ACE agency for care effectiveness

Technology Guidance

Aortic hybrid stent graft

for treating complex aortic disease

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has recommended aortic hybrid stent graft for patients who:

- ✓ Require a two-stage repair for complex aortic disease extending into or beyond the distal aortic arch into the proximal descending aorta; AND
- ✓ Do not need additional intervention (such as stent grafting) in the descending aorta.

Funding status

Aortic hybrid stent graft is recommended for inclusion on the MOH Medical Technology Subsidy List (MTSL). Listed models 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 aortic hybrid stent graft for treating complex aortic disease. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for aortic hybrid stent graft 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. Complex aortic disease occurs in the aorta which may extend into or beyond the distal aortic arch into proximal descending aorta. This includes acute and chronic aortic dissections, as well as thoracic aortic aneurysms (TAA) in the aortic arch with or without involvement of the ascending aorta. The global estimated annual incidence of aortic dissections and TAA is 4.4 to 15 and 5.3 per 100,000 persons per year, respectively. The prehospital death rates can be up to 49% in patients with acute aortic dissections and up to 59% in patients with ruptured TAA. However, only a small proportion of patients are eligible for surgical repair, as this is limited to those able to tolerate open surgery.

2.2. The main aim of surgical repair is to prevent dissection or rupture by restoring the normal dimensions of the aorta. Traditionally, patients with complex aortic disease are managed by two-stage open surgery. Conventional surgical approaches are complex and associated with high perioperative risks and mortalities.

2.3. Aortic hybrid stent graft consists of a stent graft sutured to the distal end of a conventional vascular graft. It is used in a single-stage open surgical procedure known as 'frozen elephant trunk' for treating complex aortic disease. By enabling single-stage surgical repair, the aortic hybrid stent graft addresses the clinical need for lower operative risks. However, a potential limitation of aortic hybrid stent graft is insufficient implant coverage when the pathology extends beyond the distal descending aorta.

Overall benefit of technology

3.1. The Committee acknowledged that vascular graft and/or stent graft implanted in a two-stage procedure was the most appropriate comparator for aortic hybrid stent graft. The Committee noted that the evidence base for safety and clinical effectiveness of aortic hybrid stent graft comprised two health technology assessment (HTA) reports. These reports included only case series, and one systematic review of cohort studies and case series that compared two different models of aortic hybrid stent graft.

3.2. The Committee noted that despite the limited evidence, aortic hybrid stent graft was reasonably safe and effective for patients with complex aortic disease. The mortalities and risk of adverse events reported for aortic hybrid stent graft were generally not worse than those reported for the two-stage comparator. Aortic hybrid stent graft was associated with higher rate of intraoperative bleeding (13.9%), relative to the two-stage comparator (4.2% to 8.1% at stage 1, 3.7% to 5.6% at stage 2), possibly due to incorrect choice of device size during early experiences with use of the aortic hybrid stent graft. Direct comparison of outcomes between aortic hybrid stent graft and the comparator was not possible as combined outcomes for the latter were not available. Nonetheless, the key benefit of aortic hybrid stent graft over the two-stage comparator was the avoidance of a second surgical procedure with its associated risks.

3.3. The Committee noted that there was a lack of comparative studies between aortic hybrid stent graft and the two-stage open surgical treatments. Potential confounders in the evidence included heterogeneity in patient characteristics, setting, surgical team, and postoperative care regime.

Cost effectiveness

4.1. The Committee noted that only one cost analysis, conducted in the UK in 2018, was available. No local cost-effectiveness analysis was conducted.

4.2. The Committee noted that in the short-term (1-year), aortic hybrid stent graft was more expensive than its comparator by £867 to £7,761, largely due to higher technology costs and longer length of hospital stay. However, aortic hybrid stent graft resulted in cost savings ranging from £10,225 to £13,334 at 5 years, and from £40,993 to £53,587 at 20 years. These cost savings were attributed to fewer surgery-related adverse events including bleeding, stroke, paraplegia, and renal failure.

4.3. The Committee noted that based on sensitivity analyses, the probability of in-hospital mortality and paraplegia, and costs of complications management did not substantially change the expected cost savings in the base case estimate.

Estimated annual technology cost

5.1. The Committee noted that the estimated annual cost of subsidising aortic hybrid stent graft was less than $1 million. The estimate was based on the projection of up to ten patients with complex aortic disease in Singapore who would benefit from Government subsidy for aortic hybrid stent graft. Aortic hybrid stent graft was likely to result in cost savings in the long term, due to avoidance of second surgical procedure with its associated risks of adverse events.

Organisational feasibility

6.1. No organisational feasibility issues were identified.

Additional considerations

7.1. The Committee noted that aortic hybrid stent graft is recommended or reimbursed in several reference jurisdictions including Australia, Belgium, France, Taiwan, and UK.

Recommendations

8.1. Based on the evidence presented for safety, clinical- and cost-effectiveness, the Committee considered it reasonable to recommend subsidy for aortic hybrid stent graft for patients who:

- Require a two-stage repair for complex aortic disease extending into or beyond the distal aortic arch into the proximal descending aorta; AND
- Do not need additional intervention (such as stent grafting) in the descending aorta.

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 6 July 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.

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

Chief HTA Officer
Agency for Care Effectiveness
Email: ACE_HTA@moh.gov.sg

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