Technology Guidance

Wingspan Stent System

for intracranial atherosclerotic stenosis

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has not recommended the Wingspan stent system for intracranial atherosclerotic stenosis.

Funding status

The Wingspan stent system is not recommended for subsidy in patients with the abovementioned indications.

Published: 15 January 2024

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 the Wingspan stent system to restore patency in the intracranial arteries in patients with intracranial atherosclerotic stenosis (ICAS). The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for the Wingspan stent system 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. ICAS is an advanced form of intracranial atherosclerotic disease (ICAD), a progressive disease caused by atherosclerotic plaques affecting major intracranial arteries. As one of the most significant causes of ischaemic stroke, ICAS is associated with recurrent stroke. In Singapore, the prevalence of ICAS ranges from 9% to 64% in patients with stroke. The choice and intensity of treatments depend on whether ICAS is symptomatic and the severity of stenosis. Medical management (MM) is the standard therapeutic approach to ICAS. In patients with severe (≥70% stenosis) and symptomatic intracranial stenosis despite MM, percutaneous transluminal angioplasty and stenting (PTAS) could be considered.

2.2. The Wingspan stent system is a self-expandable nitinol stent and delivery system. Prior to its insertion and deployment, an over-the-wire balloon catheter is used to pre-dilate the lesion. The Wingspan stent system is registered with the Health Sciences Authority (HSA) for the treatment of ICAS in patients with severe disease (≥70% stenosis), a history of at least 2 previous strokes while on MM, a modified Rankin

Scale (mRS) score of 3 or less, and the most recent stroke occurring more than 7 days prior to PTAS using Wingspan. The use of Wingspan in the acute phase of stroke (≤7 days) constitutes an off-label use.

Overall benefit of technology

3.1. The Committee acknowledged that the main comparator for patients with ICAS undergoing PTAS with the Wingspan stent system is MM alone. The evidence base comprised one health technology assessment (HTA) report and five systematic reviews and/or meta-analyses (SRMAs). They included two key randomised controlled trials (RCTs) that compared Wingspan plus MM with MM alone – the Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis (SAMMPRIS) trial published in 2011, and the China Angioplasty and Stenting for Symptomatic Intracranial Severe Stenosis (CASSISS) trial published in 2022. Key post-market surveillance studies included in the evidence base were the Wingspan StEnt System PostmArket SurVEillance (WEAVE) study, an FDA-mandated registry that assessed the periprocedural safety of the Wingspan stent system in patients who met the revised FDA on-label indication; and the WOVEN study, the 1-year follow-up of the WEAVE study cohort.

3.2. The Committee noted that SAMMPRIS led to revisions in the FDA-approved indications, which introduced restrictions such as the most recent stroke needing to have occurred more than seven days prior to PTAS with Wingspan. The primary endpoint in the SAMMPRIS trial was a composite of stroke or death within 30 days after enrolment or after a revascularization procedure for the qualifying lesion during the follow-up period or stroke in the territory of the qualifying artery beyond 30 days. The trial showed that the probability of the primary endpoint was higher in the patients who received PTAS with the Wingspan stent system plus MM compared to MM alone at 30 days (14.7% vs 5.8%, p=0.002) and at 1-year (20% vs 12%, p=0.009). However, the later CASSISS trial showed no between-group difference for the primary outcome of composite stroke or death within 30 days or stroke in the qualifying artery territory beyond 30 days through one year (8.0% vs 7.2%; HR 1.10, 95% CI 0.52 to 2.35, p=0.82). Nevertheless, the CASSISS trial reported a numerically higher risk of death at three years (HR 3.75, 95% CI 0.77 to 18.13, p=0.08) for patients received PTAS with Wingspan plus MM.

3.3. The Committee further noted that the WEAVE and the WOVEN studies also reported better outcomes than the SAMMPRIS trial at the periprocedural period (2.6% periprocedural stroke, bleed and death rate) and one-year follow-up (8.5% stroke or death rate) in patients who received PTAS with Wingspan. The reported rates are similar to that reported in the PTAS with Wingspan group in the CASSISS trial. The Committee agreed that the observed difference could be due to more experienced interventionalists and improved patient selection for stenting when following the revised FDA on-label indications in CASSISS and the WEAVE studies. No significant difference was observed in any study for other outcomes including stroke, or

composite outcomes comprising stroke, death, or transient ischaemic attack (TIA).

3.4. The Committee noted that supplementary evidence based on pooled analyses of studies using various intracranial stents – not specific to Wingspan stent system – generally showed similar results between stenting and MM alone, with some inconsistency. Limited evidence for rescue intracranial stenting after failed mechanical thrombectomy or high-risk mechanical thrombectomy showed favourable functional outcomes and lower symptomatic intracranial haemorrhage rate compared to no rescue stenting. However, this would constitute an off-label use of the Wingspan stent system in Singapore.

Cost effectiveness

4.1. One cost-effectiveness analysis published in 2013 from the United States reported that PTAS plus MM compared to MM alone for secondary stroke prevention in symptomatic ICAS yielded an ICER of US$1.4M per quality-adjusted life year (QALY) gained. The Committee noted the key limitations of the study, such as the use of clinical evidence prior to the SAMMPRIS trial and the heterogeneity of the studies included (e.g. different stent systems used and variation in period for dual antiplatelet therapy). The Committee acknowledged that the study result is unlikely to be applicable to current clinical practice in Singapore.

4.2. Currently, the Wingspan stent system is reimbursed in Australia, South Korea, and Taiwan, but not in Belgium, France, New Zealand or the UK.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be <SG$1 million, based on the projection of approximately 10 eligible patients in Singapore who would benefit from Government subsidy for the Wingspan stent system.

Organisational feasibility

6.1. The Committee noted that adequate clinician training and experience with PTAS with the Wingspan stent system, timing of the procedure, and proper patient selection are key to ensure safe intracranial stenting.

Additional considerations

7.1. The Committee acknowledged that major international guidelines do not recommend PTAS as initial treatment for patients with prior ischaemic stroke or TIA related to severe ICAS. Moreover, the guidelines state that optimal stroke prevention for patients with symptomatic ICAS who have recurrent stroke despite MM is unknown and that the use of PTAS for stroke prevention in any subpopulation with symptomatic ICAS is investigational. However, based on expert consensus, PTAS may be considered as a rescue therapy in selected patients.

7.2. The Committee noted that, despite the lack of evidence supporting the additional benefits of PTAS with Wingspan over MM, local clinician experts highlighted that intracranial stenting could be considered on a case-by-case basis in patients with recurrent stroke despite optimal MM, especially if further supported by vessel wall magnetic resonance imaging (MRI) localising the atherosclerotic plaque away from the origins of the major perforators. However, clinicians also acknowledged that the Wingspan stent system was unergonomic and is not commonly used locally, with most operators using it selectively depending on disease and patient characteristics. In the emergency setting where approximately 75% of patients with ICAS who experienced stroke are treated, other stents are preferred.

7.3. The Committee noted that another intracranial stent, CREDO® Stent, was registered with HSA in April 2023 for managing ICAS. Compared to the Wingspan stent system, clinical evidence on CREDO® is weaker, with multiple ongoing trials.

Recommendations

8.1. Based on available evidence, the Committee recommended not to subsidise Wingspan stent system to restore patency in the intracranial arteries in patients with ICAS. This was mainly in view of the lack of evidence supporting the additional benefits of PTAS with the Wingspan stent system over MM alone, international guideline recommendations, and its limited use in the local setting.

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 July 2023. 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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