Title: Elective Endovascular Abdominal Aortic Aneurism Repair versus Open Surgery: A Clinical and Cost Effectiveness Review

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Context and policy issues:

Abdominal aortic aneurism (AAA) occurs in 5% of men and 1% of women over the age of 65 years, and the rupture of an AAA is a significant cause of death. Elective repair of AAA (repair of a non-ruptured aneurism) by a conventional open surgical approach has reasonable long-term survival, but it carries a high risk to older patients or those with comorbidities such as cardiovascular or pulmonary conditions. In contrast to open surgery, endovascular AAA repair (EVAR) is a catheter-based procedure that does not require an abdominal incision or dissection and clamping of the aorta. In Canada, the development of the endovascular program at London Health Sciences Centre has experienced a doubling of elective aneurism cases during 1997 to 2003, with elective EVARs constituting 28% of the entire elective AAA repairs. Because of the increased trend of EVAR and its high cost, this bulletin is looking at the clinical and cost effectiveness of elective EVAR as compared to open surgery repair.

Research questions:

1. What is the clinical effectiveness of elective EVAR compared to open repair for AAA?
2. Is there any evidence that elective EVAR is more effective for larger aneurisms?
3. What is the cost effectiveness of elective EVAR compared to open repair for AAA?

Methods:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 1, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a
focused Internet search. Results include articles published between 2003 and March 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to systematic reviews/health technology assessments, randomized controlled trials (RCTs) and economic studies.

Summary of findings:

Clinical effectiveness of EVAR

A rigorous meta-analysis with a systematic literature search from 1966 through 2006 included two RCTs comparing elective open repair to surveillance for small AAAs (< 5.5 cm) in 2226 patients, and four RCTs that compared elective EVAR versus open repair for large AAAs (≥5.5cm) in 1532 patients. Elective open repair for AAAs smaller than 5.5 cm has not been shown to cause any statistically significant difference in all-cause mortality (relative risk 1.01 [CI 0.77 to 1.32]) or AAA-related mortality (relative risk 0.78 [CI 0.56 to 1.10]) as compared to surveillance. On the other hand, for large AAAs, EVAR reduced 30-day all-cause mortality (relative risk 0.33; CI 0.17 to 0.64) but not mid-term (up to 4 years) mortality (relative risk 0.95; CI 0.76 to 1.19). Each trial found a significant reduction in length of hospital stay with EVAR compared to open repair (6.2 days vs. 11.5 days). A small prospective trial in 2008 also agreed with the systematic review and found that the 30-day mortality was reduced with EVAR.

Cost-effectiveness of EVAR

A systematic review of economic studies published between 1999 and 2005 reporting the cost and/or cost-effectiveness of elective EVAR and/or open surgery of non-ruptured AAAs included three RCTs, 12 case series, four Markov models, and one systematic review. All studies found that EVAR costs more than open surgery. For patients with AAA < 5.5cm, immediate open surgery costs more than active surveillance with selective open surgery with no improvement in survival. Among patients with AAA ≥5.5cm, EVAR has greater short and long term costs with no improvement in overall survival or quality of life beyond one year.

A recent randomized trial compared the cost-effectiveness of elective EVAR and open repair in 351 patients in The Netherlands. EVAR was associated with additional €4293 direct costs (€18,179 vs €13,866; CI €2770 to €5830). Routine use of elective EVAR in patients also eligible for open repair does not result in a quality adjusted life-year (QALY) gain at one year postoperatively, provides only a marginal overall survival benefit, and is associated with a substantial increase in costs.

A decision model to estimate the lifetime costs in UK and QALYs with elective EVAR and open repairs was constructed. EVAR costs £3,800 (CI £2,400 to £5,200) more per patient than open repair but produced fewer lifetime QALYs.

EVAR for repair of ruptured AAA

In addition to elective repair, clinical effectiveness of emergency repair of AAA (repair of a ruptured aneurism) by EVAR versus open surgery was also the focus of many clinical trials which were reviewed in a recent systematic review and meta-analysis that covered publications from 1994 to 2007. Emergency EVAR was associated with a statistically significant reduction in 30-day mortality, intensive care unit stay, hospital stay, blood loss and operative time compared to open surgery. A Cochrane review that covered trials until 2006 on the same topic also found similar results. It is important to note that none of the included trials in either of the two
systematic reviews is a RCT, which leads to caution in interpretation of the findings. Two small cost-effectiveness studies comparing emergency EVAR to emergency open repair were found.\textsuperscript{12,13} A preferential emergency EVAR protocol for ruptured AAAs can decrease mortality but does not increase overall direct medical costs as compared to emergency open repair-only protocol.\textsuperscript{12} When one-year follow-up costs were added to total in-hospital costs, the costs were lower with emergency EVAR than emergency open repair.\textsuperscript{13}

Conclusions and implications for decision making:

Despite a reduction in short term mortality in patients with aneurisms $\geq 5.5$ cm, \textit{elective} EVAR does not appear to improve overall survival beyond one year, and is unlikely to be cost-effective on the basis of existing devices, costs and evidence. No difference in mortality was seen with aneurisms $< 5$ cm with EVAR compared to open surgery. Caution should be made before the widespread use of elective EVAR. \textit{Emergency} EVAR also showed a short term clinical benefit, and appears to be cost-effective, but higher quality trials are needed to consolidate the findings.

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