OHTAC Recommendation

Endovascular Repair of Descending Thoracic Aortic Aneurysm

November 16, 2005

OHTAC Ontario Health Technology Advisory Committee

Ontario

Endovascular Repair of Descending Thoracic Aortic Aneurysm

The Ontario Health Technology Advisory Committee (OHTAC) met on November 16, 2005 and reviewed the health technology assessment report on endovascular repair of descending thoracic aortic aneurysm (TAA). The review consisted of a presentation by the Medical Advisory Secretariat and discussion.

Aneurysm is a permanent localized dilatation of the aorta and the most common condition of the thoracic aorta requiring surgery. The incidence of TAA is estimated to be 10 cases per 100,000 people per year. The descending aorta is involved in about 30% to 40% of the cases. Most aneurysms of the thoracic aorta are asymptomatic, being incidentally discovered. However, these aneurysms tend to enlarge progressively and compress surrounding structures causing clinical symptoms. They may eventually rupture and create a life threatening situation. The prognosis of large untreated TAAs is poor, with 3-year survival rate as low as 25%. Therefore, surgical treatment is justified unless comorbid medical conditions contraindicate performing surgery.

Operative mortality of surgical repair of TAA reported from centres of excellence is between 8% and 20% for elective cases, and up to 50% in patients requiring emergency operation. The large difference between mortality rate after elective and emergency operation suggest that TAA at risk of perforation should be repaired before rupture occurs. On the other hand, open surgical treatment of TAA involves left thoracotomy, which is a high-risk procedure. Therefore, surgical repair of TAA is not appropriate for all patients.

Endovascular aortic aneurysm repair (EVAAR) using a stent graft is an alternative to the traditional surgical approach. It is less invasive than surgical treatment and the initial results from several studies suggest that EVAAR reduces mortality and morbidity associated with the repair of descending TAA.

Endovascular Repair of Descending Thoracic Aortic Aneurysm

Results of a health technology assessment conducted by the Medical Advisory Secretariat (MAS) shows that based on one comparative study and a number of case series studies, short-term and medium-term outcomes of endovascular grafting are satisfactory and comparable to the surgical intervention; therefore, for patients who are at high risk of rupture in whom performing surgery is not considered to be the optimal therapy due to the presence of serious co-morbid conditions, the endovascular technique should be considered. However, since this information is not based on randomized controlled trials, there is no "high Grade" evidence to recommend this technology as the first choice of treatment for all patients with a large or symptomatic TAA. Of particular concern is the high rate of endovascular leaks using EVAAR (approximately 10%). Since reports of EVAR have included short follow-up periods, the long-term complications from endovascular leak in particular are unknown.

The average hospital direct cost per case of a Thoracic Aneurism Repair is $33,000, and the average hospital total cost per case is $42,000. Based on the field study of abdominal EVAAR vs. open surgical repair prepared by PATH (source: PATH 2005), abdominal EVAR was approximately 14% more expensive per treated patient. However, we expect this difference to be less for thoracic aneurysm repair given that operating room costs for open abdominal repair are less than for open thoracic repair while EVAAR operating room costs are similar in both locations.

OHTAC Recommendations:

OHTAC recommends the following with regard to the endovascular repair of descending thoracic aortic aneurysm.

- There is no randomized controlled trial with long-term follow-up to support the use of endovascular grafting as the first choice treatment for repair of large descending TAA. However, since short-

term and medium-term outcomes of endovascular grafting based on the above mentioned studies are satisfactory and comparable to the surgical intervention, it is of particular value in patients with coexisting conditions that would increase the risk of surgery. OHTAC recommends that endovascular repair of TAA should be performed where risks of surgery clearly outweigh those of placing an endograft based on the clinical judgment of physicians involved in the management of this disease, and after careful evaluation of benefits and risks involved in the use of each method.

- The use of this technology to be restricted to the centres with experience and expertise in the field of endovascular grafting.

- Informed consent by patients should include an understanding that the medium to long-term complications for endovascular repair of TAA are unknown and include concerns regarding leakage around the edges of the graft.