveness

4.1 The Committee noted that no local cost-effectiveness analysis was conducted. The Committee also noted that no published economic evidence for PVAS was identified.

4.2 The Committee agreed that, given the lack of additional clinical benefits and the higher cost, PVAS was unlikely to be cost-effective when compared with PVP or PKP.

Estimated annual technology cost

5.1 Based on the projection of approximately 30 people with VCFs in Singapore who would benefit from Government subsidy for PVAS, the Committee estimated that the annual cost of subsidising the service was less than $1 million.

Additional considerations

6.1 The Committee noted that none of the reference countries currently reimburse PVAS for patients with VCFs.

Recommendation

7.1 Based on the lack of supporting evidence on the clinical superiority of PVAS relative to its comparators, the lack of listings on reference reimbursement lists, relatively high costs of PVAS, the Committee has not recommended subsidy for PVAS for the treatment of patients with VCFs.