Endovascular Aneurysm Repair (EVAR) for the treatment of infra-renal Abdominal Aortic Aneurysms (AAA)

A submission to the National Institute for Health and Clinical Excellence (NICE) by Medtronic
Executive summary

Background

An infra-renal abdominal aortic aneurysm (AAA) is a localised dilatation of the abdominal aorta below the renal arteries. In the UK, AAA prevalence rates have been estimated at 1.3–12.7%, depending on the age and sex of the patient. The majority of patients with AAAs are asymptomatic, with the aneurysm detected only on routine examination, or in the course of investigations for other conditions. However, rupture is the commonest complication of AAA, the risk of which increases with aneurysm diameter, such that when an aneurysm reaches 5.5 cm, surgical intervention is considered.

In the community setting, the mortality rate from ruptured AAAs is almost 90%, as many of patients will die before reaching hospital and 50% of the remaining patients will die during surgery or prior to repair. As such, it has been estimated that AAAs cause approximately 10,000 deaths per year in England.

Only two surgical treatments are routinely used in practice in the UK for treatment of AAAs; endovascular aneurysm repair (EVAR) and open surgical repair (OSR). EVAR is a minimally-invasive surgical technique that involves two small cuts in the groin rather than an incision along the full length of the abdominal wall, and insertion of a stent–graft prosthesis through the femoral artery. When compared with OSR, EVAR is associated with marked reduction in post-operative morbidity, a decrease in mortality, and a quicker return to pre-operative health status, in addition to quality of life benefits.
Clinical effectiveness

Large randomised controlled trials have demonstrated that in patients with AAAs 5 cm or greater in diameter, 30-day mortality is significantly lower, occurring in three-times fewer patients receiving EVAR than OSR. Aneurysm-related mortality 4 years after treatment has also been found to be significantly lower with EVAR than OSR.

In the first 12 months after surgery, compared with OSR, EVAR is more beneficial to patient quality of life. Although the costs per patient of the procedure have been shown to be higher than OSR, EVAR also requires less blood products, a lower requirement for critical care, and a shorter theatre time and hospital stay.

The 30-day complication rate occurs at a lower frequency in patients receiving EVAR than OSR, although the need for re-intervention is higher. The outcomes of EVAR have improved since the RCTs were conducted. The technology has improved as has the experience and proficiency of clinicians. As such, RCT data from the EVAR 1 trial may no longer accurately reflect current clinical practice in the UK, with outcomes likely to be improved compared with those observed in past trials.

Cost effectiveness

In patients fit for surgery, EVAR is a cost-effective intervention for patients with AAAs ≥5.5 cm and represents efficient use of limited NHS resources. For the base-case analysis, the incremental cost-effectiveness ratio (ICER) at 30 years for this patient group, applying all-cause mortality rates, is £15,681 per QALY. EVAR becomes even more cost-effective when applying AAA-related mortality £11,339 per QALY.
Secondary analysis demonstrated that when extreme data points on length of stay were removed, the base-case ICER was £12,526 per QALY when applying all-cause mortality.

Sensitivity analyses demonstrated that EVAR remains cost-effective when key clinical and cost parameters are varied. The results are most sensitive to the short-term RR of mortality. At a threshold value of £30,000 per QALY, the probability of EVAR being cost effective reaches 66%.

Wider NHS implications

Across England and Wales, conservative projections estimate that the total number of patients undergoing EVAR for non-ruptured infra-renal AAAs will rise from current levels of 1,469 patients to 2,265 patients by 2012, assuming a 5% annual increase.

The projected annual budget impact of treating patients with EVAR instead of OSR is £373,697 at Year 5. This takes into account procedure, long-term monitoring and complication costs.

The budget impact by 2012 based on procedure costs only is estimated at a cost saving of £1.3 million.