OHTAC Recommendation

Fenestrated Endovascular Graft for Repair of Juxtarenal Aortic Aneurysm

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OHTAC Ontario Health Technology Advisory Committee

Issue Background

The application of the standard endovascular aneurysm repair (EVAR) technique for the treatment of infrarenal aortic aneurysms is limited to patients in whom there is sufficient healthy aortic tissue below the renal arteries to provide an adequate proximal sealing zone. Originally, the presence of a short neck (<15 mm) at the proximal site was considered to be a contraindication for EVAR but, more recently, the threshold for infrarenal neck length has been reduced to a minimum of 10 mm.

By definition, a juxtarenal aortic aneurysm (JRA) is an infrarenal aortic aneurysm that extends to within 1 cm of the renal arteries without involving them. Patients with this type of aneurysm are, therefore, not anatomically eligible for standard EVAR. Customized fenestrated grafts have thus been developed to allow patients with JRA to become eligible for endovascular repair.

Fenestrated endovascular repair (f–EVAR) allows the proximal sealing zone of the graft to be placed in a healthier part of the aorta above the renal arteries. The presence of fenestrations in the fabric that can be aligned and positioned in front of the renal and visceral arteries allows continuation of blood flow to these vessels and their respective end organs.

The conventional approach for JRA treatment is open surgical repair (OSR), a surgery that is generally more challenging than infrarenal aortic aneurysm repair and one that is associated with greater morbidity and mortality. It requires aortic clamping above one or both renal arteries, or above the visceral arteries. The resulting increase in cardiac afterload and decrease in cardiac output can lead to myocardial ischemia. Reports indicate that 6% of the patients undergoing surgical repair develop myocardial infarction. Aortic clamping can also result in renal or mesenteric ischemia causing end organ infarction.

There are benefits and harms associated with both techniques. The decision to perform a prophylactic intervention on asymptomatic patients must take into account the risk of mortality due the intervention compared to the risk of aneurysm rupture if it remains untreated. Generally, patients will have a survival benefit if the size of their aneurysm exceeds 5.0-5.5 cm. Fenestrated EVAR requires appropriate patient selection to identify those patients who will most likely benefit from the repair. The target patient population for f-EVAR are those with infrarenal abdominal aortic aneurysm who are:

1. at high risk of aneurysm rupture,
2. unsuitable for OSR due to the presence of significant comorbid conditions, and
3. unsuitable for standard EVAR because of the presence of a short proximal neck.

OHTAC Findings

Results of case series studies of f-EVAR for the repair of JRA were compared to the results of OSR studies published over the same time period. Analysis of the results shows that the short- and medium-term results (up to 2 years) of f–EVAR compare favourably with OSR figures. These observations are, however, based on low quality evidence. Among the principal finding of the analysis were that:

- F–EVAR had a lower 30-day mortality than OSR (1.8% versus 3.1%) and a lower late mortality (12.8% versus 23.7%) over the period that patients were followed (conclusion is based on low quality evidence).

- There is a potential for loss of target vessels during or after f–EVAR procedure. This risk is mainly due to branch vessel ischemia or occlusion, primarily among the renal arteries and superior mesenteric artery.
- Kidney loss occurred in 1.5% of patients undergoing f–EVAR.
- Rate of permanent dialysis ranged from 0.0% to 2.5% among the f–EVAR studies and from 0% to 3.5% among the OSR studies.
- The rate of mesentric ischemia was 3.3% among f–EVAR studies and 2.9% among OSR studies.
- Rates of postoperative cardiac complications were 1.5% among f–EVAR studies and 10.7% among OSR studies.
- Rates of postoperative pulmonary complications were 0.7% among f–EVAR studies and 13.4% among OSR studies.
- The rate of secondary intervention (non-endoleak) was 8.8% among f–EVAR studies and 7.8% among OSR studies.
- Length of hospital stay was shorter among f–EVAR studies compared to the OSR studies (mean range 5.9-6.4 versus 8.0-16.7 days).
- Rates for type I, II, and III endoleaks among the f-EVAR studies were 4%, 16.8%, and 1.8% respectively. Overall, 7.7% of f-EVAR patients required treatment for endoleak.
- Rates for graft migration and component separation among the f-EVAR studies were 1.5% and 0.7%, respectively.

OHTAC Recommendations

Based on the above evidence, OHTAC recommends that f–EVAR should be made available to patients with juxtarenal abdominal aortic aneurysms greater than 5.5 cm in diameter and whose comorbidities place them at high risk from open surgical repair. While this recommendation is based on low quality evidence, it is unlikely that better quality evidence can be expected due to ethical considerations of denying treatment to high-risk patients in a randomized controlled trial.

This technique should be restricted to centres with experience and expertise in the field of endovascular graft repair and sufficient volumes to maintain their level of expertise. This would involve consideration of facilities currently performing standard endovascular abdominal aortic aneurysm repair (EVAR) as per OHTAC recommendations for EVAR dated December 15, 2006.

Future Considerations

Given the low quality of evidence of effectiveness and safety, funding for EVAR should include a requirement for evidence development through the collection of patient outcomes to inform further decision making by OHTAC.