Technology Guidance

Thoracic and abdominal endovascular repair (T/EVAR)

for the structural support of aortic aneurysm

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has recommended thoracic and abdominal endovascular repair (T/EVAR) to provide structural support of aortic aneurysm, in line with the following criteria:

- ✓ Patients with abdominal aortic aneurysm (AAA; ruptured or unruptured), who are not suitable for open surgical repair (OSR) and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - asymptomatic and with an aneurysm that has grown by more than 1cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - presenting with a small aneurysm (less than 5 cm), but who will also require chemotherapy, radiation therapy, or solid organ transplantation (a shared multidisciplinary decision-making approach should be considered to decide on treatment options).
- ✓ Patients with thoracic aortic aneurysm (TAA; ruptured or unruptured) who are not suitable for OSR and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5.5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - asymptomatic and with an aneurysm that has grown by more than 1 cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter).
- ✓ Patients with thoraco-abdominal aortic aneurysm (TAAA) who are not suitable for OSR and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5.5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR

- asymptomatic and with an aneurysm that has grown by more than 1 cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter).

✓ Patients with type B aortic dissection (TBAD) with suitable anatomy for TEVAR and the TBAD is:

- Complicated (presence of malperfusion syndrome or rupture) hyperacute (<24 hours), acute (1–14 days), or subacute (15–90 days); OR
- Uncomplicated with high-risk features (refractory pain, refractory hypertension, bloody pleural effusion, aortic diameter of more than 40 mm, imaging evidence of malperfusion, entry tear on lesser curvature, or false lumen of more than 22 mm).

✓ Patients with traumatic aortic injury who do not have contraindications to endovascular repair.

Funding status

Aortic stent graft for T/EVAR is recommended for inclusion on the MOH Medical Technology Subsidy List (MTSL). Listed model packages are recommended for subsidy when used in line with the abovementioned recommendations.

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Factors considered to inform the recommendations

Technology evaluation

1.1. The MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of T/EVAR for the structural support of aortic aneurysm. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for T/EVAR 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. The Committee noted that aortic aneurysm refers to dilatation of the aorta, and includes AAA, TAA, and TAAA. Most aortic aneurysm can be further subdivided into unruptured or ruptured aneurysm. Patients with small- to medium-sized aneurysms are often treated with medication, e.g. beta blockers, antibiotics, angiotensin II receptor blockers, and statins. Patients with larger or symptomatic aneurysms are considered for surgical treatment. In Singapore, approximately 100 T/EVAR cases are performed annually in public healthcare institutions.

2.2. The aim of aortic aneurysm repair is to reinforce the weakened section of the aorta, to prevent aneurysm rupture and its associated high morbidity and mortality. Traditionally, invasive OSR is used to replace the abdominal aneurysm with a vascular graft. The availability of T/EVAR addresses the clinical need for minimally invasive repair with reduced operative risk.

2.3. The Committee noted that T/EVAR involves endovascular placement of one or more aortic stent grafts in an aneurysm. Aortic stent grafts are inserted through a femoral

artery and use fluoroscopic guidance to locate the aneurysm. Implantation of aortic stent grafts prevents aortic rupture by excluding the aneurysm from systemic blood circulation. Patients unsuitable for standard T/EVAR may be considered for complex T/EVAR using fenestrated, branched or chimney aortic stent grafts.

Overall benefit of technology

3.1. The Committee acknowledged that OSR with a vascular graft is the main comparator for T/EVAR.

3.2. The Committee noted that the level of evidence for abdominal endovascular aortic aneurysm repair (EVAR) was considered high, comprising health technology assessment reports and systematic reviews of randomised controlled trials. In patients with AAA, EVAR resulted in lower short-term (<6 months follow-up) mortality when compared with OSR. There was no difference in long-term mortality between EVAR and OSR for both unruptured AAA (uAAA) or ruptured AAA (rAAA). Compared with OSR, EVAR had higher rates of reintervention, but lower risk of pulmonary complications in patients with uAAA; in patients with rAAA, EVAR resulted in lower risk of bowel ischaemia.

3.3. The Committee noted that the level of evidence for thoracic endovascular aortic aneurysm repair (TEVAR) was considered low, and largely based on observational studies. In patients with unruptured TAA (uTAA), the results for perioperative mortality between TEVAR and OSR were inconsistent, but there was no difference in long-term mortality between the procedures. In patients with ruptured TAA (rTAA), TEVAR reduced risk of perioperative mortality compared with OSR, but long-term mortality was uncertain. Further, when compared with OSR, TEVAR resulted in higher rates of reintervention and vascular complications, but lower risks of paraplegia and renal failure in patients with uTAA; in patients with rTAA, TEVAR had higher rates of myocardial infarction.

3.4. The Committee further noted that the level of evidence for fenestrated EVAR was considered very low and largely limited to observational studies, indicating uncertainty in the validity of the study results. In patients with TAAA, there were no differences between fenestrated EVAR and OSR for perioperative and long-term mortality. Compared with OSR, fenestrated EVAR had fewer perioperative cardiovascular complications, but higher hazard of death in people who survived the perioperative period.

Cost effectiveness

4.1. The Committee noted that a systematic review of economic evidence, comprised of over 50 publications of various economic analysis types (cost comparison and cost-

effectiveness analyses), covered all evaluated patient populations. Most studies evaluated patients with uAAA and rAAA.

4.2. The Committee noted that when considering only costs of implants, T/EVAR was more expensive than the vascular grafts used in OSR. However, when adjusting for quality of life, T/EVAR generally resulted in greater health gains with additional cost when compared with OSR. The incremental cost-effectiveness ratios (ICERs) varied widely across the analyses, mainly due to differences in study methodology and potentially due to costs. Despite the variation, the Committee noted that, when compared with OSR, ICERs of EVAR were most favourable in patients with rAAA. None of the analyses were conducted in Singapore. Most studies were conducted in Europe and North America.

4.3. The Committee noted that despite the difference in cost of implants between T/EVAR and OSR, the local episodic procedural charges were comparable between the two interventions.

Estimated annual technology cost

5.1. The Committee noted that the estimated annual incremental cost of impact to the public healthcare system to subsidise aortic stent grafts for T/EVAR was less than $1 million, with EVAR accounting for most of the spending. The incremental overall episodic charges may also be lower for T/EVAR. This estimate was based on the projection of approximately 100 patients annually with aortic aneurysm in Singapore who would benefit from Government subsidy for aortic stent grafts for T/EVAR.

Organisational feasibility

6.1. The Committee noted there is sufficient expertise and capacity in Singapore to manage current and future patients with aortic aneurysm using T/EVAR. Given the complexity of the intervention, specific training relevant to the deployment of T/EVAR in these patients is required to ensure successful and safe procedures.

Additional considerations

7.1. The Committee noted that implants used to repair aortic aneurysm are publicly funded in Australia, Belgium, France, New Zealand, South Korea, and Taiwan.

Recommendations

8.1. Based on available evidence, the Committee recommended listing aortic stent graft on the MTSL for T/EVAR to provide structural support of aortic aneurysm in line with the following criteria:

- Patients with AAA (ruptured or unruptured) who are not suitable for OSR and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - asymptomatic and with an aneurysm that has grown by more than 1cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - presenting with a small aneurysm (less than 5 cm), but who will require chemotherapy, radiation therapy, or solid organ transplantation (a shared multidisciplinary decision-making approach should be considered to decide on treatment options).
- Patients with TAA (ruptured or unruptured) who are not suitable for OSR and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5.5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - asymptomatic and with an aneurysm that has grown by more than 1 cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter)
- Patients with TAAA who are not suitable for OSR and are:
  - symptomatic; OR
  - asymptomatic and with an aneurysm of 5.5 cm or larger (measured outer-to-outer maximum anterior-posterior aortic diameter); OR
  - asymptomatic and with an aneurysm that has grown by more than 1 cm in one year (measured outer-to-outer maximum anterior-posterior aortic diameter).
- Patients with TBAD with suitable anatomy for TEVAR and the TBAD is:
  - complicated (presence of malperfusion syndrome or rupture) hyperacute (<24 hours), acute (1–14 days), or subacute (15–90 days); OR
  - uncomplicated with high-risk features (refractory pain, refractory hypertension, bloody pleural effusion, aortic diameter of more than 40 mm, imaging evidence of malperfusion, entry tear on lesser curvature, or false lumen of more than 22 mm).
- Patients with traumatic aortic injury who do not have contraindications to endovascular repair.

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

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 funding 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 22 November 2022. 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.

Find out more about ACE at www.ace-hta.gov.sg/about

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