Technology Guidance

Robot-assisted endovascular intervention systems

for coronary artery disease and other vascular diseases

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 robot-assisted endovascular intervention systems for coronary artery disease (CAD) and other vascular diseases.

Funding status

Robot-assisted endovascular intervention systems are not recommended for subsidy in patients with the abovementioned indications.

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Factors considered to inform the recommendations for funding

Technology evaluation

1.1. The MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of robot-assisted endovascular intervention systems for treating CAD and other vascular diseases. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from the public healthcare institutions. Published clinical and economic evidence for robot-assisted endovascular intervention systems were considered in line with its 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) – 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 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. Vascular diseases are one of leading causes of disease burden in Singapore and may affect various areas of the body such as the heart (CAD), the brain (cerebrovascular disease) and the extremities (peripheral artery disease or PAD). Treatment plan for CAD and other vascular diseases depend on disease severity, symptoms, and presence of co-morbidities. Manual endovascular interventions, such as manual percutaneous coronary intervention (M-PCI) or manual percutaneous peripheral intervention (M-PPI), are the standard of care to treat most vascular diseases using a minimally invasive approach.

2.2. Percutaneous interventions with robot-assisted endovascular systems (R-PCI and R-PPI) are emerging technologies which can replace manual interventions. Robotic systems generally consist of a bedside unit and an interventional cockpit where the operator would perform the procedure. R-PCI and R-PPI is perceived to potentially result in better procedural control, reduced radiation exposure to the patient and operator, and decreased orthopaedic injuries/fatigue to the operator by elimination of lead aprons.

2.3. The Committee noted that the clinician experts from multiple specialties consulted perceived a low need for this technology in current local practice. R-PCI is not yet adopted in any public healthcare institution (PHIs) in Singapore, and clinician experts opined that there are no immediate plans to introduce the technology to the PHIs.

Overall benefit of technology

3.1. The Committee acknowledged that the main comparator for R-PCI and R-PPI was M-PCI and M-PPI, respectively. No relevant HTA reports were identified. Four systematic reviews and/or meta-analyses were found for R-PCI in CAD, comprising nine primary observational studies. Most of these studies used either the CorPath® GRX and/or CorPath® 200 (the older CorPath® model). No evidence was identified for R-PPI in other vascular indications.

3.2. The Committee noted that compared to M-PCI, R-PCI had reduced patient and operator radiation dose, contrast media volume, and fluoroscopy time at up to one month follow-up. Given that these measures are surrogate safety outcomes, the clinical meaningfulness of any difference reported was unclear. Although radiation exposure and fluoroscopy time may proxy for radiation injury or iatrogenic malignancy, while contrast media volume may proxy for incidence of nephropathy, studies with long-term follow-up will be necessary to assess the clinical significance of the differences reported. None of the studies reported outcomes related to operator fatigue and orthopaedic injuries.

3.3. The Committee noted that there was no significant difference between R-PCI and M-PCI in short-term (up to one month) effectiveness outcomes reported such as main adverse cardiac events (MACE), all-cause mortality, myocardial infarction, and clinical success rates. None of the studies reported target vessel revascularisation (TVR), angina relief, and health-related quality of life.

3.4. The Committee further noted that the main limitations of the evidence base were the low level of primary evidence (only observational studies identified) and the short follow-up period (i.e., perioperative outcomes up to one month).

Cost effectiveness

4.1. The Committee noted that no local cost-effectiveness analysis was conducted. Only one published economic evidence from a cost comparison analysis was identified. R-PCI was associated with additional costs related to equipment and consumables (e.g., the single-use cassette, sterile sleeve, etc). The main limitation of the study was its small sample size and the exclusion of the amortisation of the robotic system in the analysis.

4.2. In view of the additional costs related to R-PCI and the lack of established difference in clinical benefits when compared with M-PCI, it is unlikely that the robot-assisted endovascular intervention systems would be cost-effective.

4.3. The Committee further noted that no overseas reimbursement information specific to the use of robot-assisted endovascular interventions was identified.

Estimated annual technology cost

5.1. Based on the projection, 550 patients with CAD may benefit from Government subsidy for R-PCI, if available. The annual cost impact to the public healthcare system was estimated to be between SG$1 million to <SG$3 million in the first year of subsidising robot-assisted endovascular intervention systems. Additional spending was driven mostly by the cost of R-PCI consumables, i.e., cost of single-use sterile cassette. The capital cost for the robotic systems was not considered.

Organisational feasibility

6.1. The Committee noted that additional training would be required for clinicians to focus on familiarity with equipment controls and the lack of tactile feedback. Infrastructure changes such as dedicated space and reconfiguration of the catheterisation laboratory should be considered. The system is stationary and can be installed only in a single room in the catheterization laboratory. In the setting of a multi-specialty PHI, the organisation may need to consider workflow that would allow sharing of the robotic system amongst various specialties.

6.2. If introduced, local experts opined that R-PCI should be limited to specialised centres or high-volume centres because of the high-cost capital investments on the machine, need for specialised expertise training or staff, and the small number of cases that are suitable for R-PCI.

Additional considerations

7.1. In local clinical practice, interventional cardiologists opined that R-PCI is limited to simple lesions that usually could be treated more efficiently and less costly with M-PCI. Vascular surgeons also opined that it is difficult to perform manoeuvres required in complicated lesions with R-PPI. The clinician experts corroborated that the robotic systems lack haptic feedback to the operator, which can increase the potential for vessel wall damage. They further highlighted that although the operator can control guidewires and catheters within the robotic system's radiation-shielded cockpit, the operator and ancillary staff would still need to perform the initial catheter placement and deploy the devices at the patient's bedside (where shielding by the robotic system to reduce radiation exposure is absent).

Recommendations

8.1. Based on available evidence, the Committee recommended not subsidising robot-assisted endovascular intervention systems for treating CAD and other vascular diseases in view of the low clinical need, insufficient clinical and economic evidence, the high capital and maintenance/operating costs, and organisational feasibility issues (e.g., training, infrastructure, compatibility with off-the-shelf consumables), compared to M-PCI and M-PPI.