Coronary intravascular lithotripsy

for patients with severely calcified, stenotic de novo coronary artery

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

Guidance Recommendations

The Ministry of Health's MTAC has not recommended subsidy for coronary intravascular lithotripsy (IVL) for treating severely calcified, stenotic de novo coronary artery.

Subsidy status

Coronary IVL is 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 of coronary IVL for treating severely calcified, stenotic de novo coronary artery. The evaluation was conducted in consultation with clinical experts from the public healthcare institutions. Available clinical and economic evidence for coronary IVL was considered in line with the 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 to 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 Coronary artery disease (CAD) is characterised by the narrowing of coronary arteries which reduces blood supply to the heart muscle. Coronary calcification arising from the build-up of calcium deposits in the coronary arteries is a marker of significant CAD and increases long-term mortality. Severely calcified coronary lesions complicate percutaneous coronary intervention (PCI) due to impaired vessel compliance and are frequently associated with failure to restore perfusion and need for revascularisation. In Singapore, CAD is the most common form of cardiovascular disease, with a prevalence rate of 1.8% and incidence rate of 0.2% in 2019.

2.2 Patients with severely calcified coronary arteries may be managed by standard calcium modification treatments including non-compliant balloon, high pressure and ultra-high-pressure balloon, cutting/scoring balloon, and atherectomy. Each of these standard treatments can be used alone or in combination with one

another. Although these treatments can modify the severely calcified lesions, they may also lead to localised wall injury which can in turn lead to restenosis.

2.3 The Committee noted that coronary IVL uses pulsatile mechanical energy to fracture calcified coronary lesions. It was indicated for the treatment of severely calcified, stenotic de novo, balloon crossable coronary artery, prior to coronary stenting. Coronary IVL could be used as an add-on or to replace standard calcium modification treatments to fracture the calcified coronary lesions sufficiently for optimal coronary stent implantation. In local clinical practice, coronary IVL was more commonly used as an add-on to standard calcium modification treatments.

Clinical effectiveness and safety

3.1 The Committee agreed that the main comparator for coronary IVL in patients with severely calcified, stenotic de novo coronary artery was standard calcium modifications treatments.

3.2 The Committee noted that the evidence base on safety and clinical effectiveness of coronary IVL comprised two health technology assessment (HTA) reports, one meta-analysis of case series, two case series, and an aggregated local registry data. The Committee agreed that the evidence for coronary IVL was limited in quantity and quality, and characterised as low level (case series, registry). No comparative evidence was identified.

3.3 The Committee noted that coronary IVL was likely safe despite some potential safety concerns. Coronary IVL was associated with low perforation rate (0 to 2.6%) and generally acceptable major adverse cardiac events (MACE) (0 to 10%). However, higher ranges of coronary dissection (0 to 42.1%) and device failure rates (4.2 to 14.3%) were also reported.

3.4 The Committee also agreed that the current available low-quality non-comparative evidence of coronary IVL was mainly based on the acute post-procedural period for patients with severely calcified, stenotic de novo coronary artery. Although coronary IVL consistently showed promising acute post-procedural outcomes in coronary patency with high clinical (75 to 100%) and angiographic (97 to 100%) success, there was uncertainty surrounding the longer-term effectiveness outcomes of coronary IVL such as continued coronary patency or reinterventions.

3.5 The Committee noted that the lack of comparative evidence made it difficult to determine how coronary IVL compared with standard calcium modification treatments.

Cost-effectiveness

4.1 The Committee noted that no published economic evidence on coronary IVL was identified.

4.2 The Committee noted that in UK, the National Institute for Health and Care Excellence (NICE) recommended the use of coronary IVL with special arrangements for clinical governance. No recommendation or reimbursement information was available for coronary IVL in most reference jurisdictions including Australia, Canada, France, New Zealand, South Korea, and Taiwan.

Estimated annual technology cost

5.1 Based on the projection of approximately 231 to 237 patients with severely calcified, stenotic de novo coronary artery in Singapore who would benefit from Government subsidy for coronary IVL, the Committee estimated that the annual cost of subsidising the service was <$1 million.

Organisational feasibility

6.1 The Committee noted that public healthcare institutions (PHIs) would need to have the requisite level of medical capability (LMC) to provide coronary IVL service. Any increase in coronary IVL use would unlikely impact current workflows at the PHIs as the technology was perceived as relatively easy to learn and use.

Additional considerations

7.1 The Committee noted that coronary IVL was in its early stage of clinical adoption in the PHIs with some potential learning curve. There were eight ongoing randomised controlled trials (RCTs) comparing coronary IVL with standard calcium modification treatments and were estimated to complete within the next four years. These studies could address the current lack of comparative evidence to determine the benefits of coronary IVL relative to standard calcium modification treatments.

Recommendation

8.1 Based on the limited low-quality non-comparative clinical evidence, the lack of economic evidence, and ongoing RCTs comparing coronary IVL with standard calcium modification treatment, the Committee has not recommended subsidy for coronary IVL for the treatment of severely calcified, stenotic de novo coronary artery prior to stenting.

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

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

This guidance is based on the evidence available to the MOH Medical Technology Advisory Committee as at 3 November 2021. It is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

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