OHTAC Recommendation

Transcatheter Aortic Valve Implantation for Treatment of Aortic Valve Stenosis

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OHTAC Ontario Health Technology Advisory Committee

Issue Background

Surgical aortic valve replacement (sAVR), a cardiac procedure with a proven record of safety, has long been available as an effective treatment for patients with severe aortic valve stenosis. In patients with concomitant aortic valve disease and coronary artery disease, sAVR can be performed during coronary artery bypass graft surgery. However, some patients with severe aortic valve stenosis are denied surgery owing to their advanced age and/or multiple coexisting health conditions.

Over the last decade, transcatheter aortic valve implantation (TAVI) technology has emerged as an alternative treatment option for these patients. In this procedure, a new, functioning valve is implanted through a catheter and without the need for sternotomy and cardiopulmonary bypass. This procedure was previously reserved for very high-risk patients and given on a compassionate basis. However, Health Canada has recently issued a license for the technology, which may create interest in broadening the selection criteria to include individuals expected to have excellent clinical outcomes with sAVR.

Summary of Findings

The results of the first randomized controlled trial on 1 of the 2 available TAVI devices have recently been published. The PARTNER trial had 2 cohorts of patients and 2 separately published studies. Both cohorts included patients with severe aortic valve stenosis at high risk for sAVR. In both cohorts, patients had about an 11% risk of dying within 30 days of surgery. However, patients in the first cohort had certain risk factors that made them ineligible for sAVR, and a less invasive treatment was considered a worthwhile alternative. These patients were randomized to receive either TAVI or standard treatment. Patients in the second cohort were randomized to receive either TAVI or sAVR.

Our review of the results of the first cohort (in which TAVI was compared with standard treatment) suggests that TAVI improves survival at 1-year follow-up compared with standard treatment in patients ineligible for sAVR. However, TAVI was also associated with adverse effects, which included a significantly higher risk of stroke/transient ischemic attack, major vascular complications, and major bleeding.

Our review of the results of the second cohort (in which TAVI was compared with sAVR) suggests that TAVI relieves symptoms as effectively as sAVR and has a comparable 1-year mortality rate. However, TAVI was associated with adverse effects including a significantly higher risk of stroke/transient ischemic attack, major vascular complications, and high rates of aortic regurgitation following valve implantation. On the other hand, patients who underwent sAVR had significantly higher rates of major bleeding.

OHTAC Recommendations

Based on the current available evidence, OHTAC recommends the following:

In patients with severe aortic valve stenosis who are candidates for surgery, in light of the high complication rates of TAVI, and similar effectiveness and unfavourable cost-effectiveness compared with surgery, OHTAC does not recommend using TAVI.

In patients with severe aortic valve stenosis who are not candidates for open-heart surgery, TAVI is a reasonable option. However, given the high complication rates and uncertainty regarding short- and long-term effectiveness and cost-effectiveness of TAVI, OHTAC recommends close follow-up of patient resource use, quality-of-life preference information, and clinical outcome data as a coverage with evidence development through Programs for Assessment of Technology in Health (PATH) and in collaboration with the Cardiac Care Network. A final decision regarding the use of this technology, including appropriate patient selection in Ontario, should be predicated on the outcomes from the coverage with evidence development.

Given the complexity of this technology and significant complications associated with its use, OHTAC recommends in the interests of the highest quality of patient care that TAVI be restricted to institutions that have broad-based experience in its use with an appropriate volume of patients.